



Clinical Guidance for COVID-19 Vaccination

Version 52.1 17/04/2024

This document has been created and updated by the HSE National Immunisation Office



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Update	<p>This Clinical Guidance document has been significantly updated throughout in line with current guidance from the National Immunisation Advisory Committee, particularly to introduce:</p> <ul style="list-style-type: none">• the single dose primary course, and• the Spring 2024 Booster Vaccination Programme. <p>OF NOTE: Further updated on 17/04/2024 to include the minimum intervals for Nuvaxovid XBB.1.5 when used for primary schedule for immunocompromised.</p>

Contents

1. Introduction	5
2. Vaccine recommendations	6
2.1 Medical conditions at very high risk and high-risk of severe COVID-19 disease	8
3. COVID-19 Vaccines	10
4. Infection Prevention and Control for the administration of COVID-19 Vaccines	11
5. Vaccine details, storage and instructions for preparation and administration	12
6. COVID-19 mRNA Vaccines	13
6.1 Comirnaty® Omicron XBB.1.5 30 micrograms (0.3ml)	13
7. Protein Sub-Unit Vaccine: Nuvaxovid® XBB.1.5	17
8. Contraindications and precautions to COVID-19 vaccines	21
8.1 mRNA Vaccines	21
8.2 Protein sub-unit vaccine Nuvaxovid® XBB.1.5	22
8.3 Vaccination after COVID-19	23
9. Clinical considerations for COVID-19 vaccines	24
9.1 Pregnancy	24
9.2 Breastfeeding	25
9.3 Individuals with a bleeding disorder.....	25
9.4 Individuals taking anticoagulants.....	26
9.5 Technique for IM injections in persons with bleeding disorders or on anticoagulants	26
9.6 Co-administration of COVID-19 vaccines with other inactivated or live vaccines for those aged 12 years and over:.....	26
9.7 Immunosuppression due to disease or treatment	26
9.8 Primary course for those with immunosuppression due to disease or treatment aged 12 years and older	27
9.9 People being treated with chemotherapy for cancer	27
10. Booster COVID-19 Vaccines	28
11. Post Vaccination	32
11.1 Recording vaccination.....	32
11.2 Observation period.....	32
12. Adverse Reactions	33
12.1 Adverse reactions of COVID-19 vaccines.....	33
12.2 Adverse events following Comirnaty® (Pfizer/BioNTech) and Spikevax® (Moderna) and very rare cases of Myocarditis and Pericarditis	34
12.3 Adverse events following Nuvaxovid® (Novavax) and unknown frequency of cases of Myocarditis and Pericarditis.....	35
12.4 Reporting adverse reactions.....	36
12.5 Reporting of incidents during the vaccination session to HSE	36
13. Vaccination of children aged 5-11 years	37
13.1 NIAC recommendations	37
13.2 Vaccine storage for Comirnaty® formulations for those aged 5-11 years.....	39
13.3 Infection prevention and control.....	41
13.4 Vaccine, Preparation and Dilution.....	41
13.5 Vaccine Administration of Comirnaty® for 5-11 years.....	44
13.6 Method of IM Vaccine Administration	45
13.7 Positioning for vaccination.....	45
13.8 Techniques for vaccinating children	46
13.9 Contraindications and precautions to COVID-19 vaccination in children aged 5-11 years for for Comirnaty® Omicron XBB.1.5 10 micrograms.....	47
13.10 Post-vaccination Procedures	47
13.11 Adverse Events	48
13.12 Clinical considerations	49
14. Vaccination of Children Aged 6 months to 4 years:	52
14.1 NIAC Recommendation.....	52
14.2 Vaccine storage	53
14.3 Vaccine dose	54
14.4 Prior to vaccination	54



14.5 Consumables needed.....55
14.6 Infection prevention and control55
14.7 Vaccine Administration.....56
14.8 Contraindications and precautions to COVID-19 vaccination in children aged 6 months to 4 years59
14.9 Post-vaccination Procedures60
14.10 Adverse Events60
14.11 Clinical Considerations61
Useful links 63

This guidance is intended for vaccinators administering COVID-19 vaccines. Vaccinators should be trained and competent in immunisation practice.

Vaccinators should have undergone training in the administration of COVID-19 vaccine(s), recognition and management of anaphylaxis, and basic life support and intramuscular injection technique. They should also be familiar with the anaphylaxis protocol outlined in the Immunisation Guidelines for Ireland (see useful links section).

In some circumstances, advice in these guidelines may differ from that in the Summary of Product Characteristics (SmPC) of the vaccines. When this occurs, the recommendations in these guidelines, which are based on current expert advice from the National Immunisation Advisory Committee should be followed.

1. Introduction

The objective of the vaccination programme for SARS-CoV-2 is to ensure equitable access to a safe and effective vaccine with the goals of limiting mortality and morbidity from COVID-19, protecting healthcare capacity and enabling social and economic activity.

Purpose of the document

This document has been prepared as a means of providing clinical guidance to all clinicians implementing the COVID-19 vaccination programme.

Indemnity for vaccinators

Claims management in relation to claims and litigation initiated in connection with COVID-19 vaccination is to be delegated to the State Claims Agency by means of Government Order.

Registered medical practitioners (including GPs), nurses, pharmacists, physiotherapists, dentists, dental hygienists, optometrists, radiographers and radiation therapists, paramedics, advanced paramedics, emergency medical technicians and relevant healthcare students (as per the Statutory Instruments for the administration of COVID-19 vaccines), in receipt of relevant training with regard to administration of the vaccines, who are administering vaccines on the direction of, or on behalf of, the Health Service Executive (HSE) will be indemnified with regard to any adverse product liability-related events arising from their administration of the vaccine. Vaccinators working in GP surgeries and retail pharmacies however, will not be indemnified in respect of malpractice events occurring during the administration of the vaccine. Such malpractice events will be indemnified by their professional insurers.

2. Vaccine recommendations

Recommendations for primary and booster vaccination are summarised in the table below.

Table 1: NIAC recommendations for COVID-19 vaccines by age and immune status Spring 2024

Age	Primary schedule	Spring 2024 Recommendations		Available COVID-19 vaccines
		Interdose interval ¹	Further booster doses	
Comirnaty XBB.1.5 is the preferred COVID-19 vaccine				
80 years and older	Recommended: Single dose of Comirnaty mRNA COVID-19 vaccine.	Six months	Irrespective of number of prior booster doses: A spring booster vaccine is recommended.	For those aged 12 years and older <i>As primary and booster:</i> Comirnaty Omicron XBB.1.5 30 micrograms Nuvaxovid XBB.1.5 5 micrograms
70-79 years	Recommended: Single dose of Comirnaty mRNA COVID-19 vaccine.	Six months	Access to a spring vaccine should be available for those aged 70 to 79 years who, following discussion with a healthcare provider (e.g., GP, pharmacist or vaccination centre), request vaccination.	
12-69 years	Recommended: Single dose of Comirnaty mRNA COVID-19 vaccine.	Six months	A spring booster vaccine is recommended for: <ul style="list-style-type: none"> those with immunocompromise associated with a suboptimal response to vaccination 	
5-11 years	Recommended: Single dose of Comirnaty mRNA COVID-19 vaccine for those with underlying conditions. ² Available to others at appropriate dose.	Six months	A spring booster vaccine is recommended for: <ul style="list-style-type: none"> those with immunocompromise associated with a suboptimal response to vaccination 	For those age 5-11 years <i>As primary and booster:</i> Comirnaty Omicron XBB.1.5 10 micrograms
6 months-4 years	Recommended: For those with underlying conditions ² . Available to others Two doses for those with no prior history of SARS-CoV-2 infection. Four weeks interval between dose one and dose two. Single dose for those with a prior history of SARS-CoV-2 infection.	Not applicable	A spring booster vaccine is not recommended .	For those aged 6 months-4 years <i>As primary:</i> Comirnaty Omicron XBB.1.5 3 micrograms

<p>Immunocompromised aged 5 years and older</p>	<p>Recommended: Two doses of Comirnaty mRNA COVID-19 vaccine. A third dose may be administered following instruction from a relevant specialist physician. Four weeks interval between doses one and two; and eight weeks interval between doses two and three, if three doses are required³.</p>	<p>Six months</p>	<p>A spring booster vaccine is recommended for:</p> <ul style="list-style-type: none"> those with immunocompromise associated with a suboptimal response to vaccination. 	<p>Age related as listed above</p>
<p>Health Care Workers</p>	<p>Recommended: Single dose of Comirnaty mRNA COVID-19 vaccine.</p>	<p>Six months</p>	<p>A spring booster is not recommended unless immunocompromised.</p>	<p>Age related as listed above</p>
<p>Pregnancy</p>	<p>Recommended: Single dose of Comirnaty mRNA COVID-19 vaccine.</p>	<p>Six months</p>	<p>Recommendation is all year and is not seasonal. For pregnant adolescents and adults, a COVID-19 booster vaccine once⁴ in pregnancy is recommended if it is more than six months since their previous COVID-19 vaccine or infection.</p> <ul style="list-style-type: none"> COVID-19 vaccine can be given at any stage in pregnancy the booster is ideally given between 20-34 weeks' gestation <p>If it is more than 12 months since their previous COVID-19 vaccine or infection administration earlier in pregnancy should be considered.</p>	<p>Age related as listed above</p>

¹ Interval since last vaccine dose or SARS-CoV-2 infection, in exceptional circumstances a minimum interval of three months may be used.

² Medical conditions associated with a higher risk of COVID-19 hospitalisation, severe disease or death are outlined in Table 5a.2. For immunocompromised two doses are recommended with a four week interval between dose one and dose two. A third dose may be administered, eight weeks after the second dose, following instruction from a relevant specialist physician.

³ A minimum interval of four weeks between the second and third dose may be used if there is urgency to achieve protection

⁴ For those who are pregnant and are immunocompromised, a second booster dose within the same pregnancy may be considered if six months has elapsed since their last booster dose or SARS-CoV-2 infection

OF NOTE: NIAC Recommendations for Spring 2024 COVID-19 Vaccination

1. A Spring COVID-19 vaccine is recommended for:
 - those living in long term care facilities for older adults
 - those aged 80 years and older
 - those aged 5 years and older with immunocompromise associated with a suboptimal response to vaccination (see Table 2 of this document or NIAC Chapter 5a Table 5a.2 Conditions or treatments associated with very high or high risk of severe COVID-19 disease)
2. Access to a Spring vaccine should be available for those aged 70 to 79 years who, following discussion with a health care provider (e.g., GP, pharmacist or vaccination centre), request vaccination.
3. COVID-19 vaccines may be given to the above-mentioned risk groups irrespective of the number of previous doses or types of COVID-19 vaccines, with an interval of six months recommended following any previous COVID-19 vaccine dose or infection. A minimum interval of three months is permissible in exceptional circumstances e.g., planned immunosuppressive therapy or operational reasons.
4. The most recently adapted mRNA COVID-19 vaccine, Comirnaty Omicron XBB.1.5, is the preferred vaccine for use in Spring 2024.
5. Protein based vaccines may be used as alternatives for those in whom mRNA vaccine is contraindicated or declined. Nuvaxovid XBB.1.5 is the preferred alternate.

2.1 Medical conditions at very high risk and high-risk of severe COVID-19 disease

Conditions at high risk or very high risk of severe COVID-19 disease are detailed in Table 2 on page 9.

Those with conditions in the **blue shaded** areas are immunocompromising conditions that may be associated with a suboptimal response to vaccines. People with these conditions should be given an mRNA vaccine if practicable and timely.

Table 2. Conditions or treatments associated with very high or high risk of severe COVID-19 disease (May also include others, based on clinical judgement and a needs assessment)

Underlying condition or treatment	Very high risk	High risk
Cancer	<p>Receiving or within 6 weeks of receiving systemic cytotoxic chemotherapy, targeted therapy, monoclonal antibodies or immunotherapies</p> <p>Receiving treatment or pending treatment for a haematological cancer</p> <p>Undergoing or within 6 weeks of surgery or radical radiotherapy for lung or head and neck cancer</p> <p>Advanced/ metastatic cancer</p>	<p>Haematological¹ - within 5 years of treatment</p> <p>Non haematological cancer within 1 year following immunomodulating treatment</p> <p>All other cancers being treated (excluding hormonal treatment)</p>
Chronic heart and vascular disease		e.g. heart failure, hypertensive cardiac disease
Chronic kidney disease	On dialysis, or eGFR <15 ml/min	eGFR <30ml/min
Chronic liver disease		e.g., cirrhosis or fibrosis
Chronic neurological disease or condition	With evolving respiratory failure requiring non- invasive ventilation e.g., motor neurone disease, spinal muscular atrophy	Significantly compromised respiratory function and/or the ability to clear secretions e.g., Parkinson's disease, cerebral palsy
Chronic respiratory disease	Severe e.g., severe cystic fibrosis, severe COPD, severe pulmonary fibrosis	Other conditions e.g., stable cystic fibrosis, severe asthma (continuous or repeated use of systemic corticosteroids), moderate COPD
Diabetes	HbA1c ≥58mmol/mol	All other diabetes (Type 1 and 2)
Immunocompromise due to disease or treatment	<p>Severe e.g.,</p> <p>Transplantation:</p> <ul style="list-style-type: none"> - Listed for solid organ or haematopoietic stem cell transplant (HSCT) - Post solid organ transplant at any time - Post HSCT within 12 months <p>Genetic diseases:</p> <ul style="list-style-type: none"> - APECED² - Inborn errors in the interferon pathway - Some B and T cell deficiencies <p>Treatment e.g.:</p> <ul style="list-style-type: none"> - included but not limited to Cyclophosphamide, Rituximab, Alemtuzumab, Cladribine or Ocrelizumab in the previous 6 months 	<p>Other e.g.,</p> <p>High dose systemic steroids³</p> <p>HIV, not on treatment or CD4 count <200 x10⁶ L for adults</p>
Inherited metabolic diseases	Disorders of intermediary metabolism at risk of acute decompensation e.g., Maple Syrup Urine Disease	Disorders of intermediary metabolism not fulfilling criteria for very high risk
Intellectual disability	Down syndrome	Intellectual disability excluding Down Syndrome
Obesity	BMI >40 kg/m ²	BMI >35 kg/m ²
Severe mental illness		e.g., schizophrenia, bipolar disorder, severe depression
Sickle cell disease	Sickle cell disease	

1. Including e.g., leukaemia, lymphomas, blood dyscrasias or other malignant neoplasms affecting the bone marrow or lymphatic systems
2. APECED - autoimmune polyendocrinopathy candidiasis ectodermal dystrophy
3. The following doses of prednisolone (or equivalent dose of another glucocorticoid) are likely to be immunosuppressive:
 - Adults and children ≥10kg: ≥40mg/day for more than 1 week, or ≥20mg/day for 2 weeks or longer
 - Children <10 kg: 2mg/kg/day for 2 weeks or longer

3. COVID-19 Vaccines

Table 3 shows the vaccines that are recommended by the National Immunisation Advisory Committee (NIAC) following approval by the European Medicines Agency (EMA) that are used in the COVID-19 Immunisation Programme in Ireland.

The following vaccines are no longer available for use in the COVID-19 Immunisation Programme in Ireland:

- Comirnaty® Original 30 micrograms (0.3ml, for those aged 12 years and older)
- Comirnaty® RTU 30 micrograms (0.3ml, for those aged 12 years and older)
- Comirnaty® Original/Omicron BA.1 30 micrograms (0.3ml, for those aged 12 years and older)
- Comirnaty® Original/Omicron BA.4-5 30 micrograms (0.3ml, for those aged 12 years and older)
- Comirnaty® Original 10 micrograms (0.2ml, for those aged 5-11 years)
- Comirnaty® Original/Omicron BA.4-5 10 micrograms (0.2ml, for those aged 5-11 years)
- Comirnaty® Original 3 micrograms (0.2ml, for those aged 6 months-4 years)
- JCOVDEN® (Janssen) (0.5ml, for those aged 18 years and older)
- Spikevax® Original 100 micrograms (0.5ml, for those aged 30 years and older)
- Spikevax® bivalent Original/Omicron BA.1 50 micrograms (0.5ml, for those aged 30 years and older)
- Spikevax® bivalent Original/Omicron BA.4-5 50 micrograms (0.5ml, for those aged 30 years and older)
- Nuvaxovid® (Novavax) (0.5ml, for those aged 12 years and older).
- VidPrevtyn Beta® (for those aged 18 years and older)

Table 3: Vaccines used in the COVID-19 Immunisation Programme

mRNA VACCINES		
Comirnaty® Omicron XBB.1.5 3mcg (0.2ml) <i>(Maroon Cap- requires Dilution before use)</i>	Pfizer/BioNTech	Vaccination of children aged 6 months-4 years
Comirnaty® Omicron XBB.1.5 30mcg (0.3ml) <i>(Grey Cap – Ready to Use (RTU))</i>	Pfizer/BioNTech	Vaccination of individuals aged 12 years and older
Comirnaty® Omicron XBB.1.5 10mcg (0.2ml) <i>(Orange Cap – requires Dilution before use)</i>	Pfizer/BioNTech	Vaccination of individuals aged 5-11 years
Comirnaty® Omicron XBB.1.5 10mcg (0.3ml) <i>(Blue Cap – Ready to Use (RTU))</i>	Pfizer/BioNTech	Vaccination of individuals aged 5-11 years
PROTEIN SUB-UNIT VACCINES		
Nuvaxovid® XBB.1.5 5mcg (0.5ml)	Novavax	Vaccination of individuals aged 12 years and older who cannot receive an mRNA vaccine (because of a contraindication or clinical precaution) or have chosen not to receive an mRNA vaccine

Further regulatory information on COVID-19 vaccines can be found in the approved product information (Summary of Product Characteristics (SmPC) for health care professionals, and Package Leaflet (PIL) for the public), and is available via the EMA website www.ema.europa.eu.

4. Infection Prevention and Control for the administration of COVID-19 Vaccines

Prior to preparation and administration of COVID-19 vaccines, hand hygiene should be performed as per the “WHO five moments of hand hygiene” with emphasis on:

- Before vaccine preparation
- Before drawing up and administering the vaccine
- Before and after each recipient contact

Check Health Protection Surveillance Centre (HPSC) website for latest guidance on infection prevention and control (IPC) for healthcare workers:

National Clinical Guideline No. 30 (2023) – Infection Prevention and Control (IPC)

<https://www.gov.ie/en/publication/a057e-infection-prevention-and-control-ipc/>.

It is not necessary to use gloves for vaccine injections, unless the health care worker has an infected lesion on the hand.

It is not necessary to use a skin disinfectant at the injection site prior to injection. If the skin at the injection site is visibly dirty, clean with soap and water. If an alcohol swab is used, delay injection for ≥ 30 seconds, to ensure the alcohol has evaporated.

There is no need to routinely check temperature either at registration or before vaccination.

- Follow HPSC standard precautions (sharps management, Personal Protective Equipment (PPE) and healthcare waste management etc.)
- National Clinical Guideline No. 30 (2023) – Infection Prevention and Control (IPC)
<https://www.gov.ie/en/publication/a057e-infection-prevention-and-control-ipc/>.

5. Vaccine details, storage and instructions for preparation and administration.

Vaccines undergo rigorous checks and quality steps prior to final release from the manufacturer.

SmPCs usually state: "The vaccine should be inspected visually for particulate matter and discolouration prior to administration. Discard the vial if the suspension is discoloured or visible particles are observed." When a vaccinator is concerned regarding a vial the following steps should be followed:

- The vaccinator should contact another healthcare professional (HCP) who has experience in using this product and ask for a second opinion
- The affected vial should be returned to the **fridge** and kept there in **Quarantine** (between +2°C and +8°C)
- The vial in quarantine should be placed in a clearly marked area in the fridge "Quarantine - do not use"
- The vaccinator and senior experienced HCP should check the other vials in this batch in their fridge by removing one vial at a time and ensuring that the duration out of the fridge is kept to a minimum
- If more vials are considered defective, they should calculate the impact of placing vials into quarantine and arrange for additional deliveries if required.
- The Health Products Regulatory Authority (HPRA), manufacturer and HSE National Immunisation Office (NIO) should be emailed with details of the issue and with a photograph of vial identifying the defect (if possible).
- The NIO will follow up and contact other locations where this batch has been delivered if necessary.

Please ensure vaccines are stored between +2°C and +8°C.

Should vaccines be exposed to temperatures outside of these parameters please contact the NIO immediately.

NIO Pharmacists:

Cora Kerrigan: mobile 087 1881565

Leah Gaughan: mobile 087 1881667

Achal Gupta: mobile 087 4064810

Email pharmacynio@hse.ie

Pre-drawn syringes of COVID-19 vaccines from multi-dose vials that are prepared within designated vaccine preparation areas may be available within the HSE vaccination clinics. National clinical guidance specific to these HSE settings on this matter should be adhered to.

6. COVID-19 mRNA Vaccines

The following vaccine is recommended for primary and booster vaccination. Please refer to Section 10 for further details in relation to booster vaccination.

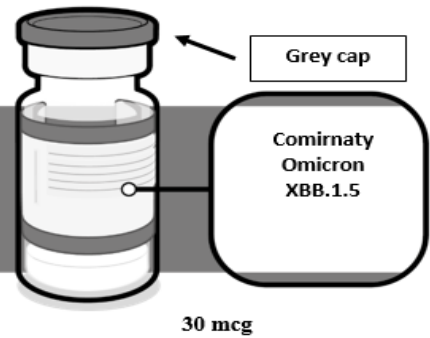
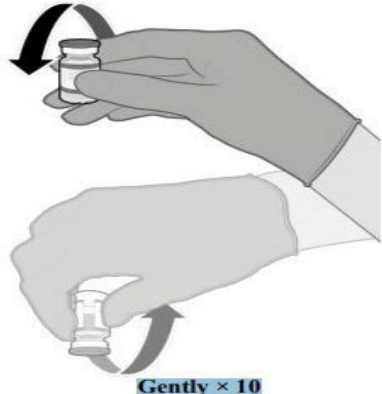
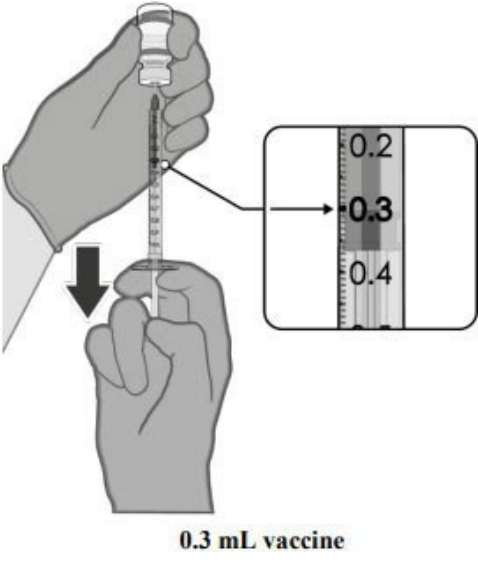
- **Comirnaty® Omicron XBB.1.5 30 micrograms (0.3ml)** is the preferred vaccine for primary and booster vaccination for those aged 12 years and older.

Of note:

- For information about vaccines for children aged 5-11 years see **Section 13 Vaccination of Children aged 5-11 years.**
- For information about vaccines for children aged 6 months-4 years see **Section 14 Vaccination of Children aged 6 months-4 years.**

6.1 Comirnaty® Omicron XBB.1.5 30 micrograms (0.3ml)

Title	Description
Manufacturing process	mRNA
Name of vaccines and description	Comirnaty® Omicron XBB.1.5 30 micrograms/dose dispersion for injection
Indication	Primary and booster vaccination of individuals aged 12 years and older
Excipients	<ul style="list-style-type: none"> • ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate) (ALC-0315) • 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide (ALC-0159) • 1,2-Distearoyl-sn-glycero-3-phosphocholine (DSPC) • Cholesterol • Trometamol • Trometamol hydrochloride • Sucrose • Water for injections
Presentation	The vaccines are contained in a multi-dose clear vial (type I glass)
Number of doses in each vial	6 doses. If a seventh dose of 0.3ml can be safely and accurately withdrawn from a diluted vial, it is a valid dose. No more than 7 valid doses are available.
Dilution	DO NOT DILUTE
Latex	The vial stopper does not contain latex.
Dosage	0.3ml (30 mcg) intramuscularly

VIAL VERIFICATION OF COMIRNATY OMICRON XBB.1.5 (12 YEARS AND OLDER)	
 <p>A diagram of a vial with a grey cap. A callout box points to the cap with the text 'Grey cap'. The label on the vial reads 'Comirnaty Omicron XBB.1.5' and '30 mcg'.</p>	<ul style="list-style-type: none"> • Check “Use before” date and time on the vaccine box • Verify that the vial has a grey plastic cap and the product name is Comirnaty® Omicron XBB.1.5 30 micrograms/dose dispersion for injection.
 <p>Two illustrations showing hands gently mixing a vial. The first shows the vial being inverted. The second shows the vial being held upright. A blue box at the bottom says 'Gently × 10'.</p>	<ul style="list-style-type: none"> • Gently mix by inverting vials 10 times prior to use. Do not shake • Prior to mixing, the thawed dispersion may contain white to off-white opaque amorphous particles • After mixing, the vaccine should present as a white to off-white dispersion with no particulates visible. Do not use the vaccine if particulates or discolouration are present.
REPARATION OF INDIVIDUAL 0.3 ml DOSES OF COMIRNATY OMICRON XBB.1.5	
 <p>A diagram showing a hand holding a vial and another hand drawing vaccine into a syringe. A callout box shows a close-up of the syringe scale with the 0.3 ml mark highlighted. A blue box at the bottom says '0.3 mL vaccine'.</p>	<ul style="list-style-type: none"> • Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab. • Withdraw 0.3 ml of vaccine. <p>Low dead-volume syringes and/or needles should be used in order to extract 6 doses from a single vial. If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial.</p> <ul style="list-style-type: none"> • Each dose must contain 0.3 ml of vaccine. • If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 ml, discard the vial and any excess volume. • Record the appropriate date/time on the vial. Discard any unused vaccine 12 hours after first puncture.

Shelf life and transportation

	Description
Expiry date	The date the vaccine expires when continuously stored in an ULT freezer at -90°C to -60°C. The batch number on the side of each vial is recorded in the patient record. This is linked to the expiry date.
“Use before” date and time Maximum time from removal from ultra-low temperature (ULT) freezer to expiry, when stored at +2°C to +8°C	USE BEFORE date and time. This time and date will be labelled on the box by NCCS. The vials must be used before the use before date and time. The use before date must be recorded in the person’s record.
“Discard” date and time Maximum time allowed from first puncture of vial to expiry	After first puncture, the vaccine must be used within 12 hours (when stored at +2 °C to +30 °C) e.g. Vial is punctured 15/09/2023 at 10.00. Discard time is 15/09/2023 at 22.00. This is the date and time that should be written on the vial. Any unused or partially unused vials must be discarded when this time has been reached. From a microbiological point of view, unless the method of opening precludes the risks of microbial contamination, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user
Transportation time	Unpunctured vial. No limit within the use before date and time, when stored at +2 to +8 °C Punctured vial Up to 6 hours transportation time within the 12 hour discard date and time when stored at +2 °C to +30 °C.

Comirnaty® XBB.1.5 30 micrograms (0.3ml), dosage and scheduling for the primary vaccination course for those aged 12 years and older

A primary schedule of a single dose of Comirnaty mRNA COVID-19 vaccine is recommended for those aged 12 years and older.

The preferred COVID-19 vaccine for primary vaccination is Comirnaty Omicron XBB.1.5 30 micrograms where available, for all those eligible for primary vaccination schedule aged 12 years and older, and should be given as a single dose to those who are immunocompetent.

For those who are immunocompromised with a suboptimal response to vaccines (see Table 2) aged 12 years and older:

For those who are immunocompromised a second dose is recommended **four weeks** after the first dose and a third dose may be given on advice from a relevant specialist physician and this should be **eight weeks** after the second dose.

If the second dose is given more than four days before the minimum interval to an immunocompromised person this is not considered a valid dose. A further dose should be given at least eight weeks after the invalid dose. If a recommended third dose, for an immunocompromised person, is given more than four days before the minimum interval then this is not considered a valid dose and a further dose should be given eight weeks after the invalid dose. For immunocompromised a relevant specialist physician may recommend a **minimum interval of three weeks between dose one and dose two** or **four weeks between dose two and dose three**, if there is urgency to achieve protection.

7. Protein Sub-Unit Vaccine: Nuvaxovid® XBB.1.5

Nuvaxovid XBB.1.5 can be offered for primary and booster vaccination in people aged 12 years and older who cannot receive an mRNA COVID-19 vaccine because of a contraindication or a precaution, or in people who have chosen not to receive an mRNA COVID-19 vaccine.

Table 5: Details of Nuvaxovid® XBB.1.5 for primary and booster vaccination

Title	Description
Type of vaccine	Protein sub-unit vaccine
Name of vaccine	Nuvaxovid®XBB.1.5 dispersion for injection COVID-19 Vaccine (recombinant, adjuvanted)
Constituents	<p>One dose (0.5 ml) contains 5 micrograms SARS-CoV-2 (Omicron XBB.1.5) spike protein* and is adjuvanted with Matrix-M.</p> <ul style="list-style-type: none"> • Disodium hydrogen phosphate heptahydrate • Sodium dihydrogen phosphate monohydrate • Sodium chloride • Polysorbate 80 • Sodium hydroxide (for adjustment of pH) • Hydrochloric acid (for adjustment of pH) • Water for injections <p><u>Adjuvant (Matrix-M)</u></p> <ul style="list-style-type: none"> • Matrix-M adjuvant contains Fraction-A (42.5 micrograms) and Fraction-C (7.5 micrograms) of Quillaja saponaria Molina extract per 0.5 ml dose. • Cholesterol • Phosphatidylcholine (including all-rac-α-Tocopherol) • Potassium dihydrogen phosphate • Potassium chloride • Disodium hydrogen phosphate dihydrate • Sodium chloride • Water for injections
Presentation	2.5 ml of dispersion in a vial (type I glass). The dispersion is colourless to slightly yellow, clear to mildly opalescent
Number of doses in each vial	Up to 5 doses If more than five 0.5ml doses can be safely and accurately withdrawn from a vial, they can be used as valid vaccines. There should be no pooling of vaccine from different vials
Dilution	NO DILUTION REQUIRED
Latex	No, the vaccine is latex free Each vial has a stopper (bromobutyl rubber) and an aluminium overseal with blue plastic flip-off cap
Dosage	0.5 ml
Number of doses required	1

* produced by recombinant DNA technology using a baculovirus expression system in an insect cell line that is derived from Sf9 cells of the Spodoptera frugiperda species.

Nuvaxovid® XBB.1.5 storage

The vaccine will be delivered by the NCCS at +2°C to +8°C.

Unopened (unpunctured) multidose vial should be stored in a pharmaceutical grade refrigerator (+2°C to +8°C) until expiry.

Unopened vaccine should be kept within the outer carton to protect from light. Unopened Nuvaxovid XBB.1.5 vaccine has been shown to be stable up to 12 hours at 25°C.

Opened multi-dose vial

Chemical and physical in-use stability has been demonstrated for **6 hours at +2°C to +25°C** from the time of first needle puncture to administration. The “discard” date and time i.e. 6 hours after the vial is first punctured must be written on the vial using a 24 hour format.

Table 6: Definitions of terms for expiry date and usage times of Nuvaxovid® XBB.1.5

	Description
Expiry date	This is date after which the vial must not be punctured. It is printed on the vaccine vial and original box
“Discard” date and time Maximum time allowed from first puncture to vaccine administration	When the vaccine is first punctured it must be used within 6 hours The “discard” date and time i.e. 6 hours from first puncture of the vial, should be written on the vial using a 24 hour format. E.g. Vial is first punctured on 20/104/2024 at 10.00. Discard date and time is 20/04/2024at16.00. This is the date and time that should be written on the vial. Any unused or partially used vials must be discarded when this time has been reached.

Preparation and administration of Nuvaxovid® XBB.1.5

Vaccine dose preparation and administration should be carried out at the point of administration i.e. beside the person being vaccinated.

- The same needle and syringe should be used to draw up and administer the vaccine
- Once the multidose vial is punctured, the vaccine should be used immediately. If not used, it may be kept for a single period between +2°C to +25°C and used within six hours. There should be no pooling of vaccine from different vials.

Requirements for administration of vaccine

- One Nuvaxovid® XBB1.5 multidose vial
- 70% alcohol swabs
- Size 23 gauge / 25 gauge and 25mm in length needle
- 1ml syringes

Note: A 40 mm needle should be used in females >90kg and males >120kg

Preparation and administration of one dose of vaccine

Preparation for use:

- The vaccine comes ready to use.
- Unopened vaccine should be stored at +2°C to +8°C and kept within the outer carton to protect from light.
- Immediately prior to use, remove the vaccine vial from the carton in the refrigerator.
- Record the date and time of discard on the vial label. Use within 6 hours after first puncture.

Inspect the vial:

- Gently swirl the multidose vial before and in between each dose withdrawal. Do not shake.
- Each multidose vial contains a colourless to slightly yellow, clear to mildly opalescent dispersion free from visible particles.
- Visually inspect the contents of the vial for visible particulate matter and/or discolouration prior to administration. Do not administer the vaccine if either is present.

Administer the vaccine:

- Each 0.5 ml dose is withdrawn into a sterile needle and sterile syringe to be administered by intramuscular injection, preferably in the deltoid muscle of the upper arm.
- Do not mix the vaccine in the same syringe with any other vaccines or medicinal products.
- Do not pool excess vaccine from multiple vials.

Storage after first needle puncture:

- Nuvaxovid does not contain a preservative. Store the opened vial between +2°C to +25°C for up to 6 hours after first puncture

Discard:

- Discard this vaccine if not used within 6 hours after first puncture of the vial
- Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Nuvaxovid® XBB.1.5 dosage and scheduling if used for the primary vaccination course for those aged 12 years and older

Nuvaxovid XBB.1.5. can be offered for primary vaccination in adults and children aged 12 years and older with a contraindication to a mRNA vaccine, or in those who choose not to receive a mRNA vaccine. For immunocompetent adults and children aged 12 years and above, a single dose is recommended. For those with immunocompromising conditions, two doses should be administered with a **four week interval between dose one and dose two**. If a third dose is recommended by a relevant specialist physician, there should be an interval of **eight weeks between dose two and three**.

OF NOTE - regarding minimum intervals for primary schedule with Nuvaxovid XBB.1.5 in immunocompromised: For Nuvaxovid XBB.1.5 the recommended intervals of four weeks between dose one and dose two and eight weeks between dose two and dose three (if a third dose is recommended by a relevant specialist physician) **should also be taken as the minimum intervals**. There is insufficient evidence to recommend shorter intervals for Nuvaxovid XBB.1.5 in immunocompromised.

Nuvaxovid® XBB.1.5 for booster vaccination

The booster dose of 0.5ml should be administered intramuscularly. The preferred site of administration is the deltoid muscle.

Nuvaxovid XBB.1.5 may be used for homologous and heterologous boosters. Booster doses are recommended as per Table 1 of this document (or Table 5a.1 of Chapter 5a of the NIAC Immunisation Guidelines for Ireland).

If there is a contraindication or precaution to an mRNA vaccine booster, or a person has chosen not to receive an mRNA COVID-19 vaccine booster, Nuvaxovid XBB.1.5 may be used as an alternate.

Please refer to section 10 for more information on booster vaccination with Nuvaxovid XBB.1.5.

8. Contraindications and precautions to COVID-19 vaccines

8.1 mRNA Vaccines

Contraindications to mRNA vaccines

- Anaphylaxis (serious systemic allergic reaction requiring medical intervention) after an mRNA vaccine
- Anaphylaxis after polyethylene glycol (PEG, e.g., some bowel preparations for endoscopy, certain laxatives such as Movicol)
- Anaphylaxis after trometamol¹, (contained in all presentations of Comirnaty® currently in use in Ireland)

Those with a contraindication to one mRNA COVID-19 vaccine should not receive another authorised mRNA vaccine.

Consideration may be given to non-mRNA vaccination for anyone aged 12 years and older following an individual benefit risk assessment, including pregnant women.

The preferred vaccine for primary and booster vaccination in those aged 12 years and older is **Comirnaty Omicron XBB.1.5 (30 micrograms)**.

If there is a contraindication or precaution to an mRNA vaccine, or a person has chosen not to receive an mRNA COVID-19 vaccine, Nuvaxovid XBB.1.5 (a protein based vaccine) may be used as an alternate following an individual benefit risk assessment. There is limited experience with use of Nuvaxovid in pregnancy. Administration of Nuvaxovid XBB.1.5 in pregnancy should only be considered when the potential benefits outweigh any potential risks for the mother and fetus.

Precautions:

- Acute severe illness; defer until recovery. Routine physical examination and temperature measurement of persons who appear to be healthy are not necessary prior to vaccination.
- Previous history of myocarditis or pericarditis after any COVID-19 vaccine - seek specialist advice before vaccination (i.e., consult with a Cardiologist).
- There should be an interval of at least 4 weeks between mpox (formerly known as monkeypox)/smallpox vaccine and a subsequent COVID-19 vaccine because of the unknown risk of myocarditis.
- Children with a previous history of MIS-C - defer vaccination until clinical recovery or at least 3 months since diagnosis, whichever is the longer.
- Consider a non-mRNA vaccine (Nuvaxovid® XBB.1.5) for those aged 12 years and older, including pregnant women, with:
 - Anaphylaxis after multiple different drug classes, with no identified allergen (may indicate PEG allergy)

¹ Trometamol has been implicated in one report of contrast medium anaphylaxis relating to gadolinium based contrast agents (GBCAs) used in MRI radiological studies.

- Anaphylaxis after a vaccine or a medicine known to contain PEG
- Unexplained anaphylaxis (may indicate PEG allergy)

Patients with planned immunosuppressing therapy should ideally complete vaccination two weeks before treatment.

For more information please refer to the NIAC Immunisation Guidelines for Ireland **Table 5a.3 Contraindications and precautions to mRNA COVID-19 vaccines** and see Frequently Asked Questions about COVID-19 vaccines for people with pre-existing allergic conditions www.rcpi.ie

Of note: Refer to section 13 for details of vaccination of children aged 5-11

Refer to section 14 for details of vaccination of children aged 6 months-4 years

8.2 Protein sub-unit vaccine Nuvaxovid® XBB.1.5

Contraindications

Anaphylaxis (serious systemic allergic reaction requiring medical intervention) following a previous dose of the vaccine or any of its constituents including polysorbate 80.

Precautions

Acute severe illness; defer until recovery.

Previous history of myocarditis or pericarditis after any COVID-19 vaccine, seek specialist advice.

There should be an interval of 4 weeks between mpox (formerly known as monkeypox)/smallpox vaccine and a subsequent Nuvaxovid XBB.1.5 vaccine because of the unknown risk of myocarditis. No interval is required between Nuvaxovid XBB.1.5 and subsequent mpox vaccines.

Advice from a relevant specialist should be sought for a person with:

- a history of an immediate severe allergic reaction to multiple drug classes with no identified allergen,
- any other vaccine injected antibody preparation or medicine likely to contain polysorbate 80 or
- idiopathic anaphylaxis

The risks should be weighed against the benefits of vaccination.

There is limited experience with use of Nuvaxovid in pregnancy. Administration of Nuvaxovid XBB.1.5 in pregnancy should only be considered when the potential benefits outweigh any potential risks for the mother and fetus.

Please refer to the NIAC Immunisation Guidelines for Ireland for details. <https://www.rcpi.ie/healthcare-leadership/niac/immunisation-guidelines-for-ireland>

Appropriate support should be available in case of anaphylaxis or fainting after vaccine administration. Precautions should also be in place to minimise risk of injury from fainting.

8.3 Vaccination after COVID-19

Unvaccinated

Those who are unvaccinated and develop SARS-CoV-2 infection should complete a primary vaccination schedule, with the single dose (or first dose for immunocompromised) at least four weeks after diagnosis or onset of symptoms, or four weeks from the first PCR positive specimen in those who are asymptomatic.

Those with persisting symptoms following COVID-19 may be vaccinated, unless there is evidence of recent clinical deterioration.

Partially vaccinated

Those who are immunocompromised who have had SARS-CoV-2 infection after their first dose of COVID-19 vaccine should be given the subsequent dose at least four to eight weeks after diagnosis or onset of symptoms.

If those who are immunocompromised, have SARS-CoV-2 infection more than seven days after the second vaccine dose, a third dose of the primary schedule is not required. They should proceed to their booster dose if recommended in Table 1 of this document (or Table 5a.1 of the NIAC Immunisation Guidelines for Ireland). For those with infection within seven days of their second dose they should have a third dose after an interval of four to eight weeks if a third dose is recommended by a relevant specialist physician.

Booster vaccination

Those who have had SARS-CoV-2 infection after completing their primary schedule (i.e., a breakthrough infection), should proceed to booster vaccination as recommended in Table 1 of this document (or Table 5a.1 of the NIAC Immunisation Guidelines for Ireland).

Serological testing prior to giving an additional dose (either for immunocompromised in primary schedule or for any booster dose) is not recommended.

9. Clinical considerations for COVID-19 vaccines

9.1 Pregnancy

Pregnant women should be offered mRNA COVID-19 vaccines and should be up to date with COVID-19 vaccines in line with NIAC recommendations. For details of the recommended timing of booster vaccination in pregnancy please see Section 10.

Continuing evidence regarding mRNA COVID-19 vaccination during pregnancy has demonstrated it to be safe and effective. The primary schedule may be given at any stage in pregnancy (see Table 1 of this document or Table 5a.1 of the NIAC Immunisation Guidelines for Ireland).

Pregnant women are at similar risk of COVID-19 infection to non-pregnant women of the same age.

However, pregnant women with COVID-19 infection are more likely to be admitted to ICU or to die than similar aged non-pregnant women with COVID-19. Pregnant women from Black, Asian and minority ethnic backgrounds may be more likely to be admitted to hospital with COVID-19 disease than other pregnant women.

COVID-19 in pregnancy may increase the risk of adverse pregnancy outcomes, such as miscarriage, stillbirth and preterm birth.

The following factors may increase the risks of severe illness in pregnancy:

- Underlying conditions listed in Table 5a.2 of the NIAC Immunisation Guidelines for Ireland
- Age over 35 years
- Infection in the third trimester (28 weeks' or more)
- BMI of 30 or more.

There is now a growing body of evidence on the safety and effectiveness of mRNA COVID-19 vaccination - clearly indicating that the benefits of vaccination outweigh any known or potential risks of COVID-19 vaccination during pregnancy. Long term follow-up is on-going.

Vaccination is the best way to protect both mother and baby from serious harm and mRNA vaccines should be available to pregnant women at all stages of pregnancy. Emerging data indicates that the maternal COVID-19 antibodies can cross the placenta, which may offer neonatal protection.

The NIAC has reviewed the evidence regarding safety and timing of COVID-19 primary and booster vaccines in pregnancy. Current data are very reassuring regarding the safety of COVID-19 mRNA vaccines given at any stage in pregnancy either as a primary vaccine or as a booster. The EMA, UK Health Security Agency, and CDC have been monitoring the safety of COVID-19 vaccines in pregnancy^{2,3,4}. These safety monitoring

² European Medicines Agency. COVID-19: latest safety data provide reassurance about use of mRNA vaccines during pregnancy 2022 [Available from: <https://www.ema.europa.eu/en/news/covid-19-latest-safety-data-provide-reassurance-about-use-mrna-vaccines-during-pregnancy> accessed 21 Feb 2023.

³ Agency UHS. COVID-19 vaccine surveillance report. Week 5, 2 February 2023 2023 [Available from: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1134076/vaccine-surveillance-report-week-5-2023.pdf accessed 21 Feb 2023.

⁴ Centres for Disease Control and Prevention. COVID-19 Vaccines While Pregnant or Breastfeeding 2022

systems have not reported any safety concerns for people who receive an mRNA COVID-19 vaccine at any stage of pregnancy. Less data are available regarding non-mRNA vaccines.

NIAC and the Institute of Obstetricians and Gynaecologists have developed materials to support healthcare workers and pregnant women in decision making about COVID-19 vaccination. Visit www.rcpi.ie.

Please refer to Section 10 for further details of booster vaccinations.

Booster vaccination in pregnancy with Nuvaxovid® XBB.1.5

There is limited experience with use of the vaccine in pregnant women.

Administration of Nuvaxovid XBB.1.5 in pregnancy should only be considered when the potential benefits outweigh any potential risks to the mother and the fetus and when mRNA vaccines are contraindicated or declined. The pregnant woman and a relevant health professional should engage in shared decision-making in advance of vaccination. Counselling should balance the available data on vaccine safety, risks to pregnant women from COVID-19 infection, and a woman's individual risk for infection and severe disease.

mRNA vaccines remain the recommended COVID-19 vaccines for pregnant women as they have the most extensive safety and efficacy data. If there is a contraindication or precaution to an mRNA vaccine, or a pregnant person has chosen not to receive an mRNA COVID-19 vaccine, vaccination with Nuvaxovid XBB.1.5 may be considered following an individual benefit risk assessment.

9.2 Breastfeeding

COVID-19 vaccines can be used during breastfeeding. There is no evidence that breastfeeding after COVID-19 vaccination causes harm to the breastfed infants or interferes with ability to breastfeed.

9.3 Individuals with a bleeding disorder

Individuals with a bleeding disorder or receiving anticoagulant therapy may develop haematomas in IM injection sites. Prior to vaccination, inform the recipient about this risk. For those with thrombocytopenia (platelet count $<50 \times 10^9/L$) consult the supervising consultant.

People with mild bleeding disorders or on maintenance dose Emicizumab (Hemlibra®) do not require haemostatic cover for vaccination. Details of haemostatic cover for all others can be found in the Patient Information tab at <http://www.stjames.ie/services/hope/nationalcoagulationcentre>

Those with inherited coagulopathies receiving factor replacement therapy should receive the treatment on the day of vaccination, prior to the IM vaccination.

If there is uncertainty about the need for cover, contact the patient's Comprehensive Care Centre.

[Available from: <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/pregnancy.html> accessed 21 Feb 2023.

9.4 Individuals taking anticoagulants

Those receiving long term anticoagulation with either warfarin or heparin are not considered to be at higher risk of bleeding complications following immunisation. There is no reason to expect that there is a greater risk of bleeding complications with the newer types of anticoagulants, such as antiplatelet agents, than with other anticoagulants.

People on Warfarin® should follow their usual schedule for international normalised ratio (INR) testing and can be vaccinated if it is less than 4.0. If the INR is 4.0 or more, follow the advice of the clinic/practice managing Warfarin® and wait until the INR is less than 4.0 to be vaccinated.

9.5 Technique for IM injections in persons with bleeding disorders or on anticoagulants

- Use a 23 or 25 gauge needle to reduce the pressure gradient and cause less trauma to the tissue.
- The vaccine should be injected slowly (≥ 5 seconds) to reduce the risk of tissue damage.
- Firm pressure should be applied to the site for 5 to 10 minutes after injection.
- Stabilisation of the limb will reduce the risk of a haematoma.
- The site should not be rubbed or massaged.
- Instruct the patient/caregiver to monitor the injected limb and to report any concerns to their supervising consultant.

9.6 Co-administration of COVID-19 vaccines with other inactivated or live vaccines for those aged 12 years and over:

COVID-19 and adult seasonal influenza vaccines should be co-administered where practicable, to maximise uptake. Vaccinees should be informed there may be a slight increase in short term mild adverse events after co-administration with a seasonal influenza vaccine. These include pain at the site of injection, fatigue, headache, and myalgia.

There should be an interval of at least four weeks between mpox vaccine and a subsequent COVID-19 vaccine because of the unknown risk of myocarditis. No interval is required between a COVID-19 vaccine and a subsequent mpox vaccine.

COVID-19 vaccines and other adult vaccines may be administered at the same time or at any interval. Co-administered vaccines should be given in different arms.

9.7 Immunosuppression due to disease or treatment

Individuals with immunosuppression due to disease or treatment should be vaccinated if they have no contraindications.

Patients with planned immunosuppressing therapy should ideally complete vaccination two weeks before treatment.

9.8 Primary course for those with immunosuppression due to disease or treatment aged 12 years and older

Those with severe immunocompromise (see Table 5a.2 of the NIAC Immunisation Guidelines for Ireland) due to disease or treatment at the time of their primary COVID-19 vaccination may have suboptimal response to their vaccines. A two dose primary course (with an option for an additional dose following specialist recommendation) and subsequent booster vaccination are recommended, see Table 1 of this document (or Table 5a.1 of the NIAC Immunisation Guidelines for Ireland). Serological testing prior to giving an additional dose is not recommended.

Comirnaty Omicron XBB.1.5 mRNA COVID-19 vaccine is the preferable vaccine, and should be given as follows:

Recommended intervals for the primary series for those with immunocompromise aged 12 years and older

Two doses of Comirnaty Omicron XBB.1.5 30 micrograms (0.3ml), with a 4 week interval between dose one and dose two i.e.

- An **interval of 4 weeks** between the first and second doses is now recommended

A third dose may be administered following instruction from a relevant specialist physician

- The third dose should be given **8 weeks** after the second vaccine dose

For immunocompromised receiving Comirnaty Omicron XBB.1.5 30 micrograms, a relevant specialist physician may recommend a **minimum interval of three weeks between dose one and dose two or four weeks between dose two and dose three**, if there is urgency to achieve protection.

OF NOTE: For immunocompromised receiving Nuvaxovid XBB.1.5, the recommended intervals of four weeks between dose one and dose two and eight weeks between dose two and dose three (if a third dose is recommended by a relevant specialist physician) **should also be taken as the minimum intervals**. There is insufficient evidence to recommend shorter intervals for Nuvaxovid XBB.1.5 in immunocompromised.

Specialists should consider the individual's risk and likelihood of disease exposure, and provide advice based on knowledge and understanding of the patient's immune status and likely immune response to vaccination.

See [Table 5a.2 of the NIAC Immunisation Guidelines for Ireland](#) for conditions that may be associated with a suboptimal response to vaccines (shaded in blue in the table)

9.9 People being treated with chemotherapy for cancer

Chemotherapy is not a contraindication to COVID-19 vaccination. People taking chemotherapy should be vaccinated according to their priority group (provided there are no contraindications).

Vaccination for children aged 5-11 years is discussed in a separate section within this guidance document (see Section 13).

Vaccination for children aged 6 months-4 years is discussed in a separate section within this guidance document (see Section 14).

10. Booster COVID-19 Vaccines

Irrespective of the vaccine type used in the primary schedule, **Comirnaty Omicron XBB.1.5 vaccines at an age-appropriate dose are the preferred booster vaccines**. Nuvaxovid XBB.1.5 may be used as an alternate booster vaccine (following an individual benefit-risk assessment) if mRNA vaccines are contraindicated or not accepted.

NIAC no longer recommends a shorter interval first booster dose. Subsequent doses should be administered as per seasonal recommendations.

Booster doses should be given as per the recommendations in Table 1 of this document (or Table 5a.1 of the NIAC Immunisation Guidelines for Ireland).

The following mRNA vaccine is available in Ireland for booster vaccination of those **aged 12 years and older**:

- **Comirnaty® Omicron XBB.1.5 30 micrograms (0.3ml)**

NOTE: The National Immunisation Advisory Committee (NIAC) recommends the preferential use of Comirnaty® Omicron XBB.1.5 30 micrograms for vaccination of those aged 12 years and older in Ireland.

Recommended intervals for booster vaccination in Spring 2024 for those aged 12 years and older:

Please see [Table 1](#) for those who are recommended to receive booster vaccines in Spring 2024.

- A **6 month** interval from previous COVID-19 vaccine dose or SARS-CoV-2 infection is recommended for those receiving a booster as part of the Spring vaccination programme 2024.
- A minimum interval of **3 months** is permissible in exceptional circumstances e.g. planned immunosuppressive therapy or for operational reasons.

Booster Vaccination after COVID-19 breakthrough infection

Those who have had SARS-CoV-2 infection after completing their primary schedule (i.e., a breakthrough infection), should proceed to booster vaccination as recommended in Table 1 (or Table 5a.1 of the NIAC Immunisation Guidelines for Ireland).

Booster vaccination with Nuvaxovid® XBB.1.5

Booster doses of Nuvaxovid XBB.1.5 are recommended as per Table 1 (or Table 5a.1. of the NIAC Immunisation Guidelines for Ireland). Nuvaxovid XBB.1.5 may be used for homologous and heterologous boosters (in those aged 12 years and older).

If there is a contraindication or precaution other than myocarditis or pericarditis to a booster dose of an mRNA vaccine, or a person has chosen not to receive an mRNA COVID-19 booster, consideration can be given to a homologous or heterologous booster of Nuvaxovid XBB.1.5 following an individual benefit-risk assessment.

For information on recommended intervals for Nuvaxovid XBB.1.5 boosters see Table 1.

In exceptional circumstances an interval of 3 months may be used (e.g., in a person scheduled to commence chemotherapy).

There is limited experience of Nuvaxovid XBB.1.5 in those who are pregnant, and this should only be considered when the potential benefits outweigh the potential risks. If pregnant women are receiving Nuvaxovid® XBB.1.5 as a booster dose, they should have a discussion with a healthcare professional (e.g. clinical lead vaccinator) on their individual risks and benefits of receiving the vaccine. Please refer to section 9.1.

Table 7. COVID-19 Vaccine Summary for those aged 12 years and older

Description	Comirnaty® Omicron XBB.1.5 30 micrograms (0.3ml)	Nuvaxovid® XBB.1.5 5 micrograms (0.5ml)
Vial cap colour	Grey cap	Blue cap
Indication for booster vaccination	Aged 12 years and older Use for primary and booster vaccination	Aged 12 years and older Use for primary and booster vaccination
Dose volume (dose)	0.3ml (30mcg)	0.5ml (5mcg)
Dilution	READY TO USE DO NOT DILUTE	READY TO USE DO NOT DILUTE
Doses per vial	6	5
Interval since last dose of COVID-19 Vaccine or SARS-CoV-2 infection	6 months (3 months in exceptional circumstances)	6 months (3 months in exceptional circumstances)

OF NOTE: For information about COVID-19 booster vaccines for children aged 5-11 years see Section 13 Vaccination of Children aged 5-11 years.

Please refer to section 5 for details of preparation, transport and storage of vaccine

Booster Vaccination in pregnancy

mRNA COVID-19 vaccines remain the preferred option for use in pregnancy. The NIAC now recommend:

For pregnant adolescents and adults, a COVID-19 booster vaccine is recommended once in pregnancy. The booster dose should be given **at least six months** after their last COVID-19 vaccine dose (primary schedule or booster dose) or SARS-CoV-2 infection. Booster doses can be given at any stage in pregnancy but ideally should be given between 20-34 weeks. If it is more than 12 months since their previous COVID-19 vaccine or infection administration earlier in pregnancy should be considered.

For those who are pregnant and are immunocompromised, a second booster dose within the same pregnancy may be considered if **six months** has elapsed since their last booster dose or SARS-CoV-2 infection.

There is more limited experience of Nuvaxovid XBB.1.5 in those who are pregnant, and this should only be considered when the potential benefits outweigh the potential risks.

11. Post Vaccination

11.1 Recording vaccination

The individual should be given a record of vaccination and HSE advice leaflet for after vaccination. Vaccine administration should be recorded in the IT system.

Record the “USE BEFORE date and the batch number in the vaccination record (written on the vaccine box by the NCCS).

11.2 Observation period

Cases of anaphylaxis have been reported following administration of COVID-19 vaccines.

Please note that NIAC recommends a 15 minute observation period following administration of a homologous or heterologous booster COVID-19 mRNA vaccine.

Recommended observation period following vaccination (includes booster vaccination):

- All vaccine recipients (see exceptions below): 15 minutes of observation
- Those with a history of mastocytosis: 30 minutes
- Those with immediate itching, swelling or urticarial reaction at the vaccination site: 30 minutes or longer as clinically indicated

Vaccine recipients should be advised to seek urgent medical attention if they have symptoms suggestive of an allergic reaction such as difficulty breathing, feeling faint, rapid heartbeat or a skin rash.

12. Adverse Reactions

12.1 Adverse reactions of COVID-19 vaccines

Please refer to the relevant Summary of Product Characteristics for further details.

The adverse events are listed below in Table 8 according to the following frequency: Very common ($\geq 1/10$), Common ($\geq 1/100$ to $< 1/10$), Uncommon ($\geq 1/1,000$ to $< 1/100$), Rare ($\geq 1/10,000$ to $< 1/1,000$), Very rare ($< 1/10,000$).

The safety of Comirnaty Omicron XBB.1.5 is inferred from safety data of the prior Comirnaty vaccines.

The safety of Nuvaxovid XBB.1.5 is inferred from the safety data of the Nuvaxovid (Original, Wuhan strain) vaccine and the safety data from the adapted Omicron BA.5 vaccine.

Table 8: Adverse reactions of COVID-19 vaccines from clinical trials and post authorisation experience

Type of Reaction	Comirnaty® (Pfizer BioNTech)	Nuvaxovid® (Novavax)
Very Common ($\geq 1/10$)	Local: injection site pain, injection site swelling	Local: Injection site tenderness, Injection site pain
	General: arthralgia, fatigue, fever, chills, headache, myalgia, diarrhea	General: headache, nausea or vomiting, myalgia, arthralgia, fatigue, malaise
Common ($\geq 1/100$ to $< 1/10$)	Local: injection site erythema	Local: Injection site redness, Injection site swelling
	General: nausea, vomiting, lymphadenopathy***	General: pyrexia, pain in extremity
Uncommon ($\geq 1/1,000$ to $< 1/100$)	Local: injection site pruritus	Local: injection site pruritus
	General: insomnia, extremity pain (refers to the vaccinated arm), hyperhidrosis, night sweats, decreased appetite, asthenia, malaise, lethargy, hypersensitivity reactions (e.g. rash, pruritus, urticaria****, angioedema****), dizziness	General: Rash, Erythema Pruritus, Urticaria, Hypertension* Lymphadenopathy Chills
Rare ($\geq 1/10,000$ to $< 1/1,000$)	General: acute peripheral facial paralysis	Injection site warmth

Very rare (< 1/10,000)	Myocarditis and pericarditis	
Not known (cannot be estimated from the available Data)	Anaphylaxis, Facial swelling in those who have had dermatological fillers, Extensive swelling of the vaccinated limb, Erythema Multiforme, Paraesthesia, Hypoaesthesia, Heavy menstrual bleeding**	Anaphylaxis, Paraesthesia, Hypoaesthesia, Myocarditis, Pericarditis

* Hypertension was not reported in adolescents aged 12 through 17 years in the clinical study. Throughout the clinical trials, an increased incidence of hypertension following vaccination with Nuvaxovid (n=46, 1.0%) as compared to placebo (n=22, 0.6%) was observed in older adults during the 3 days following vaccination.

**Most cases appeared to be non-serious and temporary in nature

*** In participants 5 years of age and older, a higher frequency of lymphadenopathy was reported after a booster (≤ 2.8%) dose than after primary (≤ 0.9%) doses of the vaccine.

**** The frequency category for urticaria and angioedema was rare.

- Events of anaphylaxis have been reported after COVID-19 vaccines. Appropriate medical treatment and supervision should always be readily available in case of an anaphylactic reaction following the administration of the vaccine
- Very rare events of neuroinflammatory disorders have been reported following vaccination with COVID-19 vaccines. A causal relationship has not been established

A higher frequency of pyrexia (after Comirnaty®) was observed after the second dose compared to the first dose.

A higher rate of injection site reactions (redness, swelling, tenderness or pain), nausea or vomiting, myalgia, arthralgia, fatigue and malaise, and pyrexia were seen after the second dose of Nuvaxovid® (Novavax).

If required, symptomatic treatment with analgesic and/or anti-pyretic medicinal products (e.g. paracetamol containing products or ibuprofen) may be used. Note: Ibuprofen is not recommended for pregnant women.

12.2 Adverse events following Comirnaty® (Pfizer/BioNTech) and Spikevax® (Moderna) and very rare cases of Myocarditis and Pericarditis

Myocarditis and pericarditis are very rare side effects of mRNA vaccines and Nuvaxovid, occurring predominantly after the second dose and in males under 30 years of age. Higher rates are reported following Spikevax compared with Comirnaty. The risk is lower following booster vaccination. The risk of vaccine associated myocarditis can be reduced by extending the interval between the first and second mRNA COVID-19 vaccine dose in the primary schedule for immunocompromised.

These conditions can develop within a few days after vaccination and have primarily occurred within 14 days. Available data suggest that the course of myocarditis or pericarditis following vaccination is not different from myocarditis or pericarditis in general. The EMA concluded that the overall risk benefit profile for all authorised COVID-19 vaccines remains favourable.

Healthcare professionals should be alert to the signs and symptoms of myocarditis and pericarditis. They should tell people receiving these vaccines to seek immediate medical attention if symptoms indicative of myocarditis or pericarditis occur. These include:

- breathlessness,
- palpitations and
- chest pain.

Healthcare professionals should consult applicable guidance and/or consult specialists (e.g. Cardiologists) to diagnose and treat these conditions.

12.3 Adverse events following Nuvaxovid® (Novavax) and unknown frequency of cases of Myocarditis and Pericarditis

There is an increased risk of myocarditis and pericarditis following vaccination with Nuvaxovid®. The safety of Nuvaxovid XBB.1.5 is inferred from the safety data of the Nuvaxovid® vaccine and the safety data from the adapted Omicron BA.5 vaccine.

These conditions can develop within a few days after vaccination and have primarily occurred within 14 days.

The EMA concluded that the overall risk benefit profile remains favourable.

Available data suggest that the course of myocarditis or pericarditis following vaccination is not different from myocarditis or pericarditis in general.

The frequency of myocarditis and pericarditis after Nuvaxovid® cannot be estimated from the available data.

Myocarditis and pericarditis may present with chest pain, shortness of breath, palpitations and fatigue. Most patients respond well to standard treatment, and the prognosis is good. However, it can occasionally progress to dilated cardiomyopathy and chronic heart failure.

Healthcare professionals should be aware of the signs and symptoms of myocarditis and pericarditis.

Vaccine recipients should be advised to promptly seek medical attention if they develop acute and persisting chest pain, palpitations or shortness of breath in the days after vaccination.

Healthcare professionals should consult applicable guidance and/or consult a Cardiologist for advice on management.

12.4 Reporting adverse reactions

The HPRA is responsible for managing the national pharmacovigilance system. The HPRA reports nationally occurring adverse reactions to the EMA.

Adverse reaction reporting is an important part of the EMA intensive monitoring plan for COVID-19 vaccines, so that any changes in benefit risk balance can be promptly detected and acted upon.

This enables the EMA to continue to safeguard public health safety.

COVID-19 vaccines are subject to additional monitoring. This will allow quick identification of new safety information.

Healthcare professionals and members of the public are encouraged to report any suspected adverse reactions to the HPRA following the instructions available on the HPRA website www.hpra.ie. As much information as is known should be provided, and where possible, the vaccine batch number should be included.

12.5 Reporting of incidents during the vaccination session to HSE

In the case of medication errors that directly involve the vaccine recipient, i.e. wrong medication/dose/route being administered or another medication error, the vaccinator must remain with the person and closely monitor them for any adverse reactions.

The incident must be reported to the relevant line manager/person in charge as soon as possible. The incident and all actions taken must be recorded and the relevant National Incident Management Report Form (NIRF) completed as soon as is practicable after the event occurs and within one working day. (National Incident Report Form (NIRF 01 – V12)) (2021) available at: <https://www.hse.ie/eng/about/qavd/incident-management/>

The vaccine recipient and/or significant others should be informed of the incident. An incident report form must be completed by the vaccinator and forwarded to local or regional Risk Manager as per local policy.

Any suspected adverse reactions associated with medication errors should be reported to the HPRA as outlined above.

13. Vaccination of children aged 5-11 years

The National Immunisation Advisory Committee advise that the preferred COVID-19 vaccine for vaccination of those aged 5-11 years is Comirnaty Omicron XBB.1.5 10 micrograms where available. Comirnaty Omicron XBB.1.5 10 micrograms is available in two age appropriate formulations for children aged 5-11 years in Ireland:

- **Comirnaty® Omicron XBB.1.5 10 micrograms (0.2ml)**
 - This formulation is a concentrate and needs to be diluted. After dilution the dose is 0.2ml.
 - For primary and booster vaccination
- **Comirnaty® Omicron XBB.1.5 10 micrograms (0.3ml)**
 - This is a ready to use formulation (which does not require dilution).
 - For primary and booster vaccination

For more information on both formulations please see table below

Name	Comirnaty® Omicron XBB.1.5 10 micrograms (0.2ml)	Comirnaty® Omicron XBB.1.5 10 micrograms (0.3ml)
SmPC name	Comirnaty Omicron XBB.1.5 10 micrograms/dose concentrate for dispersion for injection	Comirnaty Omicron XBB.1.5 10 micrograms/dose dispersion for injection
Vial Cap Colour	Orange Cap	Blue Cap
Dilution	1.3 ml Sodium Chloride (0.9%) solution for injection	DO NOT DILUTE Ready to Use
Dose Volume (dose)	0.2 ml (10 micrograms)	0.3 ml (10 micrograms)

Comirnaty® Omicron XBB.1.5 for children aged 5-11 years was recommended for authorisation by the [European Medicines Agency on 30th August 2023](#). In its decision to recommend the authorisation, the EMA’s Committee for Medicinal Products for Human Use (CHMP) considered all the available data on Comirnaty® and its other adapted vaccines, including data on safety, efficacy and immunogenicity. In addition, the Committee assessed new laboratory data showing a strong response of the adapted vaccine against XBB.1.5 and related strains of the virus that causes COVID-19.

Comirnaty® Omicron XBB.1.5 10 micrograms is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2, in children aged 5 to 11 years.

13.1 NIAC recommendations

Primary vaccination

Following approval of the original Comirnaty® 10 micrograms formulation for children aged 5-11 years by the EMA in November 2021, the NIAC has made the following recommendations:

- A primary course of COVID-19 vaccination is recommended for those aged 5 to 11 years:
 - With underlying conditions
 - Living with a younger child with complex medical needs
 - Living with a person who is immunocompromised
- COVID-19 vaccination should be offered to all other children aged 5 to 11 years
 - This is because of the favourable risk benefit profile of the vaccine, to protect them from severe disease and from the consequences that can follow infection e.g., multisystem inflammatory syndrome in children (MIS-C), long COVID as well as psychosocial and developmental impacts.

Primary vaccination schedule

- Comirnaty XBB.1.5 10 micrograms vaccine should be given as a single dose to children aged 5 to 11 years who are **immunocompetent**.
- For children aged 5 to 11 years who are **immunocompromised** a second dose is recommended **four weeks** after the first dose and a third dose may be given on advice from a relevant specialist physician and this should be **eight weeks** after the second dose.

If a child becomes 12 years of age before completion of the recommended schedule for 5-11 year olds, the schedule should be completed with the age appropriate dose, Comirnaty Omicron XBB.1.5 30 micrograms. If the interval between doses is longer than the recommended interval, the next dose should be given as soon as possible. The course does not need to be restarted.

If the second dose is given more than four days before the minimum interval to an immunocompromised child this is not considered a valid dose. A further dose should be given at least eight weeks after the invalid dose. If a recommended third dose, for an immunocompromised child is given more than four days before the minimum interval then this is not considered a valid dose and a further dose should be given eight weeks after the invalid dose. For immunocompromised a relevant specialist physician may recommend a **minimum interval of three weeks between dose one and dose two** or **four weeks between dose two and dose three**, if there is urgency to achieve protection.

Before vaccination, parents or guardians should be informed of the known benefits, risks and uncertainties of COVID-19 vaccination.

Recommendations for booster vaccination of those aged 5-11 years

A spring booster vaccine is recommended for those aged 5 – 11 years with immunocompromise associated with a suboptimal response to vaccination (See Table 5a.2 areas shaded in blue).

A spring booster vaccine if indicated should be given **six months** following the last COVID-19 vaccine or SARS-CoV-2 infection (see Table 1 of this document or Table 5a.1 of the NIAC Immunisation Guidelines for Ireland). In exceptional circumstances an interval of three months may be used (e.g., in a person scheduled to commence chemotherapy).

For healthy children aged 5 to 11 years a COVID-19 spring booster vaccination is not recommended.

For more information on the recommended intervals for Spring boosters for eligible children aged 5-11 years, please see Table 1.

The decision to accept, defer or refuse vaccination for a child should be respected.

13.2 Vaccine storage for Comirnaty® formulations for those aged 5-11 years

13.2.1 Comirnaty Omicron XBB.1.5 10 micrograms/dose concentrate for dispersion for injection (0.2ml):

- The vaccine is delivered from the manufacturer to the HSE NCCS at -90°C to -60°C and this storage condition is continued as the vaccine is stored in an ULT freezer at - 90°C to -60°C.
- The vaccine is supplied to sites/clinics by the HSE NCCS at +2 to +8°C with a shelf life of up to 10 weeks. This new “use before” time and date is labelled by NCCS once vials are removed from ULT.
- The vaccine in each multi-dose vial requires dilution with 1.3ml of 0.9% sodium chloride.
- 0.9% sodium chloride is supplied separately to the vaccine and should be stored at room temperature.
- Undiluted vials have a shelf life of 10 weeks when stored at +2 to +8°C (labelled “use before” time and date) and up to 12 hours at temperatures between +8 °C and +30 °C.
- After dilution, the vaccine must be kept at +2°C to +30°C and used within 12 hours after which the vial must be discarded.

Summary of Comirnaty Omicron XBB.1.5 10 micrograms/dose concentrate for dispersion for injection (0.2ml):

Title	Description
Name of vaccine	Comirnaty Omicron XBB.1.5 10 micrograms/dose concentrate for dispersion for injection
Constituents	((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate) (ALC-0315) 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide (ALC-0159) 1,2-Distearoyl-sn-glycero-3-phosphocholine (DSPC) Cholesterol Trometamol Trometamol hydrochloride Sucrose Water for injections
Number of doses in each vial	10 doses per vial after dilution. If more than 10 doses can be accurately withdrawn from a diluted vial, it is a valid dose. No more than 12 valid doses are available.
Dilution	Yes, dilute with 1.3mls of 0.9% Sodium Chloride (supplied separately)
Dosage	0.2ml
Latex	No
Preservatives	No

13.2.2 Comirnaty Omicron XBB.1.5 10 micrograms/dose dispersion for injection (0.3ml):

- The vaccine is delivered from the manufacturer to the HSE NCCS at -90°C to -60°C and this storage condition is continued as the vaccine is stored in an ULT freezer at - 90°C to -60°C.
- The vaccine is supplied to sites/clinics by the HSE NCCS at +2 to +8°C with a shelf life of up to 10 weeks. This new “use before” time and date is labelled by NCCS once vials are removed from ULT.
- Vials have a shelf life of 10 weeks when stored at +2 to +8°C (labelled “use before” time and date) and up to 12 hours at temperatures between +8 °C and +30 °C.
- After removal from the fridge prior to administration, the vaccine must be kept at +2°C to +30°C and used within 12 hours, after which the vial must be discarded
- The vial is ready to use and is not to be diluted.

Summary of Comirnaty Omicron XBB.1.5 10 micrograms/dose dispersion for injection (0.3ml)

Title	Description
Manufacturing process	mRNA
Name of vaccines and description	Comirnaty® Omicron XBB.1.5 10 micrograms/dose dispersion for injection
Excipients	((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate) (ALC-0315) 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide (ALC-0159) 1,2-Distearoyl-sn-glycero-3-phosphocholine (DSPC) Cholesterol Trometamol Trometamol hydrochloride Sucrose Water for injections
Presentation	The vaccines are contained in a multi-dose clear vial (type I glass)
Number of doses in each vial	6 doses. If a seventh dose of 0.3ml can be safely and accurately withdrawn from a diluted vial, it is a valid dose. No more than 7 valid doses are available.
Dilution	DO NOT DILUTE
Dosage	0.3ml (10 mcg) intramuscularly
Latex	The vial stopper does not contain latex.
Preservatives	None

Prior to vaccination

- Check valid consent has been obtained
- Check for contraindications or precautions
 - See later in this chapter and the NIAC Immunisation guidelines for COVID-19 available at <https://www.rcpi.ie/healthcare-leadership/niac/immunisation-guidelines-for-ireland>
- Vaccinators who are vaccinating using a medicines protocol should check vaccine recipient's eligibility under the protocol
- Check the interval when administering a second dose
- Explain the procedure
- Answer questions
- Maintain privacy & dignity

13.3 Infection prevention and control

- Prior to preparation and administration of COVID-19 vaccines, hand hygiene should be performed as per the “WHO five moments of hand hygiene” with emphasis on:
 - Before vaccine preparation
 - Before drawing up and administering the vaccine
 - Before and after each recipient contact
- It is not necessary to use a skin disinfectant prior to injection. If the skin at the injection site is visibly dirty, clean with soap and water. If an alcohol swab is used, delay injection for ≥30 seconds, to ensure the alcohol has evaporated.
- Gloves are not routinely recommended for vaccine preparation and administration
- There is no need to routinely check temperature either at registration or before vaccination.
- Follow HPSC standard precautions (sharps management, healthcare waste management etc.) National Clinical Guideline No. 30 (2023) – Infection Prevention and Control (IPC) <https://www.gov.ie/en/publication/a057e-infection-prevention-and-control-ipc/>.
- Check HPSC website for latest guidance on infection prevention and control for healthcare workers:

National Clinical Guideline No. 30 (2023) – Infection Prevention and Control (IPC)
<https://www.gov.ie/en/publication/a057e-infection-prevention-and-control-ipc/>.

13.4 Vaccine, Preparation and Dilution

13.4.1 Comirnaty Omicron XBB.1.5 10 micrograms/dose concentrate for dispersion for injection (0.2ml): Prior to dilution

- Perform hand hygiene
- Check you are using the correct formulation
- Verify that the vial has an orange plastic cap and the product name is:
- Comirnaty® Omicron XBB.1.5 10 micrograms/dose concentrate for dispersion for injection.

Preparation for dilution

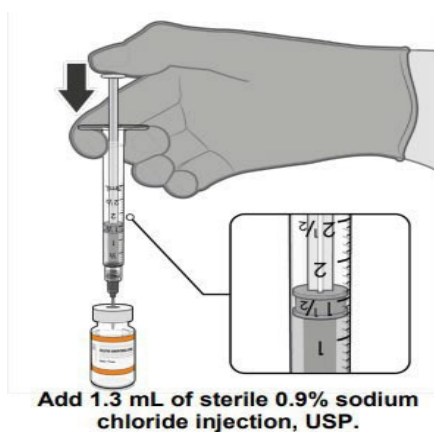
Prepare the equipment needed for dilution:

- A clean tray
- One multidose vial of Comirnaty® for 5-11 years.
- One plastic ampoule of Sodium Chloride 0.9% Solution for Injection This should not be kept in the fridge
- A needle and a syringe to dilute
- Needles and syringes will be supplied
- Two 70% alcohol swabs

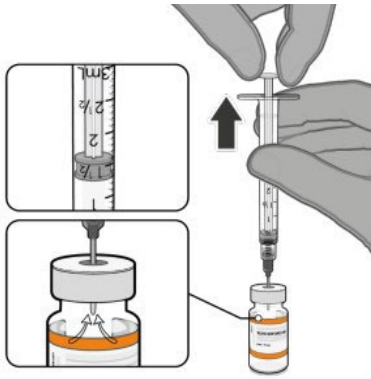
Check the **use before date and time** on the box containing the vials. Before dilution mix by inverting vaccine vial gently 10 times, do not shake. Inspect the liquid in the vial prior to dilution, the liquid is a white to off-white suspension and may contain opaque amorphous particles. Do not use if the liquid is discoloured or if other particles are observed.

Dilution

- Take one ampoule of sodium chloride and check expiry date.
- Clean with 70% alcohol swab
- Open the ampoule by twisting the cap
- Connect the syringe tightly (No needle is required)
- Follow Aseptic technique
- Do not touch the key parts of the ampoule & syringe
- Withdraw 1.3 ml of Sodium Chloride 0.9% Solution for Injection
- Cross check with colleague
- Discard the ampoule and any remaining diluent in it
- Attach needle to the syringe
- Insert diluent into the vaccine vial
- You may feel some pressure in the vial as you add the diluent



- Do not remove the needle and syringe from the vial until you have equalised the vial pressure by slowly withdrawing 1.3 ml of air into the empty diluent syringe before removing the needle from the vial



Pull back plunger to 1.3 mL to remove air from vial.

- Gently invert the diluted solution 10 times, do not shake



Gently × 10

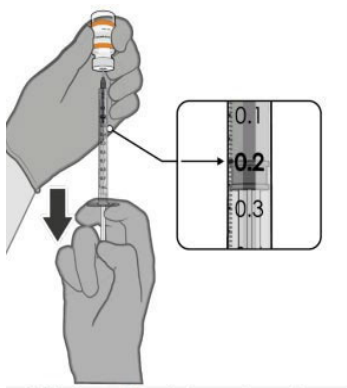
- Inspect the vial
- The diluted vaccine should be an off-white suspension
- Do not use if vaccine is discoloured or contains particulate matter

Labelling the diluted vial

- Label the diluted vial with the discard time and date (12 hours after time of dilution) using a 24-hour format. Do not use it after this time and date
e.g., time of dilution was 08.00 20/09/2023. The discard time and date is 20.00 20//09/2023
- After dilution, the vial contains 2.6 ml from which 10 doses of 0.2ml can be extracted
 - **The volume of each dose is smaller than the adult dose**
- Diluted vaccines can be stored between +2°C and +30°C but must be used within 12 hours following dilution
- Bring the vial to your vaccination table/site.

Vaccine Dose Preparation

- Check that the time of vaccine dilution was within the last 12 hours
- Perform hand hygiene
- Clean top of vial with a single use 70% alcohol swab and allow it to air dry fully
- Attach 23 gauge / 25 gauge in size and 25mm in length needle to 1ml syringe
- The needle size is the same as for those aged 12 years and older
- Withdraw **0.2 ml** of diluted product



Withdraw 0.2 mL dose of vaccine.

- Make sure correct dose is drawn up as smaller dose may not provide protection
- Before the needle is withdrawn ensure all air bubbles have been removed
- Do not change the needle between the vial and the patient unless the needle is contaminated or damaged.

Note: If more than ten 0.2ml doses can be safely and accurately withdrawn from a diluted vial, they can be used as valid doses. There is a **maximum of 12 doses** in each vial.

13.4.2 Comirnaty Omicron XBB.1.5 10 micrograms/dose dispersion for injection (0.3ml):

Note: This is a multidose vial with a BLUE cap. Do NOT dilute prior to use. Check the use before date and time on the box containing the vials.

- Verify that the vial has a blue plastic cap and the product name is Comirnaty Omicron XBB.1.5 10 micrograms/dose dispersion for injection (children 5 to 11 years). If the vial has another product name on the label, please make reference to the Summary of Product Characteristics for that formulation.
- Preparation of 0.3 ml doses. Allow the vial to come to room temperature and gently invert it 10 times prior to dilution. Do not shake.
- Prior to mixing, the thawed dispersion may contain white to off-white opaque amorphous particles.
- After mixing, the vaccine should present as a clear to slightly opalescent dispersion with no particulates visible. Do not use the vaccine if particulates or discolouration are present.
- Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab.
- Withdraw 0.3 ml of dose.
- Low dead-volume syringes and/or needles should be used in order to extract 6 doses from a single vial. The low dead-volume syringe and needle combination should have a dead volume of no more than 35 microlitres. If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial.
- Each dose must contain 0.3 ml of vaccine.
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 ml, discard the vial and any excess volume.
- Record the appropriate date/time on the vial. Discard any unused vaccine 12 hours after first puncture.

13.5 Vaccine Administration of Comirnaty® for 5-11 years.

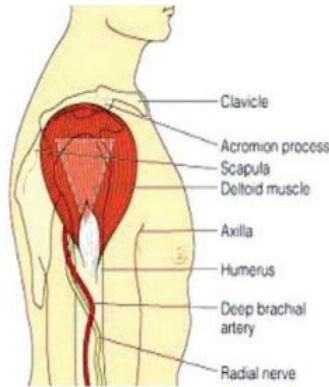
- Administer vaccine to patient intramuscularly, into the deltoid muscle
- Dispose the syringe and the needle into the sharps bin
- Do not leave the empty vials unattended
- Dispose the empty vials safely into a sharps bin
- Low dead space syringes should be used if available in order to maximise the number of doses that

can be drawn from the vial

- **There should be no pooling of vaccine** solution from different vials.

13.6 Method of IM Vaccine Administration

- Intramuscular injection technique for children aged 5-11 is the same as for older children and adults
- Vaccine to be given Intramuscularly into the deltoid muscle
- The light triangle in figure indicates site for IM injection into the deltoid muscle

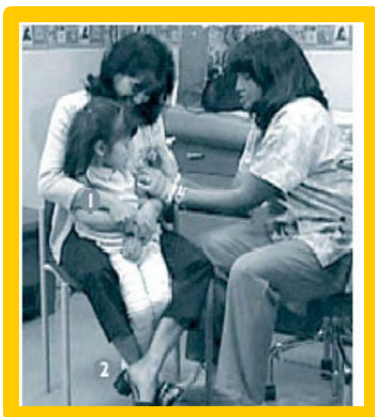


- The upper border of the triangle is approximately two finger-breadths below the acromion process and the apex is at the midpoint of the humerus
- The needle size for IM injection is the same as that for adults (23 gauge / 25 gauge in size and 25mm in length needle)
- At the injection site spread the skin taut between the thumb and forefinger with the non- dominant hand
- Do not bunch up the skin as this leads to administering the vaccine into subcutaneous tissue inadvertently
- Further information is available at www.immunisation.ie

13.7 Positioning for vaccination

For younger/smaller children:

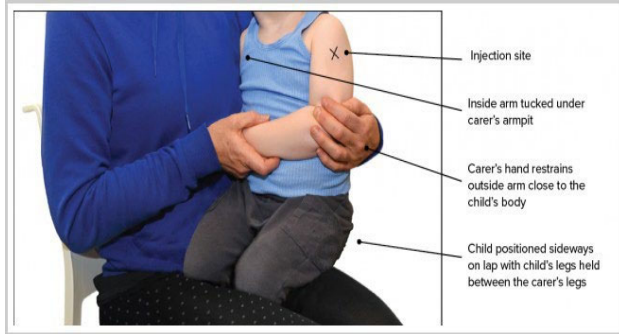
- The child sits on the parent/carer’s lap or stands in front of them as they sit
- The parent/carer embraces the child during the process, holding both the child’s arms as they do so both of the child’s legs are anchored between the parent/carer’s thighs



Source: Immunisation guidelines of the NIAC

Alternative positioning

- Sit child facing to the side. One arm is tucked under the parent/carer's armpit (A cuddle position)



Source: Australian Immunisation handbook

For older/bigger children

- It may be appropriate to ask the parent/carer and the child the preferred sitting position for vaccine administration
- They may prefer to sit on the parent/carer's lap or to sit independently

13.8 Techniques for vaccinating children

- Be honest and calm. Take time to explain in simple terms what to expect. Explain that the child may feel a little pinch and it will go away very quickly.
- Use words like “pressure” or “pinch” rather than “pain” or “shot”
- Distraction techniques can help in reducing pain and anxiety during vaccination. Keep the distraction going after the vaccine is given
 - Looking at toys, books, etc.
 - Pointing out interesting things in the room
 - Telling or reading stories
 - Taking deep breaths to help “blow out” the pain
 - Counting to five backwards

What to do if the child does not want to be vaccinated

- Only one person should hold the child for vaccination at any time (to avoid risk of needle stick injury)
- If the child cannot be held/positioned by the parent/carer so that vaccination is possible, then the child should not be vaccinated
- Repeated attempts to vaccinate the child are unlikely to help
- Check with your clinical lead for advice
- It may be better to bring the child back another time
- With the parent if parent was not present.
- They may benefit from vaccination during quiet times

Prevention and Management of Syncope in Vaccination Clinics

- Syncope is rare in younger children, it is more common in adolescents
- Syncope episodes mostly occur within 15 minutes of vaccine administration
- Reassurance about the procedure may help to prevent fainting
- Recipients should be seated (or lying down - if past history of fainting) when being administered their vaccines in case of an immediate faint
- There should be facilities in place in case of fainting
 - So that the person can be placed in a recumbent position/lie down or sit with head between knees

for several minutes if lying down is not possible

- It may be helpful to loosen any tight clothing and apply cool, damp cloths to the person's face and neck
- Further information is available on the www.immunisation.ie and at <https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/>

13.9 Contraindications and precautions to COVID-19 vaccination in children aged 5-11 years for Comirnaty® Omicron XBB.1.5 10 micrograms

Contraindications

- Anaphylaxis (serious systemic allergic reaction requiring medical intervention) following a previous dose of the vaccine or any of its constituents (including polyethylene glycol (PEG) and trometamol).
- Anaphylaxis after an mRNA vaccine

Appropriate support should be available in case of anaphylaxis or fainting after vaccine administration. Precautions should be in place to minimise injury from fainting

Precautions:

- Acute severe illness; defer until recovery
- Previous history of myocarditis or pericarditis after any COVID-19 vaccine – seek specialist advice (i.e. consult with a Cardiologist)
- **Vaccination should be postponed in children with a previous history of MIS-C, until clinical recovery or until 90 days or more since diagnosis, whichever is the longer.**
- There should be an interval of at least 4 weeks between mpox/smallpox vaccine and a subsequent COVID-19 vaccine because of the unknown risk of myocarditis.

If vaccination is advised for a child with prior history of mastocytosis, observe for 30 minutes after vaccination.

For full list of contraindications and precautions see **Table 5a.3 of the NIAC Immunisation Guidelines for Ireland.**

The following are **not contraindications or precautions** to vaccination:

- Food allergy (non-anaphylactic)
- Family history of allergy, including anaphylaxis
- Previous local reaction to any vaccine
- Underlying asthma
- Hay fever
- Hereditary angioedema
- Contact dermatitis to PEG containing cosmetic product
- NSAID allergy
- Chronic spontaneous urticaria

13.10 Post-vaccination Procedures

Documentation post vaccination

- Record vaccine batch number in the record/IT system
 - It will automatically link to the expiry date, so there is no need to record the expiry date
- Boxes delivered by NCCS will be labelled with a Use before date and time

- **This use before date and time should be recorded in the patient record**
- Give record card to vaccinee or parent/guardian
- Give post vaccination information sheet to vaccinee or parent/guardian

Observation post-vaccination

- Vaccine recipients: 15 minutes of observation
- Those with a history of mastocytosis: 30 minutes of observation
- Those with immediate itching, swelling or urticarial reaction at the vaccination site: 30 minutes or longer as clinically indicated

Advice following vaccination

- Give the parent/carer the after-care leaflet information
- Parent/carer should be advised that COVID-19 vaccines may cause a fever which usually resolves within 48 hours. This is a common, expected reaction and isolation and further investigation is not required unless COVID-19 is suspected
- If fever lasts for > 48 hours, or if other symptoms of COVID-19 are present, the person should self-isolate and seek medical advice
- Paracetamol or ibuprofen can be taken after vaccination if the child develops pain, fever or myalgia
- Advise the child's parent/carer that vaccinated children may still get infected and transmit the virus so they should continue to follow all current public health guidance to protect themselves and others
- Please refer to the NIAC immunisation guidelines available at <https://www.rcpi.ie/healthcare-leadership/niac/immunisation-guidelines-for-ireland>

13.11 Adverse Events

Adverse Events - Comirnaty® Omicron XBB.1.5 10 micrograms for those aged 5-11 years

The safety of Comirnaty® Omicron XBB.1.5 is inferred from safety data of the prior Comirnaty® vaccine.

Common adverse events are listed below, a full list of adverse reactions may be found in the Summary of Product Characteristics (SmPC).

Local:	Very common: injection site pain, swelling Common: injection site redness
General:	Very common: arthralgia, chills, diarrhoea, fatigue, headache, myalgia, pyrexia Common: nausea, vomiting

Myocarditis and pericarditis

Myocarditis and pericarditis are **very rare** side effects of mRNA vaccines, occurring predominantly after the second dose and in males under 30 years of age. Higher rates are reported following Spikevax compared with Comirnaty. The risk is lower following booster vaccination.

The risk of vaccine associated myocarditis can be reduced by extending the interval between the first and second mRNA COVID-19 vaccine dose in the primary schedule for immunocompromised.

These conditions can develop within a few days after vaccination and have primarily occurred within 14 days. Available data suggest that the course of myocarditis or pericarditis following vaccination is not different from myocarditis or pericarditis in general.

Data are very limited on those 5 to 11 years of age.

Myocarditis has also been associated with COVID-19 infection and these events can also occur in all age groups unrelated to vaccines or to COVID-19. Available data suggest that the course of myocarditis and pericarditis following vaccination is similar to the typical course of these conditions and in most individuals, symptoms resolved with conservative management. The long-term follow-up of these cases is ongoing.

Reporting of adverse events following immunisation

Adverse Events Following Immunisation should be reported to the HPRA:

<https://www.hpra.ie/homepage/about-us/report-an-issue/human-adverse-reaction-form>

13.12 Clinical considerations**Vaccination after COVID-19 infection****Unvaccinated**

Those who are unvaccinated and develop SARS-CoV-2 infection should complete a primary vaccination schedule, with the single dose (or first dose for immunocompromised) at least four weeks after diagnosis or onset of symptoms, or four weeks from the first PCR positive specimen in those who are asymptomatic.

Those with persisting symptoms following COVID-19 may be vaccinated, unless there is evidence of recent clinical deterioration.

Partially vaccinated

Those who are immunocompromised who have had SARS-CoV-2 infection after their first dose of COVID-19 vaccine should be given the subsequent dose at least four to eight weeks after diagnosis or onset of symptoms.

If those who are immunocompromised, have SARS-CoV-2 infection more than seven days after the second vaccine dose, a third dose of the primary schedule is not required. They should proceed to their booster dose if recommended in Table 1 of this document (or Table 5a.1 of the NIAC Immunisation Guidelines for Ireland). For those with infection within seven days of their second dose they should have a third dose after an interval of four to eight weeks if a third dose is recommended by a relevant specialist physician.

Booster vaccination

Those children who have had SARS-CoV-2 infection after completing their primary schedule (i.e., a breakthrough infection), should proceed to booster vaccination if eligible as recommended in Table 1 of this document (or Table 5a.1 of the NIAC Immunisation Guidelines for Ireland).

Co-administration with other vaccines

COVID-19 vaccine may be given at the same time or at any interval as other vaccines (live and non-live) including influenza vaccine and the vaccines administered in the school immunisations programme. The only exception to this is children who have received mpox (formerly known as monkeypox) vaccine. In this instance, there should be an interval of at least four weeks between

mpox vaccine and a subsequent COVID-19 vaccine because of the unknown risk of myocarditis. No interval is required between a COVID-19 vaccine and a subsequent mpox vaccine.

Children who are immunocompromised

Children with severe immunocompromise (see Table 2 of this document or Table 5a.2 of the NIAC Immunisation Guidelines for Ireland) due to disease or treatment at the time of their primary COVID-19 vaccination may have suboptimal response to their vaccines. A two dose primary course (with an option for an additional dose following specialist recommendation) and subsequent booster vaccination are recommended, see Table 1 of this document (or Table 5a.1 of the NIAC Immunisation Guidelines for Ireland). Serological testing prior to giving an additional dose is not recommended.

Children with planned immunosuppressing therapy should ideally complete vaccination two weeks before treatment.

For immunocompromised a relevant specialist physician may recommend a minimum interval of three weeks between dose one and dose two or four weeks between dose two and dose three, if there is urgency to achieve protection.

Specialists should consider the individual's risk and likelihood of disease exposure, and provide advice based on knowledge and understanding of the patient's immune status and likely immune response to vaccination.

Booster vaccination of children who are immunocompromised

A booster dose is recommended for children aged 5 – 11 years with immunocompromise associated with a sub optimal response to vaccines.

A spring booster vaccine if indicated should be given **six months** following the last COVID-19 vaccine or SARS-CoV-2 infection, see Table 1 of this document (or Table 5a.1 of the NIAC Immunisation Guidelines for Ireland). In exceptional circumstances an interval of three months may be used (e.g., in a person scheduled to commence chemotherapy).

For information on recommended intervals for Spring boosters for eligible children aged 5-11 years, please see Table 1.

Vaccination of those with bleeding disorders or on anticoagulants

Individuals with a bleeding disorder or receiving anticoagulant therapy may develop haematomas in IM injection sites. Prior to vaccination, inform the parent or guardian about this risk.

For those with thrombocytopenia (platelet count $<50 \times 10^9$ /L consult the supervising consultant. People with mild bleeding disorders or on maintenance dose Emicizumab (Hemlibra) do not require haemostatic cover for vaccination.

Those with inherited coagulopathies who require factor replacement therapy should receive it on the day of vaccination, prior to the IM vaccination. If there is uncertainty about the need for replacement therapy, contact the child's supervising consultant.

Those receiving long-term anticoagulation with either Warfarin or heparin are not considered to be at higher risk of bleeding complications following vaccination. There is no reason to expect that there is a greater risk of bleeding complications with the oral anticoagulants or antiplatelet agents, than with other anticoagulants.

See Chapter 2 of the NIAC guidelines, sections 2.4.6 and 2.4.7 for further information, including technique for IM injection, in this patient group.

14. Vaccination of Children Aged 6 months to 4 years:

Comirnaty® Omicron XBB.1.5 3 micrograms/dose concentrate for dispersion for injection (Infants and children aged 6 months to 4 years)

For children aged 6 months to 4 years, the recommended COVID-19 vaccine is Comirnaty® Omicron XBB.1.5 3 micrograms. The dose of Comirnaty® Omicron XBB.1.5 for children aged 6 months to 4 years is 3 micrograms (0.2ml).

Comirnaty® Omicron XBB.1.5 3 micrograms is licensed for active immunisation to prevent COVID-19 caused by SARS-CoV-2 virus in children aged 6 months to 4 years.

14.1 NIAC Recommendation

Primary Vaccination Schedule

A primary schedule of Comirnaty mRNA COVID-19 vaccination is **recommended** for those aged 6 months-4 years with underlying conditions that place them at higher risk of severe COVID-19:

- a. **two doses** of Comirnaty Omicron XBB.1.5 3 micrograms for those with no prior history of SARS-CoV-2 infection (**four weeks** interval).
- b. a **single dose** of Comirnaty Omicron XBB.1.5 3 micrograms for those with a prior history* of SARS-CoV-2 infection.

* Prior history of COVID-19 can be confirmed by any of: positive PCR test, antigen test or clinical diagnosis. For example, a single dose primary series could be considered in a child who had symptoms consistent with COVID-19 at a time when household contacts tested positive.

For **immunocompromised two doses** are recommended with a **four week** interval between dose one and dose two. A third dose may be administered, **eight weeks** after the second dose, following instruction from a relevant specialist physician.

COVID-19 vaccination should be offered to all others aged 6 months-4 years because of:

- the protection provided against severe COVID-19 and Multisystem Inflammatory Syndrome in Children (MIS-C) and their late consequences
- the enhanced protection vaccination gives to those who have had COVID-19 infection
- the additional protection for immunocompromised household contacts
- the safety profile of the vaccines
- similar vaccine immunogenicity to that in older children and adolescents.

Before vaccination, parents/guardians should be informed of the known benefits, risks, and uncertainties of COVID-19 vaccination.

Booster dose

Booster vaccination is **not recommended** in those aged 6 months-4 years.

The decision by their parent or legal guardian, to accept, defer, or refuse vaccination for a child should be respected.

14.2 Vaccine storage

- From delivery by the manufacturer to the NCCS the vaccine is stored at -90°C to -60°C.
- The vaccine is supplied to sites/clinics by the NCCS at +2°C to +8°C with a shelf life of up to 10 weeks. Vials should be stored in pharmaceutical fridge between +2°C to +8°C. The new “use before “date and time is on the “HSE Scan me label” which has been affixed by the NCCS once vials are removed from ULT freezer. Do not refreeze vials. The vaccine in each multi-dose vial requires dilution with 2.2ml of 0.9% sodium chloride.
- 0.9% sodium chloride is supplied separately to the vaccine and should be stored at room temperature.
- Undiluted vials of Comirnaty Omicron XBB.1.5 ® 6 months to 4 years (Maroon Cap) have a shelf life of up to 10 weeks. Prior to use, the unopened vials can be stored for up to 12 hours at temperatures between +8 °C and +30 °C.
- After dilution, the vaccine must be kept at +2°C to +30°C and used within 12 hours, after which the vial must be discarded.

Summary of Comirnaty Omicron XBB.1.5 3 micrograms (0.2ml)

Title	Description
Name of vaccine	Comirnaty Omicron XBB.1.5 3 micrograms/dose concentrate for dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified)
Constituents	((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate) (ALC-0315) 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide (ALC-0159) 1,2-Distearoyl-sn-glycero-3-phosphocholine (DSPC) Cholesterol Trometamol Trometamol hydrochloride Sucrose Water for injections
Number of doses in each vial	Post-dilution 10 doses If more than 10 doses can be accurately withdrawn from a diluted vial, it is a valid dose. No more than 12 doses are available.
Dilution	Yes, dilute with 0.9% sodium chloride (supplied separately).
Latex	The vial stopper does not contain latex.
Preservatives	No
Dosage	0.2ml
Number of doses required and interval between doses	The number of recommended doses of Comirnaty Omicron XBB.1.5 3 micrograms depends on a prior history of SARS-CoV-2 infection at the time of vaccination: a. two doses of Comirnaty Omicron XBB.1.5 3 micrograms for those with no prior history of SARS-CoV-2 infection (four weeks interval). b. a single dose of Comirnaty Omicron XBB.1.5 3

	<p>micrograms for those with a prior history* of SARS-CoV-2 infection.</p> <p>* Prior history of COVID-19 can be confirmed by any of: positive PCR test, antigen test or clinical diagnosis. For example, a single dose primary series could be considered in a child who had symptoms consistent with COVID-19 at a time when household contacts tested positive.</p>
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14.3 Vaccine dose

The Comirnaty Omicron XBB.1.5 vaccine for children aged 6 months to 4 years contains a lower dose of antigen (3 micrograms per dose) than for other age groups. The dose of the diluted vaccine is 0.2ml.

If a child becomes five years of age before completion of the recommended schedule for those aged 6 months-4 years, the schedule should be completed with the age appropriate dose, Comirnaty Omicron XBB.1.5 10 micrograms as follows:

- If they have received one dose of Comirnaty 3 micrograms give a single dose of Comirnaty Omicron XBB.1.5 10 micrograms: with an interval of **four weeks** between dose one and dose two. See section above (Primary vaccination schedule)
- If they have received two doses of Comirnaty 3 micrograms and a third dose is recommended by a relevant specialist physician: leave an interval of **eight weeks**, then give one dose of Comirnaty Omicron XBB.1.5 10 micrograms.

Interval between doses

The date of administration of the first dose is to be calculated as Day 0.

If the interval between doses is longer than the recommended interval, the next dose should be given as soon as possible. The course does not need to be restarted.

If the second dose is given more than four days before the minimum interval this is not considered a valid dose. A further dose should be given at least eight weeks after the invalid dose. If a recommended third dose, for an immunocompromised child, is given more than four days before the minimum interval then this is not considered a valid dose and a further dose should be given eight weeks after the invalid dose. For immunocompromised a relevant specialist physician may recommend a minimum interval of three weeks between dose one and dose two or four weeks between dose two and dose three, if there is urgency to achieve protection.

14.4 Prior to vaccination

- Check valid consent has been obtained from a parent of legal guardian.
- Check for contraindications or precautions
 - See later in this chapter and the NIAC Immunisation guidelines for COVID-19 available at https://rcpi.access.preservica.com/uncategorized/IO_15ead882-dd37-4d61-a213-b692c930564c/
- Vaccinators who are vaccinating using a medicines protocol should check vaccine recipient's eligibility under the protocol
- Check the interval when administering a second or third dose
- Explain the procedure

- Answer questions
- Maintain privacy and dignity

14.5 Consumables needed

Low dead-volume syringes and/or needles are recommended. The low dead-volume syringe and needle combination should have a dead volume of no more than 35 microlitres.

- For dilution- 3ml syringes should be used and needle (length and size) 25 mm ,23-25 gauge (21 gauge or narrower needle)
- For administration- 1ml syringes should be used and needle (length and size) 25 mm ,23-25 gauge

Ampoules of Sodium Chloride 0.9% Solution for Injection will also be required. You will need 2.2ml of Sodium Chloride (0.9%) to dilute every vial

14.6 Infection prevention and control

- Prior to preparation and administration of COVID-19 vaccines, hand hygiene should be performed as per the “WHO five moments of hand hygiene” with emphasis on:
 - Before vaccine preparation
 - Before drawing up and administering the vaccine
 - Before and after each recipient contact
- It is not necessary to use a skin disinfectant prior to injection. If the skin at the injection site is visibly dirty, clean with soap and water. If an alcohol swab is used, delay injection for ≥30 seconds, to ensure the alcohol has evaporated.
- Gloves are not routinely recommended for vaccine preparation and administration
- There is no need to routinely check temperature either at registration or before vaccination.
- Follow HPSC standard precautions (sharps management, healthcare waste management etc.) National Clinical Guideline No. 30 (2023) – Infection Prevention and Control (IPC) <https://www.gov.ie/en/publication/a057e-infection-prevention-and-control-ipc/>.
- Check HPSC website for latest guidance on infection prevention and control for healthcare workers:
- National Clinical Guideline No. 30 (2023) – Infection Prevention and Control (IPC) <https://www.gov.ie/en/publication/a057e-infection-prevention-and-control-ipc/>.

Vaccine Dilution and Preparation for Administration

- Check “Use before” date and time on the vaccine box.
- Verify that the vial has a maroon plastic cap and the product name is Comirnaty Omicron XBB.1.5 (3 micrograms)/dose concentrate for dispersion for injection (infants and children 6 months to 4 years).

Dilution

- =Allow the vial to come to room temperature and gently invert it 10 times prior to dilution Do not shake.
- Prior to dilution, the thawed dispersion may contain white to off-white opaque amorphous particles.
- diluted in its original vial with 2.2 ml sodium chloride 9 mg/mL (0.9%) solution for injection, using a 21 gauge or narrower needle and aseptic techniques. •
- Equalise vial pressure before removing the needle from the vial stopper by withdrawing 2.2 ml air into the empty diluent syringe.
- Gently invert the diluted dispersion 10 times. Do not shake.
- The diluted vaccine should present as a white to off-white dispersion with no particulates visible. Do not use the diluted vaccine if particulates or discolouration are present.

- The diluted vials should be marked with the appropriate discard date and time.
- After dilution, store at 2 °C to 30 °C and use within 12 hours.
- Do not freeze or shake the diluted dispersion. If refrigerated, allow the diluted dispersion to come to room temperature prior to use.

Preparation of 0.2mL doses

- After dilution, the vial contains 2.6 mL from which 10 doses of 0.2 mL can be extracted.
- Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab.
- Withdraw 0.2 mL of Comirnaty Omicron XBB.1.5 for infants and children aged 6 months to 4 years. Low dead-volume syringes and/or needles should be used in order to extract 10 doses from a single vial. The low dead-volume syringe and needle combination should have a dead volume of no more than 35 microlitres. If standard syringes and needles are used, there may not be sufficient volume to extract ten doses from a single vial.
- Each dose must contain 0.2 mL of vaccine.
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.2 mL, discard the vial and any excess volume.

14.7 Vaccine Administration

- Administer the vaccine to the patient intramuscularly (via IM injection)
 - For infants aged 6 months to 11 months, the recommended injection site is the anterolateral aspect of the thigh.
 - For children aged 1 year to 3 years of age, either the anterolateral aspect of the thigh or the deltoid muscle can be used as the injection site.
 - For children aged 3 years and older, the recommended injection site is the deltoid muscle.

Recipient's Age	Site	Needle length & Size
6months to <12 months	Vastus lateralis muscle	25 mm 23-25 gauge
1 to 4 years	Vastus lateralis or deltoid muscle (depending on muscle mass)	25 mm 23-25 gauge

- Dispose the syringe and the needle into the sharps bin
- Do not leave the empty vials unattended
- Dispose of the empty vials safely into a sharps bin
- Low dead space syringes and needles should be used if available in order to maximise the number of doses that can be drawn from the vial
- There should be no pooling of vaccine solution from different vials

Method of IM Vaccine Administration

- Intramuscular injection technique is to be used
 - For infants aged 6 months to 11 months, the recommended injection site is the vastus lateralis muscle (anterolateral aspect of the thigh).
 - For children aged 1 year to 3 years of age, either the deltoid muscle or the vastus lateralis muscle (anterolateral aspect of the thigh) can be used as the injection site.
 - For children aged 3 years and older, the recommended injection site is the deltoid muscle.

IM injection into the deltoid muscle

- The light triangle in the below figure indicates the site for IM injection into the deltoid muscle. The upper border of the triangle is approximately two finger-breadths / 2.5cms below the acromion process and the apex is at the midpoint of the humerus.



Figure 8: IM injection site into the deltoid muscle

IM injection site is the Vastus lateralis muscle

- The vastus lateralis muscle is located on the anterolateral aspect of the thigh, from one of the patient's hand breadths below the greater trochanter to one hand's breath above the knee. The middle third of the muscle is the site for injections. The width of the injection site extends from the mid-line of the thigh anteriorly to the mid-line of the outer thigh.
- The injection site is the middle third of the Vastus lateralis, in the anterolateral thigh (shaded area)

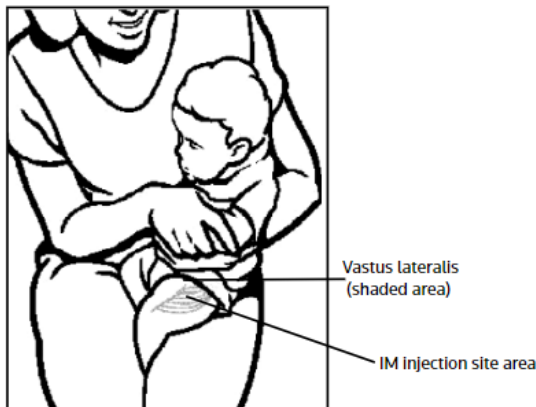


Figure 9: IM injection site into the middle third of the vastus lateralis

At the injection site (whether using deltoid or vastus lateralis), spread the skin taut between the thumb and forefinger with the non-dominant hand. Do not bunch up the skin as this leads to administering the vaccine into subcutaneous tissue inadvertently.

- Further information is available at https://rcpi.access.preservica.com/uncategorized/IO_67b1011b-87ed-4b8a-94ac-416bfe112caa/

Positioning for vaccination

For infants:

- Sit the infant on parent/guardian’s lap, facing to the side.
- One arm is tucked under the parent/guardian’s armpit (cuddle position). The infant’s other arm is held in the parent/guardian’s arms.
- Both of the infant’s legs are anchored between the parent/guardian’s thighs

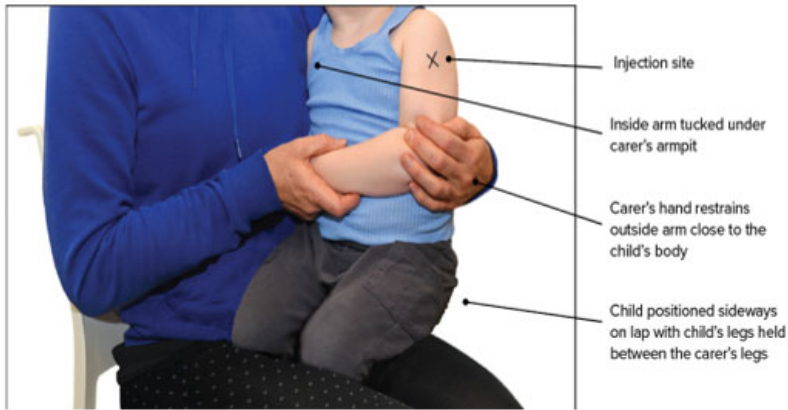


Figure 10: Positioning of infants (Source: Australian Immunisation handbook)

For older children:

- The child sits on the parent/guardian’s lap or stands in front of them while the parent/guardian is sitting
- The parent/guardian embraces the child during the process, holding both the child’s arms as they do so both of the child’s legs are anchored between the parent/guardian’s thighs
- Some children may prefer to sit on the guardian/parent’s lap or sit independently
- Alternatively, the positioning for infants may also be used



Figure 11: Positioning for older children (Source: Immunisation Guidelines of the National Immunisation Advisory Committee)

Techniques for vaccinating children

- Be honest and calm. Take time to explain in simple terms what to expect. Explain that the child may feel a little pinch and it will go away very quickly.
- Use words like “pressure” or “pinch” rather than “pain” or “shot”
- Distraction techniques can help in reducing pain and anxiety during vaccination. If possible, keep the distraction going after the vaccine is given.

- Looking at toys, books, etc.
- Pointing out interesting things in the room
- Telling or reading stories
- Taking deep breaths to help “blow out” the pain
- Counting from 5 backwards

What to do if the child does not want to be vaccinated

- Only one person should hold the child for vaccination at any time (to minimise risk of needle stick injury)
- If the child cannot be held/positioned by the parent/carer so that vaccination is possible, then the child should not be vaccinated
- Repeated attempts to vaccinate the child are unlikely to help
- Check with your clinical lead for advice
- It may be better to bring the child back another time with a parent/guardian if they were not present
- They may benefit from vaccination during quiet times

Prevention and Management of Syncope in Vaccination Clinics

- Syncope is rare in babies and young children; it is more common in adolescents
- Syncope episodes mostly occur within 15 minutes of vaccine administration
- Reassurance about the procedure may help to prevent fainting
- Recipients should be seated (or lying down, if past history of fainting) when being administered their vaccines in case of an immediate faint
- There should be facilities in place in case of fainting
 - So that the patient can be placed in a recumbent position/lie down or sit with head between knees for several minutes if lying down is not possible
- It may be helpful to loosen any tight clothing and apply cool, damp cloths to the person’s face and neck
- Further information is available at www.immunisation.ie and at <https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/>

14.8 Contraindications and precautions to COVID-19 vaccination in children aged 6 months to 4 years

Contraindications

- Anaphylaxis following a previous dose of the vaccine or any of its constituents (including polyethylene glycol (PEG) and trometamol).

Appropriate support should be available in case of anaphylaxis or fainting after vaccine administration. Precautions should be in place to minimise injury from fainting.

Precautions

- Acute severe illness; defer until recovery.
- Previous history of myocarditis or pericarditis after any COVID-19 vaccine - seek specialist advice.
- Vaccination should be postponed in children with a previous history of MIS-C, until clinical recovery or until 90 days or more since diagnosis, whichever is the longer.

The following are not contraindications or precautions to vaccination:

- Food allergy (non-anaphylactic)
- Family history of allergy, including anaphylaxis
- Previous local reaction to any vaccine

- Underlying asthma
- Hay fever
- Hereditary angioedema
- Contact dermatitis to PEG containing cosmetic product
- NSAID allergy
- Chronic spontaneous urticaria

Please see **Table 5a.3: Contraindications and precautions to mRNA COVID-19 vaccines** in the NIAC Immunisation Guidelines for Ireland for more information on contraindications and precautions to mRNA COVID-19 vaccines.

14.9 Post-vaccination Procedures

Documentation post-vaccination

- Record vaccine batch number in the record/IT system
 - It will automatically link to the expiry date, so there is no need to record the expiry date
- Boxes delivered by NCCS will be labelled with a “use before” date and time
- This “use before” date and time should be recorded in the patient record
- Give the record card to the parent/guardian

Observation post-vaccination

- Vaccine recipients: 15 minutes of observation
- Those with a history of mastocytosis: 30 minutes of observation
- Those with immediate itching, swelling or urticarial reaction at the vaccination site: 30 minutes or longer as clinically indicated

Advice following vaccination

- Parent/guardian should be advised that COVID-19 vaccines may cause a fever which usually resolves within 48 hours. This is a common, expected reaction and isolation and further investigation is not required unless COVID-19 is suspected.
- If fever lasts for >48 hours, or if other symptoms of COVID-19 are present, the person should self-isolate and seek medical advice
- Paracetamol or ibuprofen can be taken after vaccination if the child develops pain, fever, or myalgia
- Advise the child’s parent/guardian that vaccinated children may still get infected and transmit the virus so they should continue to follow all current public health guidance to protect themselves and others
- Please refer to the NIAC immunisation guidelines available at https://rcpi.access.preservica.com/uncategorized/IO_15ead882-dd37-4d61-a213-b692c930564c/

14.10 Adverse Events

The safety of Comirnaty Omicron XBB.1.5 is inferred from safety data of the prior Comirnaty vaccines.

Common adverse events are listed below, a full list of adverse reactions may be found in the Summary of Product Characteristics (SmPC).

Local:	Very common: tenderness injection site, injection site redness (6-23 months); injection site pain and redness (age 2-4 years), Common: injection site redness
General:	Very common: irritability, drowsiness, decreased appetite, fever, (6-23 months), fatigue, headache, irritability myalgia, fever (2 -4 years), Common: nausea, vomiting

A higher rate of pyrexia was seen after administration of the second dose.

Reporting of adverse events following immunisation

This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions to the HPRA.

<https://www.hpra.ie/homepage/about-us/report-an-issue/human-adverse-reaction-form>

14.11 Clinical Considerations

Vaccination after COVID-19 infection

Unvaccinated

Those who are unvaccinated and develop SARS-CoV-2 infection should complete a primary vaccination schedule, with the single dose (or first dose for immunocompromised) at least four weeks after diagnosis or onset of symptoms, or four weeks from the first PCR positive specimen in those who are asymptomatic.

Those with persisting symptoms following COVID-19 may be vaccinated, unless there is evidence of recent clinical deterioration.

Partially vaccinated

Those who are immunocompromised who have had SARS-CoV-2 infection after their first dose of COVID-19 vaccine should be given the subsequent dose at least four to eight weeks after diagnosis or onset of symptoms.

If those who are immunocompromised, have SARS-CoV-2 infection more than seven days after the second vaccine dose, a third dose of the primary schedule is not required.

For those with infection within seven days of their second dose they should have a third dose after an interval of four to eight weeks if a third dose is recommended by a relevant specialist physician.

Co-administration with other vaccines

In this age group, there must be at least a 14 days between the administration of the COVID-19 vaccine and any other vaccines. No interaction studies in young children have been performed on co-administration of Comirnaty® with childhood vaccines. **Priority should be given to other routine childhood immunisations.** Until there is more evidence it is prudent to separate COVID-19 vaccination in children aged 6 months-4 years from other vaccines for a period of 14 days.

As a precaution, if the child has recently received the monkeypox vaccine (Imvanex or Jynneos), they need to wait 4 weeks before they get their COVID-19 vaccine because of the unknown risk of myocarditis.

Children who are immunocompromised

Children who are immunocompromised due to disease or treatment may be vaccinated if they have no contraindications.

For immunocompromised children aged 6 months to 4 years, two doses are recommended with a **four week** interval between dose one and dose two. A third dose may be administered, **eight weeks** after the second dose, following instruction from a relevant specialist physician (see Table 1 of this document or Table 5a.1 of the NIAC Immunisation Guidelines for Ireland).

For immunocompromised, a relevant specialist physician may recommend a minimum interval of three weeks between dose one and dose two or four weeks between dose two and dose three, if there is urgency to achieve protection.

Specialists should consider the child's risk and likelihood of disease exposure, and provide advice based on knowledge and understanding of their immune status and likely immune response to vaccination. Children with planned immunosuppressing therapy should ideally complete vaccination two weeks before treatment.

Vaccination of those with bleeding disorders or on anticoagulants

Individuals with a bleeding disorder or receiving anticoagulant therapy may develop haematomas in IM injection sites. Prior to vaccination, inform the parent/guardian about this risk.

For those with thrombocytopenia (platelet count $<50 \times 10^9/L$), consult the supervising consultant. For children with mild bleeding disorders or on maintenance dose Emicizumab (Hemlibra) do not require haemostatic cover for vaccination.

Those with inherited coagulopathies receiving factor replacement therapy should receive it on the day of vaccination, prior to IM vaccination. If there is uncertainty about the need for replacement therapy, contact the child's supervising consultant.

Those receiving long-term anticoagulation with either warfarin or heparin are not considered to be at higher risk of bleeding complications following immunisation. There is no reason to expect that there is a greater risk of bleeding complications with the newer types of anticoagulants and antiplatelet agents, than with other anticoagulants.

Technique for IM injections in persons with bleeding disorders or on anticoagulants:

- Only one injection per muscle mass should be given at each visit. Use a 23 or 25 gauge needle to reduce the pressure gradient and cause less trauma to the tissue. The vaccine should be injected slowly (≥ 5 seconds) to reduce the risk of tissue damage.
- Firm pressure should be applied to the site for 5 to 10 minutes after injection.
- Stabilisation of the limb will reduce the risk of a haematoma.
- The site should not be rubbed or massaged.
- Instruct the parent/guardian to monitor the injected limb and to report any concerns to their supervising consultant.

Useful links

- Frequently Asked Questions about COVID-19 vaccines for people with pre-existing allergic conditions <https://www.rcpi.ie/news/releases/frequently-asked-questions-about-covid-19-vaccines-for-people-with-pre-existing-allergic-conditions/>
- Immunisation Guidelines for Ireland: Chapter 5a COVID-19. <https://www.rcpi.ie/healthcare-leadership/niac/immunisation-guidelines-for-ireland>
- Information for women who are pregnant or breastfeeding and their doctors about COVID-19 vaccine <https://www.rcpi.ie/news/releases/information-for-women-who-are-pregnant-or-breastfeeding-about-the-covid-19-vaccine-update/>
- HSE Management of cold chain guidance (2-8°C) <https://www.hse.ie/eng/health/immunisation/hcpinfo/vaccineordering/sopnio01.pdf>
- HSE Guidelines for maintaining the vaccine cold-chain in vaccine cool boxes <https://www.hse.ie/eng/health/immunisation/hcpinfo/vaccineordering/sopnio02.pdf>
- Licensed documentation for vaccines: Summary of Product Characteristics (SmPC) for health care professionals, and Package Leaflet (PL) for the public, available via the European Medicines Agency websites <https://www.ema.europa.eu/en>.
- Health Products Regulatory Authority. Human Medicines Adverse Reaction Report <https://www.hpra.ie/homepage/about-us/report-an-issue/covid-19-vaccine-adverse-reaction>
- HPSC COVID-19 guidance www.hpsc.ie