

REG 174 INFORMATION FOR UK RECIPIENTS

Package leaflet: Information for the recipient

COVID-19 Vaccine AstraZeneca solution for injection COVID-19 Vaccine (ChAdOx1-S [recombinant])

This medicinal product has been given authorisation for temporary supply by the UK Department of Health and Social Care and the Medicines & Healthcare products Regulatory Agency. It does not have a marketing authorisation, but this temporary authorisation grants permission for the medicine to be used for active immunisation of individuals aged 18 years and older for the prevention of coronavirus disease 2019 (COVID-19).

Reporting of side effects

As with any new medicine in the UK this product will be closely monitored to allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before the vaccine is given because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What COVID-19 Vaccine AstraZeneca is and what it is used for
2. What you need to know before you are given COVID-19 Vaccine AstraZeneca
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1. What COVID-19 Vaccine AstraZeneca is and what it is used for

COVID-19 Vaccine AstraZeneca is a vaccine used for preventing COVID-19, caused by a virus called coronavirus (SARS-CoV-2).

COVID-19 Vaccine AstraZeneca is given to adults aged 18 years and older.

COVID-19 Vaccine AstraZeneca stimulates the body's natural defences (immune system). It causes the body to produce its own protection (antibodies) against the virus. This will help to protect you against COVID-19 in the future. None of the ingredients in this vaccine can cause COVID-19.

2. What you need to know before you are given COVID-19 Vaccine AstraZeneca

Do not have the vaccine:

- If you are allergic to any of the active substances or any of the other ingredients listed in section 6.
- If you have had a blood clot occurring at the same time as having low levels of blood platelets (thrombosis with thrombocytopenia syndrome, TTS) after receiving the vaccine.
- If you have a previous diagnosis of capillary leak syndrome (a condition causing fluid leakage from small blood vessels).

If you are not sure, talk to your doctor, pharmacist or nurse.

Warnings and precautions

Tell your doctor, pharmacist or nurse before vaccination:

- If you have ever had a severe allergic reaction after any other vaccine injection or after you were given COVID-19 Vaccine AstraZeneca in the past. Signs of an allergic reaction may include itchy skin rash, shortness of breath and swelling of the face or tongue. Contact your doctor or healthcare professional immediately or go to the nearest hospital emergency room right away if you have an allergic reaction. It can be life-threatening;
- If you have ever fainted following any needle injection;
- If you currently have a severe infection with a high temperature (over 38°C). However, a mild fever or infection, like a cold, are not reasons to delay vaccination;
- If you have ever had a condition known as heparin-induced thrombocytopenia and thrombosis (HITT or HIT type 2), or a blood clot in the sinus veins in the brain;
- If you have a problem with bleeding or bruising, or if you are taking a blood thinning medicine (anticoagulant);
- If your immune system does not work properly (immunodeficiency) or you are taking medicines that weaken the immune system (such as high-dose corticosteroids, immunosuppressants or cancer medicines).

If you are not sure if any of the above applies to you, talk to your doctor, pharmacist or nurse before you are given the vaccine.

Blood disorders

Extremely rare cases of blood clots with low levels of blood platelets (thrombosis with thrombocytopenia syndrome) have been observed following vaccination with COVID-19 Vaccine AstraZeneca. This included some severe cases with blood clots in different or unusual locations and excessive clotting or bleeding throughout the body. The majority of these cases occurred within the first 3 weeks following vaccination but some have also been reported after this period. Some cases were life-threatening or had a fatal outcome. It is important to remember the benefits of vaccination to give protection against COVID-19 still outweigh any potential risks.

If you experience any of the following from around 4 days after vaccination you should seek medical advice urgently:

- a severe headache that is not relieved with simple painkillers or is getting worse or feels worse when you lie down or bend over
- an unusual headache that may be accompanied by blurred vision, confusion, difficulty with speech, weakness, drowsiness or seizures (fits)
- rash that looks like small bruises or bleeding under the skin beyond the injection site
- shortness of breath, chest pain, leg swelling, leg pain or persistent abdominal (tummy) pain.

Tell your doctor, pharmacist or nurse if you experienced a blood clot occurring at the same time as low levels of platelets after receiving a previous dose of the vaccine.

Capillary leak syndrome

Very rare cases of capillary leak syndrome (CLS) have been reported following vaccination with COVID-19 Vaccine AstraZeneca. Some affected patients had a previous diagnosis of CLS. CLS is a serious, potentially fatal condition causing fluid leakage from small blood vessels (capillaries) resulting in rapid swelling of the arms and legs, sudden weight gain and feeling faint (low blood pressure). Seek immediate medical attention if you develop these symptoms in the days following vaccination.

As with any vaccine, the 2-dose vaccination course of COVID-19 Vaccine AstraZeneca may not fully protect all those who receive it. It is not yet known how long you will be protected for. No data are

currently available in individuals with a weakened immune system or who are taking chronic treatment that suppresses or prevents immune responses.

Neurological events

Seek immediate medical attention if you develop weakness and paralysis in the extremities that are persistent and can affect both sides of the body at the same time and can progress to the chest and face (Guillain-Barré Syndrome). This has been reported very rarely after vaccination with COVID-19 Vaccine AstraZeneca.

Children and adolescents

COVID-19 Vaccine AstraZeneca is not recommended for children aged below 18 years. No data are currently available on the use of COVID-19 Vaccine AstraZeneca in children and adolescents younger than 18 years of age.

Other medicines and COVID-19 Vaccine AstraZeneca

Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take, any other medicines or vaccines.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant, or are planning to have a baby, ask your doctor, pharmacist or nurse for advice before you receive this vaccine. There are limited data on the use of COVID-19 Vaccine AstraZeneca in pregnant or breastfeeding women. Your doctor, pharmacist or nurse will discuss with you whether you can be given the vaccine.

Driving and using machines

Some of the side effects listed in section 4 may temporarily reduce your ability to drive and use machines. If you feel unwell after vaccination, do not drive or use machines. Wait until any effects of the vaccine have worn off before you drive or use machines.

COVID-19 Vaccine AstraZeneca contains sodium and alcohol (ethanol)

This medicine contains less than 1 mmol sodium (23 mg) per dose of 0.5 ml. This means that it is essentially 'sodium-free'.

This medicine contains a very small amount of alcohol (2 mg of alcohol (ethanol) per dose of 0.5 ml). This is not enough to cause any noticeable effects.

3. How COVID-19 Vaccine AstraZeneca is given

COVID-19 Vaccine AstraZeneca is given as an injection of 0.5 ml into a muscle (usually in the upper arm).

You will receive 2 injections. You will be told when you need to return for your second injection of COVID-19 Vaccine AstraZeneca.

The second injection can be given between 4 and 12 weeks after the first injection.

When COVID-19 Vaccine AstraZeneca is given for the first injection, the second injection to complete the vaccination course should also be with COVID-19 Vaccine AstraZeneca.

If you miss an appointment for your second injection of COVID-19 Vaccine AstraZeneca

If you forget to go back at the scheduled time, ask your doctor, pharmacist or nurse for advice. It is important that you return for your second injection of COVID-19 Vaccine AstraZeneca. If you miss a scheduled injection, you may not be fully protected against COVID-19.

4. Possible side effects

Like all medicines, this vaccine can cause side effects, although not everybody gets them.

Get urgent medical attention if you get symptoms of a severe allergic reaction. Such reactions may include a combination of any of the following symptoms:

- feeling faint or light-headed
- changes in your heartbeat
- shortness of breath or wheezing
- swelling of your lips, face, or throat
- hives or rash
- nausea or vomiting
- stomach pain

In clinical studies with the vaccine, fewer side effects were reported after the second dose and those that were reported were milder in nature when compared to after the first dose.

If side effects such as pain and/or fever are troublesome, medicines containing paracetamol can be taken.

The following side effects may occur with COVID-19 Vaccine AstraZeneca:

Very common (may affect more than 1 in 10 people)

- tenderness, pain, warmth, itching or bruising where the injection is given
- generally feeling unwell
- feeling tired (fatigue)
- chills or feeling feverish
- headache
- feeling sick (nausea)
- joint pain or muscle ache

Common (may affect up to 1 in 10 people)

- swelling, redness or a lump at the injection site
- fever ($\geq 38^{\circ}\text{C}$)
- being sick (vomiting) or diarrhoea
- pain in legs or arms
- flu-like symptoms, such as high temperature, sore throat, runny nose, cough and chills*

Uncommon (may affect up to 1 in 100 people)

- sleepiness or feeling dizzy
- decreased appetite
- abdominal pain
- enlarged lymph nodes
- excessive sweating, itchy skin, rash or hives

Very rare (may affect up to 1 in 10,000 people)

- Following widespread use of the vaccine there have been extremely rare reports of blood clots in combination with low level of blood platelets. When these blood clots do occur, they may be in unusual or atypical locations (e.g. brain, liver, bowel, spleen).

Not known (cannot be estimated from the available data)

- severe allergic reaction (anaphylaxis)
- rapid swelling under the skin in areas such as the face, lips, mouth and throat (which may cause difficulty in swallowing or breathing) (angioedema)
- low blood platelets (thrombocytopenia)
- hypersensitivity

- capillary leak syndrome (a condition causing fluid leakage from small blood vessels)

In clinical trials there were very rare reports of events associated with inflammation of the nervous system, which may cause numbness, pins and needles, and/or loss of feeling. However, it is not confirmed whether these events were due to the vaccine.

* Some people have reported a sudden feeling of cold with shivering/shaking accompanied by a rise in temperature, possibly with sweating, headache (including migraine-like headaches), nausea, muscle aches and feeling unwell, starting within a day of having the vaccine and usually lasting for a day or two.

If your fever is high and lasts longer than two or three days, or you have other persistent symptoms, this might not be due to side effects of the vaccine and you should follow appropriate advice according to your symptoms.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

If you are concerned about a side-effect it can be reported directly via the Coronavirus Yellow Card reporting site <https://coronavirus-yellowcard.mhra.gov.uk/> or search for MHRA Yellow Card in the Google Play or Apple App Store and include the vaccine brand and batch/Lot number if available. By reporting side effects you can help provide more information on the safety of this vaccine.

5. How to store COVID-19 Vaccine AstraZeneca

Keep this medicine out of the sight and reach of children.

Your doctor, pharmacist or nurse is responsible for storing this vaccine and disposing of any unused product correctly.

Storage

Do not use COVID-19 Vaccine AstraZeneca after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C – 8°C).

Do not freeze.

Keep vials in outer carton to protect from light.

The vaccine does not contain any preservative and should be administered by a healthcare professional. After the first dose is withdrawn, the vaccine should be used as soon as practically possible and within 6 hours. During use it can be stored from 2°C to 25°C.

Disposal

COVID-19 Vaccine AstraZeneca contains genetically modified organisms (GMOs). Any unused vaccine or waste material should be disposed of in accordance with local requirements. Spills should be disinfected using agents with activity against adenovirus.

6. Contents of the pack and other information

What COVID-19 Vaccine AstraZeneca contains

One dose (0.5 ml) contains:

COVID-19 Vaccine (ChAdOx1-S* recombinant) 5×10^{10} viral particles (vp)

*Recombinant, replication-deficient chimpanzee adenovirus vector encoding the SARS-CoV-2 Spike glycoprotein. Produced in genetically modified human embryonic kidney (HEK) 293 cells.

This product contains genetically modified organisms (GMOs).

The other excipients are L-histidine, L-histidine hydrochloride monohydrate, magnesium chloride hexahydrate, polysorbate 80 (E 433), sucrose, disodium edetate dihydrate, water for injections (see section 2 “COVID-19 Vaccine AstraZeneca contains sodium and alcohol”).

What COVID-19 Vaccine AstraZeneca looks like and contents of the pack

Solution for injection. The solution is colourless to slightly brown, clear to slightly opaque.

Pack sizes (not all pack sizes may be marketed):

- 10 dose multidose vial (5 ml) with rubber stopper and aluminium overseal in a pack of 10 vials. Each vial contains 10 doses of 0.5 ml.
- 8 dose multidose vial (4 ml) with rubber stopper and aluminium overseal in a pack of 10 vials. Each vial contains 8 doses of 0.5 ml.

Manufacturer

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Other sources of information



www.azcovid-19.com