

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 receive 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 to protect people aged 18 years and older against COVID-19.

COVID-19 is caused by a virus called coronavirus (SARS-CoV-2).

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 receive COVID-19 Vaccine AstraZeneca

Do not have the vaccine:

- If you have ever had a severe allergic reaction to any of the active substances or any of the other ingredients listed in section 6. 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 had a major blood clot occurring at the same time as having low levels of platelets after receiving any COVID-19 vaccine.
- If you had ever had a condition known as heparin-induced thrombocytopenia and thrombosis (HITT or HIT type 2)

Warnings and precautions

Tell your doctor, pharmacist or nurse before vaccination:

- If you have ever had a severe allergic reaction (anaphylaxis) after any other vaccine 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 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 have ever had a blood clot in the sinus veins in the brain, or the autoimmune condition called antiphospholipid syndrome.

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.

Extremely rare cases of blood clots with low levels of platelets have been observed following vaccination with COVID-19 Vaccine AstraZeneca. The majority of these cases occurred within the first 14 days 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 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 a COVID-19 vaccine.

As with any vaccine, COVID-19 Vaccine AstraZeneca may not protect everyone who is vaccinated from COVID-19. It is not yet known how long people who receive the vaccine 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.

Children and adolescents

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, **tell your doctor, pharmacist or nurse**. 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

COVID-19 Vaccine AstraZeneca has no known effect on the ability to drive and use machines.

However, side effects listed in section 4 may impact your ability to drive and use machines. If you feel unwell, do not 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 injected 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, COVID-19 Vaccine AstraZeneca (and not another vaccine against COVID-19) should be given for the second injection to complete vaccination course.

If you miss your second injection

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.

4. Possible side effects

Like all medicines, this vaccine can cause side effects, although not everybody gets them. In clinical studies with the vaccine, most side effects were mild to moderate in nature and resolved within a few days with some still present a week after vaccination.

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

Side effects that occurred during clinical trials with COVID-19 Vaccine AstraZeneca were as follows:

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
- being sick (vomiting) or diarrhoea

- flu-like symptoms, such as high temperature, sore throat, runny nose, cough and chills*

Uncommon (may affect up to 1 in 100 people)

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

Not known (cannot be estimated from the available data)

- severe allergic reaction (anaphylaxis)

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.

Following widespread use of the vaccine there have been extremely rare reports of blood clots occurring with low levels of platelets.

* 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.

If you notice any side effects not mentioned in this leaflet, please inform your doctor, pharmacist or nurse.

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 carton. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C to 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 with an appropriate antiviral disinfectant.

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

*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, ethanol, sucrose, sodium chloride, disodium edetate dihydrate, water for injections.

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 and particle free.

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

- 10 dose vial (5 ml) in packs of 10 vials.
- 8 dose vial (4 ml) in packs of 10 vials.

Manufacturer

MedImmune UK Ltd
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Other sources of information



www.azcovid-19.com