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Vaxzevria¹ (COVID-19 Vaccine (ChAdOx1-S [recombinant]))

An overview of Vaxzevria and why it is authorised in the EU

What is Vaxzevria and what is it used for?

Vaxzevria is a vaccine for preventing coronavirus disease 2019 (COVID-19) in people aged 18 years and older.

Vaxzevria is made up of another virus (of the adenovirus family) that has been modified to contain the gene for making a protein from SARS-CoV-2, the virus that causes COVID-19.

Vaxzevria does not contain the virus itself and cannot cause COVID-19.

How is Vaxzevria used?

Vaxzevria is given as two injections, usually into the muscle of the upper arm. The second dose should be given between 4 and 12 weeks after the first dose.

A booster dose may be given at least 3 months after the second dose. A booster dose of Vaxzevria can also be given to adults who have had two doses of an authorised mRNA COVID-19 vaccine. At national level, public health bodies may issue official recommendations, taking into account emerging effectiveness data and the limited safety data.

For more information about using Vaxzevria, see the package leaflet or consult a healthcare professional.

How does Vaxzevria work?

Vaxzevria works by preparing the body to defend itself against COVID-19. It is made up of another virus (adenovirus) that has been modified to contain the gene for making the SARS-CoV-2 spike protein. This is a protein on the surface of the SARS-CoV-2 virus which the virus needs to enter the body's cells.

¹ Previously known as COVID-19 Vaccine AstraZeneca



Once it has been given, the vaccine delivers the SARS-CoV-2 gene into cells in the body. The cells will use the gene to produce the spike protein. The person's immune system will then recognise this protein as foreign and produce antibodies and activate T cells (white blood cells) to attack it.

If, later on, the person comes into contact with SARS-CoV-2 virus, their immune system will recognise it and be ready to defend the body against it.

The adenovirus in the vaccine cannot reproduce and does not cause disease.

What benefits of Vaxzevria have been shown in studies?

Combined results from 4 clinical trials in the United Kingdom, Brazil and South Africa showed that Vaxzevria was safe and effective at preventing COVID-19 in people from 18 years of age. These studies involved around 24,000 people altogether. Half received the vaccine and half were given a control injection, either a dummy injection or another non-COVID vaccine. People did not know if they had been given the test vaccine or the control injection.

The Agency based its calculation of how well the vaccine worked on the results from study COV002 (conducted in the UK) and study COV003 (conducted in Brazil). The other two studies had fewer than 6 COVID-19 cases occurring in each, which was not enough to measure the preventive effect of the vaccine. In addition, as the vaccine was to be given as two standard doses, and the second dose should be given between 4 and 12 weeks after the first, the Agency concentrated on results involving people who received this standard regimen.

These showed a 59.5% reduction in the number of symptomatic COVID-19 cases in people given the vaccine (64 of 5,258 got COVID-19 with symptoms) compared with people given control injections (154 of 5,210 got COVID-19 with symptoms). This means that the vaccine demonstrated around a 60% efficacy in these clinical trials.

Another study conducted in the United States, Peru and Chile involved around 26,000 people, of whom 21% were above 65 years of age. The participants received the second dose 4 weeks after the first one. The study showed a 74% reduction in the number of symptomatic COVID-19 cases in people given the vaccine (73 of 17,662 got COVID-19 with symptoms) compared with people given control injections (130 of 8,550 got COVID-19 with symptoms). The study also showed that the vaccine efficacy of Vaxzevria in older people is comparable to that seen in younger people.

Further data showed a rise in antibody levels when a booster dose was given after the second dose of Vaxzevria or after two doses of an mRNA vaccine in adults aged 30 years and above with a normal immune system.

Can children be vaccinated with Vaxzevria?

Vaxzevria is not currently authorised for use in children. EMA has agreed with the company on [a plan to conduct trials involving children](#) at a later stage.

Can immunocompromised people be vaccinated with Vaxzevria?

There are limited data on immunocompromised people (people with weakened immune systems). Although immunocompromised people may not respond as well to the vaccine, there are no particular safety concerns. Immunocompromised people can still be vaccinated as they may be at higher risk from COVID-19.

Can pregnant or breast-feeding women be vaccinated with Vaxzevria?

Preliminary animal studies do not show any harmful effects in pregnancy, however data on the use of Vaxzevria during pregnancy are very limited. Although there are no studies on breast-feeding, no risk during breast-feeding is expected.

The decision on whether to use the vaccine in pregnant women should be made in close consultation with a healthcare professional after considering the benefits and risks.

Can people with allergies be vaccinated with Vaxzevria?

People who already know they have an allergy to one of the components of the vaccine listed in section 6 of the package leaflet should not receive the vaccine.

Allergic reactions (hypersensitivity) have been seen in people receiving the vaccine. Cases of anaphylaxis (severe allergic reaction) have also occurred. As for all vaccines, Vaxzevria should be given under close medical supervision, with the appropriate medical treatment available in case of allergic reactions. People who have a severe allergic reaction when they are given the first dose of Vaxzevria should not receive the second dose.

How well does Vaxzevria work for people of different ethnicities and genders?

The clinical trial included people of different ethnicities and genders. The efficacy was maintained across genders and ethnic groups.

What are the risks associated with Vaxzevria?

The most common side effects with Vaxzevria are usually mild or moderate and get better within a few days after vaccination. When compared with the first dose, side effects reported after the second dose are milder and reported less frequently. People receiving Vaxzevria may experience more than one side effect at the same time.

The most common side effects are tenderness, pain and bruising at the injection site, headache, tiredness, muscle pain, general feeling of being unwell, chills, fever, joint pain and nausea (feeling sick). They may affect more than 1 in 10 people.

Thrombocytopenia (low levels of blood platelets), vomiting, diarrhoea, pain in legs or arms, swelling and redness at the injection site, flu-like illness and asthenia (weakness) may affect up to 1 in 10 people. Lymphadenopathy (enlarged lymph nodes), decreased appetite, dizziness, sleepiness, lethargy (lack of energy), hyperhidrosis (excessive sweating), abdominal (belly) pain, muscle spasms, itching, rash and urticaria (itchy rash) may affect up to 1 in 100 people.

Weakness in muscles on one side of the face (facial paralysis or palsy) may affect up to 1 in 1,000 people.

Thrombosis (formation of blood clots in the blood vessels) in combination with thrombocytopenia (thrombosis with thrombocytopenia syndrome, TTS) and Guillain-Barré syndrome (a neurological disorder in which the body's immune system damages nerve cells) may affect up to 1 in 10,000 people.

A very small number of cases of angioedema (rapid swelling under the skin), capillary leak syndrome (fluid leakage from small blood vessels causing tissue swelling and a drop in blood pressure) and transverse myelitis (a neurological condition characterised by an inflammation in the spinal cord) have

occurred with Vaxzevria. A very small number of cases of immune thrombocytopenia (a condition in which the immune system mistakenly targets blood platelets, reducing their levels and affecting normal blood clotting) and cerebrovascular venous and sinus thrombosis (formation of blood clots in the vessels draining blood from the brain) have also occurred.

Allergic reactions have occurred in people receiving the vaccine, including some cases of severe allergic reactions (anaphylaxis). As for all vaccines, Vaxzevria should be given under close supervision with appropriate medical treatment available.

Vaxzevria must not be given to people who have had thrombosis with thrombocytopenia syndrome (TTS) after receiving the vaccine. Vaxzevria must also not be given to people who have previously had capillary leak syndrome.

Why is Vaxzevria authorised in the EU?

Vaxzevria offers a good level of protection against COVID-19 which is a critical need in the current pandemic. The main trials showed that the vaccine had around 60% efficacy against the main strain of SARS-CoV2 virus in circulation at the time. Most side effects are mild to moderate in severity and are gone within a few days.

The European Medicines Agency decided that Vaxzevria's benefits are greater than its risks and it can be authorised for use in the EU.

Vaxzevria has been given 'conditional authorisation'. This means that there is more evidence to come about the vaccine (see below), which the company is required to provide. The Agency will review any new information that becomes available and this overview will be updated as necessary.

What information is still awaited for Vaxzevria?

Since Vaxzevria has been given conditional authorisation, the company that markets the vaccine will continue to provide results from the clinical trials, which are ongoing. These trials and additional studies, including [independent studies](#) of COVID-19 vaccines coordinated by EU authorities, will provide more information on the vaccine's long-term safety and its benefits.

The company will also carry out studies to provide additional assurance on the pharmaceutical quality and testing of the vaccine as the manufacturing continues to be scaled up.

What measures are being taken to ensure the safe and effective use of Vaxzevria?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Vaxzevria have been included in the summary of product characteristics and the package leaflet.

A [risk management plan](#) for Vaxzevria is also in place and contains important information about the vaccine's safety, how to collect further information and how to minimise any potential risks. A summary of the RMP is available.

Safety measures for Vaxzevria are implemented in line with the [EU safety monitoring plan for COVID-19 vaccines](#) to ensure that new safety information is rapidly collected and analysed. The company that markets Vaxzevria will provide regular safety reports.

As for all medicines, data on the use of Vaxzevria are continuously monitored. Suspected side effects reported with Vaxzevria are carefully evaluated and any necessary action taken to protect patients.

Other information about Vaxzevria

COVID-19 Vaccine AstraZeneca received a conditional marketing authorisation valid throughout the EU on 29 January 2021.

The name of the vaccine was changed to Vaxzevria on 25 March 2021.

More information about the COVID-19 vaccines, such as expected duration of protection against infection or severe disease, mixing different vaccines and vaccination after recovery from COVID-19 disease, is available on the [COVID-19 vaccines key facts page](#).

Further information on Vaxzevria can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/vaxzevria.

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