

# **A QUICK GUIDE**

### Vaccination against COVID-19 with the ChAdOx1-S [recombinant] COVID-19 vaccine<sup>1</sup>

This quick guide offers basic information about COVID-19, the ChAdOx1-S [recombinant] COVID-19 vaccine and what to expect following vaccination

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<sup>1</sup> ChAdOx1-S [recombinant] COVID-19 vaccine refers to AstraZeneca AZD1222-Vaxzevria; Serum Institute India (SII)Covishield; and SK Bioscience

#### 1. WHAT IS COVID-19?

COVID-19 is an infection caused by a type of coronavirus (SARS-CoV-2), which affects the lungs, airways and sometimes other parts of the body. COVID-19 can cause mild to serious illness and in severe cases death may occur.

The most common signs and symptoms include:

- fever (high temperature of 38 °C or above)
- cough
- tiredness
- difficulty breathing
- loss of smell or taste.

COVID-19 is highly infectious. It spreads through droplets produced when people cough or sneeze, or indirectly by way of surfaces where the droplets have landed. In addition to vaccination, recommended prevention measures include washing hands regularly, wearing a mask and physical distancing.

#### 2. WHO IS MOST AT RISK FROM COVID-19?

Everyone is at risk for COVID-19 infection. Some people are at higher risk of becoming severely ill with the virus, meaning they may need to seek hospital care or may require intensive care or require oxygen to help them breathe due to the severity of the disease.

Older adults (aged 60 and above) and people with certain health conditions are at higher risk of developing more severe disease if they get infected with the COVID-19 virus.

Other people are at increased risk of becoming infected with the virus. Health workers are at high risk of becoming infected with the virus, because they come in close contact with many patients who could potentially be infected, or they provide direct care for those who are sick with COVID-19. Health workers are also at high risk of passing the virus on to their patients.

Residents of long-term care facilities are also at high risk of infection because the virus may spread quickly among people who live and gather together.

Other social, demographic and occupational factors may also affect the risk of exposure to COVID-19 disease. Inequality in access to healthcare may place some people at higher risk of severe illness. For some people it may be difficult to keep physical distance from others due to their work or living conditions.

To make the greatest possible impact on those at higher risk of becoming severely ill with or dying from the virus and for those at increased risk of becoming infected, the high-risk groups mentioned above need to get the vaccine first while supply of vaccines is still limited.

#### **3.** WHY GET VACCINATED AGAINST COVID-19?

Vaccination against COVID-19 is important, because it:

- will protect you from getting seriously ill from COVID-19 and greatly reduce the risk of getting infected at all.
- will help combat the pandemic by reducing the number of people hospitalized and the number of people dying from COVID-19.
- will help authorities maintain the most essential services, including health care.

#### 4. HOW IS THE VACCINE GIVEN?

The vaccine is given as an injection in the muscle of your upper arm.

#### 5. HOW DOES THE CHADOX1-S [RECOMBINANT] COVID-19 VACCINE WORK?

The ChAdOx1-S [recombinant] COVID-19 vaccine offers protection against COVID-19. It teaches the body's natural defences (immune system), including the production of antibodies against the virus, so it can be ready to fight the virus and protect you from the disease if you are exposed to it in the future.

The vaccine does not contain live SARS-CoV-2 virus and cannot cause COVID-19 disease.

The ChAdOx1-S [recombinant] COVID-19 vaccine uses a modified (altered) version of another virus, called an adenovirus. Adenovirus is a common cold virus. The adenovirus in the vaccine is weakened so that it can no longer cause infection in your body. Adenovirus acts as a vector (a carrier). It has been modified by adding material to teach your body to make the spike protein that is on the surface of the COVID-19 virus. Once your immune system recognizes this foreign protein, the spike protein, it creates antibodies to fight off what it believes to be the actual COVID-19 virus. Your body can now respond faster and stronger if faced with the actual COVID-19 virus in the future.

#### 6. DOES THE VACCINE CAUSE SIDE EFFECTS?

The common side effects following ChAdOx1-S [recombinant] COVID-19 vaccine are mild to moderate and include injection site tenderness, pain or swelling, as well as headache, nausea, sore muscles, feeling tired or mild fever. Common side effects may feel like flu and may even affect your ability to do daily activities, but they should go away in a few days.

Having these types of side effects does NOT mean that you have COVID-19. Some people have no side effects, but that does not mean they are not also protected from COVID-19 infection.

The vaccine does not contain live SARS-CoV-2 virus and cannot cause COVID-19 disease.

A very rare syndrome including blood clots and low levels of platelets (Thrombosis with Thrombocytopenia Syndrome, TTS) has occurred in some people who received the ChAdOx1-S [recombinant]COVID-19 vaccine. For further information, please see the section below titled: Is the ChAdOx1-S [recombinant] COVID-19 vaccine safe?

#### 7. WHAT SHOULD I DO IN CASE OF SIDE EFFECTS?

Ask your vaccinator or doctor for advice on how to relieve symptoms of vaccine side effects. People sometimes faint after medical procedures, including vaccination. Tell your vaccinator if you feel dizzy or have vision changes or ringing in the ears before, during, or after receiving the injection.

For other signs that concern you, call your doctor. Severe and unusual adverse reactions should be reported to health authorities to support national and global monitoring of vaccine safety. Check with your vaccinator or doctor how to report an adverse event following immunization.

#### 8. COULD I GET A SEVERE ALLERGIC REACTION?

As with any medicine, very rare severe allergic reactions are possible to vaccines, including the ChAdOx1-S [recombinant] COVID-19 vaccine. Such reactions resolve if treatment is initiated immediately. Therefore, after receiving the vaccine dose, you will be asked to wait for 15 minutes in a dedicated area to get support, should an allergic reaction develop. If signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness) develop after leaving the vaccination site, please call for emergency service support at the nearest hospital.

#### 9. IS THE CHADOX1-S [RECOMBINANT] COVID-19 VACCINE SAFE?

Global and national vaccine safety systems ensure that all vaccines authorized for use are as safe as possible. While the work to develop the ChAdOx1-S [recombinant]COVID-19 vaccine has moved much faster than usual, the process of testing and review has been the same as for other vaccines that have been in use for many years around the world. This vaccine has been tested in clinical trials on thousands of people in various countries worldwide and meets the strict standards of safety, quality and efficacy established by WHO. WHO and the European Medicine Agency have recommended this vaccine for use following thorough reviews of the clinical trial data and the vaccine has been authorized by national regulatory authorities in many countries throughout the world.

Even after these reviews the vaccine's safety is continuously monitored in each country and at the global level. These monitoring systems help to detect any rare or long-term adverse effects in a much larger patient population and over a long period.

Since March 2021, these monitoring systems began to detect a very rare, new type of condition called TTS in some people who received the ChAdOx1-S [recombinant]COVID-19 vaccine. This syndrome is rare, and few cases have been seen after millions of doses of this vaccine have been given to people worldwide. Less than 1 in 100 000 people have developed this syndrome.

If a person develops TTS, blood clots (thrombosis) may occur in specific sites in the body, such as the brain or abdomen (belly). At the same time, the person is at increased risk for bleeding due to low platelet counts (thrombocytopenia).

In people who developed TTS after receiving the ChAdOx1-S [recombinant] COVID-19 vaccine, symptoms began approximately 4 to 20 days after vaccination.

Again, the chance of having TTS occur is very rare. You should seek medical attention immediately if you have any of the following symptoms within this timeframe after receiving the ChAdOx1-S [recombinant] COVID-19 vaccine

- shortness of breath
- chest pain
- leg swelling
- persistent abdominal (belly) pain
- severe or persistent headaches or blurred vision
- easy bruising or tiny blood spots under the skin beyond the injection site.

If you have any questions or concerns, seek medical help right away.

WHO is committed to the safety of all COVID-19 vaccines and to open, transparent communication about any potential risks to vaccine recipients. Vaccine safety monitoring will continue, and any new information about TTS will be evaluated.

Scientists do not yet know whether there is a risk of TTS following the second dose of the ChAdOx1-S [recombinant] COVID-19 vaccine. This is still being investigated. People who develop TTS after the first dose of the vaccine should not get a second dose.

#### **10.** WHAT ARE BLOOD CLOTS? HOW DO THEY DEVELOP? WHAT ARE PLATELETS?

Blood clots are "clumps of blood". Certain parts of your blood get thicker and form a mass within the blood vessel. When this occurs, it is called a clot. Clots help stop us from bleeding out when we are injured or cut by plugging up the injured blood vessel. Over time, most clots will dissolve naturally. Platelets (thrombocytes) are blood cells that help our blood to form clots.

#### **11.** ARE SOME BLOOD CLOTS DANGEROUS? WHAT HAPPENS IF MY PLATELET LEVELS ARE TOO LOW?

Blood clots can pose a problem when they develop in our veins (blood vessels), and they do not dissolve naturally. This can lead to serious medical problems or even death if, for example, the blood clot travels through our veins and lands in major organs such as our lungs or our brain. Certain conditions may put you at increased risk for clots, including becoming infected with COVID-19 disease, taking medications such as oral contraceptives, obesity, smoking, pregnancy, sitting for prolonged periods, or being on bed rest for a prolonged time.

A low platelet count (less than 150 000 platelets per microlitre of blood) is called thrombocytopenia. Signs of low platelets in your body may include easy or excessive bruising on the skin, prolonged bleeding from cuts, or from your gum or nose.

When platelet counts drop very low in your body (less than 10 000 platelets per microlitre), this can be dangerous and may lead to internal bleeding or haemorrhage (heavy bleeding) in your brain or other body parts.

#### **12.** DOES THE VACCINE WORK IN EVERYONE?

The vaccine has been tested on people aged 18 and older. If you have a weakened immune system, there is NO extra risk in taking the vaccine, but the vaccine may not work as well for you.

#### **13.** WHO SHOULD NOT GET THE CHADOX1-S [RECOMBINANT]COVID-19 VACCINE?

Most people will be able to safely get the vaccine, however in rare cases vaccination may not be advised.

People who developed TTS after the first dose of the ChAdOx1-S [recombinant]COVID-19 vaccine should not receive a second dose of the vaccine.

Always talk to your doctor to assess whether you can get the ChAdOx1-S [recombinant] COVID-19 vaccine if:

- you have had a severe allergic reaction to any of the ingredients in the vaccine (including polysorbate 80).
- you have had a severe allergic reaction to a previous dose of this vaccine.
- you currently have a severe infection with a high temperature (over 38 °C).
- you have had an immediate allergic reaction to any other vaccine or injectable therapy.
- you have a problem with bleeding or bruising, or if you are taking a blood thinning medicine (anticoagulant).
- 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).
- you received antibody treatment for COVID-19 disease within the previous 90 days.
- you are pregnant.

#### **14.** I ALREADY HAD COVID-19. SHOULD I STILL GET VACCINATED?

Yes. The vaccine will reduce your risk of getting COVID-19 again; and even if you do get infected following vaccination, it can reduce the seriousness of your symptoms.

#### **15.** I CURRENTLY HAVE COVID-19. CAN I STILL GET VACCINATED?

Suppose you have tested positive for COVID-19 and you are experiencing signs and symptoms of the disease (include a hyperlink to signs and symptoms from question 1 of this document). In that case, you should not take the ChAdOx1-S [recombinant]COVID-19 vaccine until after you have recovered from your illness and you are no longer in isolation. Ask a healthcare professional to help you determine when you should receive your vaccine.

#### **16.** I AM PREGNANT (OR BREASTFEEDING). SHOULD I STILL GET VACCINATED?

All pregnant women are at higher risk of severe illness from COVID-19 infection, but some pregnant women are even more at risk including those 35 years and older or those who have medical conditions such as diabetes or high blood pressure (hypertension).

The ChAdOx1-S [recombinant]COVID-19 vaccine was not widely tested on pregnant women so the evidence available at this time is limited. However, there is no evidence that the vaccine is unsafe if you're pregnant. If you are a health worker or in another atrisk group, and you are pregnant, you should talk to your doctor about getting the Oxford/Astra Zeneca AZD1222 COVID-19 vaccine.

As the ChAdOx1-S [recombinant] COVID-19 vaccine is not a live virus vaccine, you can get vaccinated if you are breastfeeding. You should NOT discontinue breastfeeding after vaccination, as breastfeeding is very important for your child.

Please speak to your doctor if you have additional questions regarding vaccination during pregnancy or whilst breastfeeding.

## 17. I AM AN OLDER ADULT. IS IT SAFE FOR ME TO TAKE THE VACCINE? DOES THE VACCINE WORK FOR OLDER ADULTS?

Yes. The ChAdOx1-S [recombinant] COVID-19 vaccine was tested in many adults over the age of 65 years old, and it was found to be safe and effective. Also, after the trials ended and since the vaccine has been used in the United Kingdom's general population, scientists have found that the vaccine protects older adults from severe illness and death from COVID-19 disease.

# **18.** IS THE CHADOX1-S [RECOMBINANT] COVID-19 VACCINE SAFE FOR PERSONS WITH MEDICAL CONDITIONS?

People with certain medical conditions are at increased risk for severe illness from COVID-19 disease. The ChAdOx1-S [recombinant] COVID-19 vaccine was tested in people with heart disease, respiratory (lung) disease, obesity, and diabetes. The vaccine was just as safe in these persons as persons who do not have these same conditions. WHO recommends the ChAdOx1-S [recombinant] COVID-19 vaccine for persons with medical conditions that increase their risk of severe illness from COVID-19 disease.

#### CAN CHILDREN AND ADOLESCENTS BELOW 18 YEARS RECEIVE THE CHADOX1-S [RECOMBINANT] COVID-19 VACCINE?

No. As of April 2021, the ChAdOx1-S [recombinant] COVID-19 vaccine has not been tested in children or adolescents below 18 years, and it is not recommended for anyone below 18 years of age.

#### 20. HOW MANY DOSES DO I NEED?

Two doses of the ChAdOx1-S [recombinant] COVID-19 vaccine are needed to achieve full and longer-lasting protection. WHO recommends that the two doses are given within an interval of 8-12 weeks between doses. If you missed the scheduled time for the second dose, it is important to return to get it as soon as it is possible.

The WHO recommends that you receive the ChAdOx1-S [recombinant] COVID-19 vaccine for both of your doses.

The following people should not receive the second dose of vaccine:

- people who developed TTS after the first dose of the ChAdOx1-S [recombinant] COVID-19 vaccine.
- people who have had a severe allergic reaction to the first dose or any of the ingredients in the vaccine (including polysorbate 80).

#### **21.** CAN I RECEIVE THE COVID-19 VACCINE ON THE SAME DAY AS ANOTHER VACCINE?

No. WHO recommends that you wait at least 14 days after your COVID-19 vaccine before getting any other vaccine, including a flu vaccine or tetanus vaccine. If you have recently received any other vaccine first, wait at least 14 days before getting your COVID-19 vaccine.

#### 22. HOW LONG DOES IT TAKE THE VACCINE TO WORK?

It takes 3 weeks, after getting the first dose, for the vaccine to work. You will have the best protection from COVID-19 after the second dose, which according to WHO recommendation, you should get it 8-12 weeks after your first dose.

#### **23.** AFTER GETTING VACCINATED, DO I STILL NEED TO CONTINUE WITH PROTECTIVE MEASURES?

COVID-19 is a new disease and much about it is still unknown. Experts don't know yet whether vaccination will fully prevent vaccinated persons from passing the virus on to others, if they have no symptoms themselves. And they don't know how long protection gained through vaccination will last. Moreover, no vaccine is 100% effective. So, while vaccination will greatly reduce your chances of developing COVID-19 disease, there is still a chance that you could become infected.

The virus that causes COVID-19 disease is constantly changing. These changes can lead to new strains or variants (different forms) of the virus. Some of the new virus variants may be easier to spread to other people or cause more severe illness. Some people who have already had one type of the COVID-19 virus, the Sars-CoV-2 virus, may get infected again with a new strain. Scientists are studying whether the ChAdOx1-S [recombinant] COVID-19 vaccine will protect you if you get infected with one of the more recent strains.

For all these reasons, even after getting the vaccine you will need to keep wearing a mask that covers your nose and mouth, washing your hands often, and following physical distancing advice. Together with vaccination, this gives you and others the best protection from catching the virus.

#### **24.** WHAT ARE THE INGREDIENTS OF AN CHADOX1-S [RECOMBINANT] COVID-19 VACCINE?

One dose (0.5 ml) contains:

- AD26, adenovirus particles (see also Q&A above How does the ChAdOx1-S [recombinant] COVID-19 vaccine work?). The vaccine does not contain the live COVID-19 virus itself.
- and the following non-active ingredients:
  - o L-histidine
  - o L-histidine hydrochloride monohydrate
  - o magnesium chloride hexahydrate
  - polysorbate 80
  - o ethanol
  - o sucrose
  - o sodium chloride
  - $\circ \quad \ \ \text{disodium edetate dihydrate}$
  - o water.

### For more information on COVID-19 vaccines, kindly consult your doctor.

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