ATTACHMENT TO THE ANTI-COVID-19 VACCINATION CONSENT FORM

INFORMATION NOTICE

Vaxzevria (AstraZeneca COVID-19 Vaccine)

What is Vaxzevria and what is it for?

Vaxzevria vaccine (formerly known as AstraZeneca COVID-19 Vaccine) is a vaccine used for the prevention of COVID-19, a disease caused by the SARS-CoV-2 virus. Vaxzevria is given to adults aged 18 years and older. The vaccine induces the immune system (the body's natural defences) to produce antibodies and blood cells that are active against the virus, thus providing protection against the COVID-19 virus. Components of this vaccine cannot transmit COVID-19.

What do you need to know before receiving Vaxzevria?

Vaxzevria must not be inoculated:

- if you are allergic to the active substance or any other excipient of this medicine (listed below);
- if you had a blood clot which occurred at the same time with low platelet levels (thrombotic syndrome associated with thrombocytopenia) after receiving Vaxzevria.
- if you have previously been diagnosed with capillary leak syndrome (a condition that causes fluid to leak from small blood vessels).

Warnings and Precautions

Ask your doctor or health professional at the vaccination centre before receiving the vaccine if:

- You had a severe allergic reaction or breathing problems after the injection of another vaccine or after receiving Vaxzevria in the past;
- You fainted after an injection;
- You have a serious illness or infection with a high fever. However, if you have a mild fever or an upper respiratory infection (such as a cold) you can still receive the vaccination;
- You have a bleeding problem, a tendency to bruise, or if you use medicines to prevent blood clots;
- Your immune system is not working properly (immunodeficiency) or you are taking medicines that weaken the immune system (such as high-dose corticosteroids, immunosuppressants or anticancer medicines).

Blood disorders

Blood clots have been observed very rarely after the inoculation of Vaxzevria, often at unusual sites (e.g. brain, intestines, liver, spleen), in association with low platelet levels, in some cases with the presence of bleeding. This condition included severe cases with blood clots in different or unusual sites as well as excessive clotting or bleeding throughout the body. Most of these cases occurred in the 3 weeks after vaccination and occurred mainly in women under 60 years of age. In some cases this condition resulted in death.

Seek immediate medical attention if you experience shortness of breath, chest pain, leg swelling, leg pain or persistent abdominal pain after vaccination.

Moreover, seek immediate medical attention if severe or persistent headaches, blurred vision, confusion or seizures (seizures) occur after a few days after vaccination, or if there are bruises on the skin or very small round spots in one spot other than the vaccination site.

At its meeting on 7 April 2021, EMA's Pharmacovigilance Risk Assessment Committee (PRAC) concluded that the benefits of Vaxzevria in combating the still widespread threat of COVID-19 (which causes clotting problems and may be fatal) continue to outweigh the risk of side effects (https://www.aifa.gov.it/-/vaccino-covid-19-astrazeneca-ema-trova-un-possibile- link-con-cases- very-rare-of-unusual-thrombi-associated-with-low-platelet-levels).

Capillary leak syndrome

Very rare cases of capillary leak syndrome (CLS) have been reported following vaccination with Vaxzevria. Some affected individuals had a previous diagnosis of CLS. CLS is a serious, life-threatening condition that causes fluid to leak from small blood vessels (capillaries) resulting in rapid swelling of the arms and legs, sudden weight gain and fainting (low blood pressure). Contact your doctor immediately if you develop these symptoms in the days following vaccination.

Neurological events

See a doctor immediately if you develop weakness and paralysis in the limbs which may progress to the chest and face (Guillain-Barré syndrome). This syndrome has been reported very rarely following vaccination with Vaxzevria.

Other medicines and Vaxzevria

Inform your doctor or health professional at the vaccination centre if you are using, have recently used or might use any other medicine, or if you have recently been given any other vaccine.

Pregnancy and breastfeeding

Ask your doctor for advice before receiving this vaccine, if you are pregnant, if you suspect that you are pregnant or you are planning to have a baby, or you are breastfeeding.

Experience on the use of Vaxzevria in pregnant women is limited. Animal reproductive toxicity studies have not been completed. Based on the results of the preliminary study, no effects on the development of the foetus are expected. Inoculation of Vaxzevria during pregnancy should only be considered when the potential benefits outweigh the potential risks to the mother and the foetus.

Duration of protection and limitations of the effectiveness of the vaccine

The duration of the protection offered by the vaccine is unknown; clinical trials are still underway to establish it. Protection begins approximately 3 weeks after the first dose of Vaxzevria. People may not be fully protected up to 15 days after the second dose is inoculated. Similarly to all vaccines, vaccination with Vaxzevria may not protect all vaccinated individuals. It is therefore essential to continue to strictly follow public health recommendations (mask, interpersonal distance and frequent hand washing).

How Vaxzevria is given

Vaxzevria is given as an injection into the upper arm. A second dose is expected after 4-12 weeks; on the basis of the available data, the level of protection of the second dose appears more consistent the closer to the 12th week after the first dose.

It is very important that the second dose is inoculated in order to achieve an optimal immune response. If you forget to return to the appointment for the second dose, please contact your doctor or the vaccination centre where the first dose was given.

Possible side effects

Like all vaccines, Vaxzevria may cause side effects, although not everyone shows them.

In clinical studies, most of the side effects were mild to moderate and resolved within a few days. Fewer side effects were reported after the second dose.

After vaccination, more than one side effect may occur at the same time (for example, muscle/joint pain, headache, chills and general malaise). If any of the symptoms persist, ask your doctor for advice.

Blood clots in combination with low platelet levels (thrombotic syndrome associated with thrombocytopenia) have been reported very rarely.

Seek **immediate medical attention** if any of the following symptoms develop within three weeks of vaccination:

- severe or persistent headache, blurred vision, confusion or seizure (seizures);
- wheezing, chest pain, leg swelling, leg pain or persistent abdominal pain;
- unusual bruises on the skin or very small round spots somewhere other than the vaccination site.

Require **urgent** medical attention if symptoms of a severe allergic reaction occur. Reactions may include a combination of any of the following symptoms:

- feeling faint or lightheaded
- changes in heartbeat
- breathlessness
- wheezing
- swelling of the lips, face or throat
- hives or rash
- nausea or vomiting
- stomach ache.

The following side effects may occur with Vaxzevria:

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

- achiness, pain, warmth, itching or bruising at the injection site
- feeling tired (fatigue) or generally feeling unwell
- chills or a feeling of fever
- headache
- feeling sick
- nausea
- articular pain or muscle pain

Common side effects (may affect up to 1 in 10 people):

- swelling or redness at the injection site
- fever (>38°C)
- being sick (vomiting) or diarrhoea
- low levels of platelets in the blood
- pain in the legs or arms
- flu-like symptoms, such as high fever, sore throat, runny nose, cough and chills
- physical weakness or lack of energy

Uncommon side effects (may affect up to 1 in 100 people):

- sleepiness or dizziness
- abdominal pain or decreased appetite
- enlarged lymph nodes

- excessive sweating, itchy skin or rash or hives
- drowsiness or profound lack of reactivity and inactivity

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

- blood clots often in unusual sites (e.g. brain, intestines, liver, spleen) associated with low blood platelet levels.

Unknown side effects (frequency cannot be estimated from the available data)

- severe allergic reaction (anaphylaxis)
- hypersensitivity
- rapid swelling under the skin in areas such as the face, lips, mouth and throat (which may cause difficulty in swallowing or breathing)
- capillary leak syndrome (a condition that causes fluid to leak from small blood vessels)

If you have any side effects, even if not listed above, ask your doctor or contact the vaccination centre.

You can also report side effects directly via the national reporting system (https://www.aifa.gov.it/content/segnalazioni-reazioni-avverse).

What Vaxzevria contains

The active substance is a non-replicating chimpanzee adenovirus that encodes the SARS-CoV-2 spike glycoprotein.

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 (dehydrate); water for injections.