

## **ATTACHMENT TO THE ANTI-COVID-19 VACCINATION CONSENT FORM GENERAL INFORMATION**

### **Vaxzevria (COVID-19 Vaccine AstraZeneca)**

#### **What is Vaxzevria and what is it for?**

The Vaxzevria vaccine (previously known as the AstraZeneca COVID-19 vaccine) is used to prevent COVID-19, the disease caused by the SARS-CoV-2 virus. Vaxzevria is administered to adults aged 18 and over. The vaccine induces the immune system (the body's natural defenses) to produce antibodies and blood cells against the virus, thereby providing protection against COVID-19. No component of this vaccine can cause COVID-19.

#### **What do I need to know before receiving the Vaxzevria vaccine?**

You must **not** receive the Vaxzevria vaccine if you are allergic to the active ingredient or any other ingredient of this drug (see list below).

#### **Warnings and Precautions**

Inform your doctor or the health care worker at the vaccination center before receiving the vaccine if:

- you had a severe allergic reaction or respiratory problems after the injection of another vaccine or after having received Vaxzevria in the past;
- you have ever fainted after an injection;
- you have a disease or severe infection with high fever. However, if you have a low-grade fever or upper respiratory infection (like a cold), you can receive the vaccine;
- you have a bleeding disorder, you bruise easily, or you are taking medication to prevent the formation of blood clots;
- your immune system does not function properly (immunodeficiency) or you are taking any drugs that weaken your immune system (like high-dose corticosteroids, immunosuppressants, or anti-cancer drugs).

Following the administration of Vaxzevria, blood clots have been observed, although very rarely, often in unusual sites (e.g., brain, intestine, liver, spleen), in association with low platelet count, in some cases also with bleeding. This condition included severe blood clotting in various or unusual sites, as well as clots and hemorrhage throughout the body. Most of these cases occurred during the first 14 days after vaccination, particularly in women under age 60 years. In some cases, this condition was fatal.

Contact your doctor immediately if you have shortness of breath, chest pain, swelling in your legs, or persistent abdominal pain after the vaccination.

Also contact your doctor if, some days after vaccination, you have intense or persistent headaches or blurred vision or if after a few days you have bruising or round patches anywhere other than at the injection site.

The Pharmacovigilance Risk Assessment Committee (PRAC) of the European Medicines Agency (EMA), in a meeting on 7 April 2021, concluded that the benefits of the Vaxzevria vaccine against the threat of the still-widespread COVID-19 (which in turn causes problems of coagulation and can be fatal) still outweigh the risk of these side effects.

<https://www.aifa.gov.it/-/vaccino-covid-19-astrazeneca-ema-trova-un-possibilecollegamento-con-casi-molto-rari-di-trombi-inusuali-associati-a-bassi-livelli-di-piastri-ne>

#### **Other drugs and Vaxzevria**

Inform your doctor or the health worker at the vaccination center if you are taking or have recently taken any other drug, or if you have recently received any other type of vaccine.

### **Pregnancy and breastfeeding**

If you are pregnant, think you are pregnant, or planning to become pregnant, or if you are breastfeeding, ask your doctor before receiving this vaccine.

There is limited information on the use of Vaxzevria in pregnant women. Studies on reproductive toxicity in animals have not finished. Based on preliminary results, no effect on fetal development has been observed. Receiving the Vaxzevria vaccine while pregnant can be taken into consideration only when the potential benefits outweigh the potential risks to the mother and to the fetus.

### **Duration of protection and limitations of the effectiveness of the vaccine**

The duration of the protection the vaccine provides is unknown; clinical studies are underway to establish this.

Protection begins about 3 weeks after the first dose of Vaxzevria. Subjects may not be completely protected until up to 15 days after receiving the second dose. As with all vaccines, vaccination with Vaxzevria may not protect all vaccinated individuals. It is therefore essential to scrupulously continue following all public health recommendations (mask wearing, physical distancing, frequent hand washing).

### **How is Vaxzevria administered?**

The Vaxzevria vaccine is administered as an intramuscular injection in your upper arm. A second dose is necessary, and it is recommended that this second of the same vaccine be administered about 12 weeks after the first dose to complete the vaccination cycle.

It is very important that the second dose be administered to obtain the optimum response from your immune system. Should you forget to return for your second dose on the scheduled date, contact your doctor or the vaccination center where you received the first dose.

### **Possible side effects**

Like all vaccines, Vaxzevria may cause side effects, although not everyone will have them. Seek **urgent** medical assistance if you have symptoms of a serious allergic reaction. A serious allergic reaction can include any combination of any of the following symptoms:

- feeling faint or lightheaded
- changes in your heartbeat
- shortness of breath
- wheezing
- swelling of lips, face, or throat
- hives or rash
- nausea or vomiting
- stomachache

The Vaxzevria vaccine may cause the following side effects:

*Very common side effects (more than 1 person out of 10):*

- pain, heat, itching, or bruising at the injection site
- fatigue or general malaise
- chills or fever-like sensation
- headache
- nausea
- muscle or joint pain

*Common side effects (up to 1 person out of 10):*

- redness or swelling at the injection site
- fever (>38°C)
- vomiting or diarrhea
- low platelet count

*Uncommon side effects* (up to 1 person out of 100):

- sleepiness or dizziness
- loss of appetite
- swelling of lymph nodes
- excessive sweating, itching or rash

*Very rare* (up to 1 person out of 10,000):

- blood clots in unusual sites (brain, intestine, liver, spleen) associated with low platelet count.

If any side effect occurs, even if not listed above, contact your doctor or the vaccination center.

You can also report side effects directly through the national reporting system:

(<https://www.aifa.gov.it/content/segnalazioni-reazioni-avverse>).

**What does Vaxzevria contain?**

The active ingredient is a non-replicating chimpanzee adenovirus that encodes for the glycoprotein spike of SARS-CoV-2. This product contains genetically modified organisms (GMOs).

The other ingredients are: L-histidine; L-histidine hydrochloride monohydrate; magnesium chloride hexahydrate; polysorbate 80 (E 433); sucrose; disodium edetate (dihydrate); sterile water for injection preparations.