

ATTACHMENT TO THE ANTI-COVID-19 VACCINATION CONSENT FORM

GENERAL INFORMATION

Janssen COVID-19 Vaccine

What is the Janssen COVID-19 vaccine and what is it for?

The Janssen COVID-19 vaccine is used to prevent COVID-19, the disease caused by the SARS-CoV-2 virus. The Janssen COVID-19 vaccine 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 Janssen COVID-19 vaccine?

You must **not** receive the Janssen COVID-19 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 have ever had an allergic reaction to any vaccine in the past;
- you have ever fainted after any sort of injection with a needle;
- you currently have a severe infection with high fever (over 38 °C). If, instead, you have a low fever or a low-grade infection of your upper airways, like a cold, you can receive the vaccine;
- you have a bleeding disorder, you bruise easily, or you are taking a blood thinner (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 the Janssen COVID-19 vaccine, blood clots, in association with low platelet count, have been observed, although very rarely. This condition included severe cases of blood clotting in unusual sites (e.g., brain, intestine, liver, spleen), in some cases together with bleeding.

These cases occurred in the three weeks after vaccination, primarily in women under the age of 60. This event has even been fatal.

Contact your doctor immediately if, a few days after vaccination, you have intense and/or persistent headache or blurred vision, or if a bruise appears in a site other than where you were vaccinated. Also contact your doctor if you have difficulty breathing, chest pain, swelling in your legs, and/or persistent abdominal pain. Inform your doctor that you received the Janssen COVID-19 vaccine in the preceding days.

The Pharmacovigilance Risk Assessment Committee (PRAC) of the European Medicines Agency (EMA), in a meeting on 20 April 2021, concluded that the benefits of the Janssen COVID-19 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.

Other drugs and the Janssen COVID-19 vaccine

Inform your doctor or the health worker at the vaccination center if you are taking or have recently taken or may take 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 the Janssen COVID-19 vaccine in pregnant women. Studies on animals have shown that the Janssen COVID-19 vaccine does not have any direct or indirect effect on pregnancy, on embryonal or fetal development, on childbirth or on the baby's development after birth. Receiving the Janssen COVID-19 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 14 days after vaccination. As with all vaccines, vaccination with the Janssen COVID-19 vaccine 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 the Janssen COVID-19 vaccine administered?

The Janssen COVID-19 vaccine is administered in a single dose (without a second dose) as an intramuscular injection in your upper arm.

Possible side effects

Like all vaccines, the Janssen COVID-19 vaccine 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
- stomach pain

The Janssen COVID-19 vaccine may cause the following side effects:

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

- headache
- nausea
- muscle pain
- pain at the injection site
- extreme fatigue

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

- redness at the injection site
- swelling at the injection site
- chills
- joint pain
- fever
- cough

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

- rash
- muscle weakness
- pain in arms or legs
- feeling of weakness
- feeling of general malaise
- sneezing
- sore throat
- back pain
- shaking
- excessive sweating

Rare side effects (up to 1 person out of 1,000)

- allergic reaction
- hives

Very rare side effects (up to 1 person out of 10,000)

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

Side effects with unknown frequency (the frequency cannot be determined based on the available data):

- serious allergic reaction

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

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

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

What does the Janssen COVID-19 vaccine contain?

The active ingredient is a human adenovirus (adenovirus type 26) that cannot replicate, that expresses the SARS-CoV-2 spike protein.

This product contains genetically modified organisms (GMO).

The other ingredients are: 2-hydroxypropyl- β -cyclodextrin (HBCD), citric acid monohydrate, ethanol, acid chloride, polysorbate-80, sodium chloride, sodium hydroxide, trisodium citrate dihydrate, water for injection preparations.