

ATTACHMENT 1 TO THE COVID-19 VACCINATION CONSENT FORM**INFORMATION LEAFLET****Janssen COVID-19 Vaccine****What the Janssen COVID-19 Vaccine is and what it is used for**

The Janssen COVID-19 Vaccine is a vaccine used to prevent COVID-19 disease caused by SARS-CoV-2 virus. The Janssen COVID-19 Vaccine is given to adults from 18 years. The vaccine triggers the immune system (the body's natural defences) to produce antibodies and blood cells that work against the virus, to protect against COVID-19 disease. None of the ingredients in this vaccine can cause COVID-19.

What you need to know before you receive the Janssen COVID-19 Vaccine

The Janssen COVID-19 Vaccine should not be given if you are allergic to the active substance or any of the other ingredients of this medicine (listed below).

Warnings and precautions

Talk to the doctor or health care professional at the vaccination centre before you are given the vaccine if you have:

- ever had a serious allergic reaction after any other vaccine injection;
- fainted after any needle injection;
- a serious infection with high fever (above 38 °C). However, if you have a mild fever or an upper airway infection, like a cold, you can still receive the vaccination;
- bleeding problems or bruise easily or if you are taking an anticoagulant medicine (to inhibit blood clotting);
- a compromised immune system (immunodeficiency) or are on a medicine that affects your immune system (such as high-dose corticosteroids, immunosuppressants or anti-cancer drugs).

Following the administration of the Janssen COVID-19 Vaccine, very rare blood clots and low blood platelets have been observed. This condition includes severe cases with blood clots in unusual sites (e.g. brain, intestine, liver, spleen) and sometimes bleeding. The cases occurred in the three weeks following the vaccination and mainly in women under 60. This condition has also resulted in death.

Seek immediate medical attention if, a few days after vaccination, you experience intense or persistent headaches or blurred vision, or if unexpected bruising appears on the skin at a place other than the vaccination site, as well as shortness of breath, chest pain, swelling of the legs or persistent abdominal pain. In these cases, tell the doctor that you were recently given the Janssen COVID-19 Vaccine.

At its meeting of 20 April 2021, EMA's safety committee (PRAC) concluded that the benefits of the Janssen COVID-19 Vaccine in combating the still widespread threat of COVID-19 (which itself causes clotting problems and can be fatal) continue to outweigh the risk of adverse effects.

Other medicines and the Janssen COVID-19 Vaccine

Tell the doctor or health care professional at the vaccination centre if you are using, have recently used, or might use any other medicines, or have recently received any other vaccine.

Pregnancy and breast-feeding

If you are pregnant, think you may be pregnant or are planning to have a baby, or if you are breast-feeding, ask the doctor for advice before you receive this vaccine.

Experience relating to the use of the Janssen COVID-19 Vaccine in pregnant women is limited. Animal studies with the Janssen COVID-19 Vaccine do not indicate direct or indirect harmful effects with respect to pregnancy, embryo/foetal development, parturition or post-natal development. Administration of the Janssen COVID-19 Vaccine in pregnancy should only be considered when the potential benefits outweigh any potential risks for the mother and foetus.

Duration of protection and limitations of vaccine effectiveness

The duration of protection offered by the vaccine is unknown as it is still being determined by ongoing clinical trials. Protection starts around 14 days from vaccination. As with any vaccine, vaccination with the Janssen COVID-19 Vaccine may not protect all vaccine recipients. It is therefore essential to continue to strictly adhere to public health advice (mask, social distancing and frequent hand washing).

How the Janssen COVID-19 Vaccine is given

The Janssen COVID-19 Vaccine is given in a single dose (without the need for a booster) injected into a muscle in the upper arm (intramuscular injection).

Possible side effects

Like all vaccines, the Janssen COVID-19 Vaccine can cause side effects, although not everybody gets them. Most of the side effects arose within 1-2 days from the vaccination.

Blood clots combined with low levels of platelets were very rarely reported (thrombotic syndrome associated with thrombocytopenia). Immediately seek medical assistance if one of the following symptoms arises within 3 weeks from the vaccination:

- Intense or persistent headaches, blurred vision, changes in mental state or epileptic fits (convulsions);
- difficulty in breathing, chest pain, swollen legs, pain in the legs or persistent abdominal pain;
- unusual bruises on the skin or very small round marks located in a point other than the vaccination site.

Seek urgent medical assistance if any symptoms of a severe allergic reaction occur; these reactions might include a combination of any one of the following symptoms:

- feeling faint or light-headed
- changes in heart rate
- difficulty in breathing
- wheezing
- swelling of lips, face or throat
- hives or rash
- nausea or vomiting
- stomach pain.

The Janssen COVID-19 Vaccine can cause the following side effects:

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

- headache
- nausea
- muscle pain
- pain at the injection site
- feeling very tired

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

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

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

- rash
- muscle weakness
- pain in the arms or legs
- feeling of weakness
- generally feeling unwell
- sneezing
- sore throat
- back pain
- shivering
- Excessive sweating

Rare side effects (may affect up to 1 in 1,000 people)

- allergic reaction
- hives

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

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

Side effects with unknown frequency (cannot be estimated from the available data):

- serious allergic reaction

If you get any side effects, even if not listed above, talk to your doctor or contact the vaccination centre.

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

What the Janssen COVID-19 Vaccine contains

The active ingredient is a recombinant, replication-incompetent adenovirus type 26 expressing the SARS-CoV-2 spike protein.

This product contains genetically modified organisms (GMO).

The other excipients are: 2-hydroxypropyl- β -cyclodextrin (HBCD); citric acid monohydrate; ethanol; hydrochloric acid; polysorbate-80; sodium chloride; sodium hydroxide; trisodium citrate dihydrate; water for injections.

