

## ATTACHMENT TO THE ANTI-COVID-19 VACCINATION CONSENT FORM

### INFORMATION NOTICE

#### Janssen COVID-19 vaccine

##### What is Janssen and what is it for?

The Janssen COVID-19 Vaccine is a vaccine used for the prevention of COVID-19, a disease caused by the SARS-CoV-2 virus. The Janssen COVID-19 Vaccine 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 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 the Janssen COVID-19 vaccine?

Janssen COVID-19 Vaccine must not be inoculated

- if you are allergic to the active substance or to any other excipient of this medicine (listed below).
- 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 after the injection of any other vaccine;
- You fainted after any needle injection;
- You have a severe infection with a high fever (higher than 38°C). However, you can get the vaccination if you have a mild fever or a mild upper respiratory infection such as a cold;
- You have a bleeding problem or spontaneous bruising or if you are taking an anticoagulant medicine (to prevent blood clots);
- Your immune system is not working as it should (immunodeficiency) or you are taking medicines that weaken the immune system (such as high-dose corticosteroids, immunosuppressants or anticancer medicines).

##### *Blood disorders*

- **Venous thromboembolism:** blood clots in the veins (venous thromboembolism, VTE) have been rarely observed after vaccination with this vaccine.
- **Thrombosis with thrombocytopenic syndrome:** after vaccination with this vaccine, blood clots have been observed very rarely in association with low levels of blood platelets. This condition includes severe cases of blood clots even in unusual sites such as the brain, liver, intestines and spleen, in some cases with the presence of bleeding. These cases mainly occurred in the first three weeks after the vaccination and in women under 60 years of age. This condition also resulted in death.
- **Immune thrombocytopenia:** Cases of very low platelet levels (immune thrombocytopenia), even in association with bleeding, have been reported very rarely, generally within the first four weeks after vaccination with this vaccine.

Require urgent medical attention if you experience symptoms which may signal blood disorders: severe or persistent headaches, seizures (convulsions), changes in mental status or blurred vision, unusual bleeding, unusual bruising on the skin somewhere other than the vaccination site, within a few days after vaccination, very small round spots somewhere other than the vaccination site, or if you experience shortness of breath, chest pain, leg pain, leg swelling or persistent abdominal pain. Inform the healthcare professional (doctor, pharmacist or nurse) that you have recently received Janssen COVID-19 Vaccine.

### *Capillary leak syndrome*

Very rare cases of capillary leak syndrome (CLS) have been reported following vaccination with this vaccine. 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.

### *Guillain-Barré syndrome*

Inform your 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 after vaccination with Janssen COVID-19 Vaccine.

### **Other medicines and Janssen COVID-19 vaccine**

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 with 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, embryonal/foetal development, parturition or postnatal development. Inoculation of the Janssen COVID-19 vaccine 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 14 days after vaccination. Similarly to all vaccines, vaccination with the Janssen COVID-19 Vaccine 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 the Janssen COVID-19 Vaccine is given**

The Janssen COVID-19 vaccine is given as a single dose (no second dose required) by an intramuscular injection into the upper arm.

An additional dose (booster dose) of an mRNA vaccine (Comirnaty, Spikevax) may be given at least 5 months after the last vaccination, in order to ensure maximum vaccination protection over time.

### **Possible side effects**

Like all vaccines, the Janssen COVID-19 vaccine may cause side effects, although not everyone shows them. Most of the side effects occurred within 1-2 days of vaccination.

Blood clots have been reported very rarely in combination with low platelet levels (thrombotic syndrome associated with thrombocytopenia). Require urgent medical attention if you experience any of the

following symptoms within 3 weeks of vaccination:

- severe or persistent headaches, blurred vision, changes in mental status or seizures (convulsions);
- wheezing, chest pain, leg swelling, leg pain or persistent abdominal pain;
- unusual bruises on the skin or very small round spots located somewhere other than the vaccination site.

Require **urgent** medical attention if you experience symptoms of a severe allergic reaction; 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 the Janssen COVID-19 vaccine:

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

- headache
- nausea
- muscle aches
- pain at the injection site
- feeling of extreme tiredness

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

- redness at the injection site
- swelling at the injection site
- chills
- articular pains
- 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
- feeling of general malaise
- sneezing
- sore throat
- back pain
- tremor
- excessive sweating
- unusual sensation on the skin, such as tingling or pricking sensation (paraesthesia)
- diarrhoea
- dizziness

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

- allergic reaction
- hives
- swollen lymph nodes (lymphadenopathy)
- reduced sensitivity, especially on the skin (hypoesthesia)

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- persistent ringing in the ears (tinnitus)
- vomiting
- blood clots in the veins (venous thromboembolism, VTE)

*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.
- severe inflammation of the nerves which can cause paralysis and difficulty in breathing (Guillain-Barré syndrome (GBS)).

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

- severe allergic reaction
- capillary leak syndrome (a condition that causes fluid to leak from small blood vessels)
- low levels of platelets (immune thrombocytopenia), which may be associated with bleeding (see section 2, Blood disorders).

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 the Janssen COVID-19 Vaccine contains**

The active substance is a non-replicating human adenovirus (adenovirus type 26) which encodes the SARS-CoV-2 spike glycoprotein.

This product contains genetically modified organisms (GMOs).

The other excipients are: 2-hydroxypropyl- $\beta$ -cyclodextrin (HBCD), citric acid monohydrate, ethanol, hydrochloric acid, polysorbate 80, sodium chloride, sodium hydroxide, trisodium citrate dehydrate, water for injections.