ATTACHMENT TO THE ANTI-COVID-19 VACCINATION CONSENT FORM

INFORMATION NOTICE

Spikevax (Moderna COVID-19 Vaccine)

What is Spikevax and what is it for?

Spikevax Vaccine (formerly known as Moderna COVID-19 Vaccine) is used to prevent COVID-19, a disease caused by the SARS-CoV-2 virus. Spikevax can be inoculated to persons aged 12 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. Since Spikevax does not contain the virus to induce immunity, it cannot transmit you the COVID-19 disease.

What do you need to know before receiving Spikevax?

Spikevax must not be inoculated if you are allergic to the active substance or to any other excipient of this medicine (listed below).

Warnings and Precautions

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

- You have had a severe allergic reaction or breathing problems after receiving another vaccine or after receiving Spikevax 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;
- You have a weakened immune system, due to a disease such as HIV infection, or from medicines that affect the immune system, such as corticosteroids.

Very rare cases of myocarditis (inflammation of the heart) and pericarditis (inflammation of the outer lining of the heart) have been reported following vaccination with Spikevax, mainly occurring in the two weeks following vaccination, more often after the second dose and in young males. After vaccination, you should be alert for signs of myocarditis and pericarditis, such as shortness of breath, palpitations and chest pain, and seek immediate medical attention if such symptoms occur.

Other medicines and Spikevax

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.

Data relating to the use of Spikevax in pregnant women are limited. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/foetal development, parturition or postnatal development. Administration of Spikevax during pregnancy should only be considered when the potential benefits outweigh the potential risks to the mother and the foetus.

The Ministry of Health recommends SARS-CoV-2/COVID-19 vaccination for pregnant women in the second and third trimester and for breastfeeding women, without the need to stop breastfeeding; with regard to the first trimester of pregnancy, vaccination can be considered after the healthcare professional has evaluated the potential benefits and potential risks.

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. Similarly to all vaccines, vaccination with Spikevax may not protect everyone who receives it.

People may not be fully protected up to 14 days after the second dose of the vaccine. It is therefore essential to continue to strictly follow public health recommendations (mask, interpersonal distance and frequent hand washing).

How Spikevax is given

Spikevax vaccine is given by an intramuscular injection into the upper arm. There is a booster dose and it is recommended that the second dose of the same vaccine is inoculated 4 weeks (and in any case no later than 42 days) after the first dose in order to complete the vaccination cycle.

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.

In people with clinically relevant immunosuppressive conditions, an additional dose is foreseen at least 28 days after the second dose in order to ensure a good immune response. An additional dose (booster dose) can also be inoculated to adults at greater risk of severe disease or at greater risk of exposure to infection, at least 5 months after the last vaccination.

Spikevax can be used as an additional dose or as a booster dose regardless of the primary vaccination cycle (Comirnaty, Spikevax, Vaxzevria, Janssen).

Spikevax can be used to complete a mixed vaccination cycle in individuals under the age of 60 who have already received a first dose of Vaxzevria vaccine in the previous 8-12 weeks. This use is not included in the indications of the vaccine, but the Italian Medicines Agency (AIFA) allowed this use and this vaccine in the list drafted according to law no. 648/96[1] for individuals under the age of 60 who previously received Vaxzevria, following the Circular of the Ministry ref. no. 0026246-11/06/2021-DGPRE. This authorisation was made possible by the recent publication of clinical data demonstrating a good antibody response and manageable side effects following mixed cycle vaccination.

The inoculation of Spikevax can also be concomitant with that of the flu vaccine or another vaccine of the National Vaccine Prevention Plan, with the exception of live-attenuated vaccines.

Possible side effects

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

Require **urgent** medical attention if you experience any of the following symptoms of an allergic reaction:

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

Contact your doctor if any other side effects occur. These may include:

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

- swelling/achiness in the armpits
- headache
- nausea
- vomiting
- pain in muscles, joints and stiffness

[1] Law no. 648/96 allows doctors to use medicaments that have proven to be effective and safe in the treatment of a specific disease, but which are not authorized for that specific therapy, at the expense of the National Health System.

- pain or swelling at the injection site
- feeling of extreme tiredness
- chills
- fever

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

- rash
- redness or hives at the injection site (in some cases they may occur sometime after the injection)

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

- itching at the injection site

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

- temporary unilateral facial flaccid paralysis (Bell's palsy)
- swelling of the face (swelling of the face may occur in patients who have previously had facial cosmetic injections)
- dizziness
- decreased sense of touch or sensitivity

Unknown (frequency cannot be estimated from the available data):

- severe allergic reactions with breathing difficulties (anaphylaxis)
- immune system reactions of increased sensitivity or intolerance (hypersensitivity)
- inflammation of the heart (myocarditis) or inflammation of the outer lining of the heart (pericarditis) which can cause shortness of breath, palpitations or chest pain

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 Spikevax contains

The active substance is an anti-COVID-19 mRNA vaccine.

The other excipients are: lipid SM-102, cholesterol, 1,2-distearoyl-sn-glycerol-3-phosphocholine (DSPC), 1,2-dimyristoyl-rac-glycerol-3-methoxy polyethylene glycol-2000 (PEG2000 DMG), trometamol, trometamol hydrochloride, acetic acid, sodium acetate trihydrate, sucrose, water for injections.