ATTACHMENT 1 TO THE COVID-19 VACCINATION CONSENT FORM

INFORMATION LEAFLET

Spikevax (Moderna COVID-19 Vaccine)

What Spikevax is and what it is used for

The 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 is administered to adults and children aged 12 years and over. The vaccine triggers the immune system (the body's natural defences) to produce antibodies and blood cells that work against the virus, thus providing protection against COVID-19. The Spikevax vaccine does not contain the virus to trigger immunity and, therefore, it cannot transmit COVID-19.

What you need to know before you are given Spikevax

Spikevax should not be administered 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 the healthcare professional at the vaccination centre before you are given the vaccine if you:

- have ever had a severe allergic reaction or breathing problems after any other vaccine injection or after you were given Spikevax in the past.
- have ever fainted following an injection.
- have an illness or a severe infection with high fever. However, if you have a mild fever or an upper airway infection (like a cold), you can still receive the vaccination;
- have a bleeding problem, bruise easily or use a medicine to inhibit blood clotting;
- have a weakened immune system, due to a disease such as HIV infection, or are on a medicine that affects your 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, occurring mainly within two weeks after vaccination, more often after the second dose and in younger men. After vaccination, it is necessary to watch out 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

Tell the doctor or the healthcare professional at the vaccination centre if you are taking, have recently taken, or might take any other medicines, or if you 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, seek medical advice before you receive this vaccine.

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

Duration of protection and limitations of vaccine effectiveness

The duration of protection afforded by the vaccine is unknown as it is still being determined by ongoing clinical trials. As with any vaccine, vaccination with Spikevax may not protect all vaccine recipients. Individuals may not be fully protected until 14 days after the second dose of the vaccine. It is therefore essential to continue to strictly adhere to public health guidelines (face masks, social distancing and frequent hand

washing).

How Spikevax is administered

Spikevax is administered through an intramuscular injection into the upper arm. A booster shot will be scheduled, and it is recommended that the second dose of the same vaccine is given 4 weeks (and in any case no more than 42 days) after the first dose to complete the vaccination cycle.

It is very important that you get the second dose to achieve an optimal immune response. If you miss your scheduled appointment for the second dose, contact your family doctor or the vaccination centre where you received the first dose.

For severely immunocompromised people, an additional dose should be scheduled at least 28 days after the second dose, in order to ensure a good immune response. Currently, the use of additional doses is still under evaluation by the EMA (European Medicines Agency), but the Italian Medicines Agency (AIFA) has allowed it as a precautionary measure in subjects aged ≥18 years, by including the drug in the lists drawn up according to law no. 648/96[1].

Spikevax can be used to complete a mixed vaccination schedule in subjects below 60 years of age who have already received a first dose of Vaxzevria, 8-12 weeks after the administration of this vaccine. This use is not included in the indications of the vaccine, but, following the Ministry's circular letter ref. no. 0026246-11/06/2021-DGPRE, the Italian Medicines Agency (AIFA) has allowed its use, through the inclusion of the drug in the lists drawn up in accordance with Law no. 648/96[1], for individuals under the age of 60 who previously received Vaxzevria. This authorisation was made possible by the recent publication of clinical data showing a good antibody response and manageable side effects following a mixed vaccination schedule.

Possible side effects

Like all vaccines, Spikevax may cause side effects, although not everybody shows them.
Please seek **urgent** medical attention if you experience any of the following signs and symptoms of an allergic reaction:

- feeling faint or light-headed
- changes in your heartbeat
- shortness of breath
- wheezing
- swelling of the tongue, face or throat
- hives or rash
- nausea or vomiting
- stomach pain.

Contact your doctor if you develop any other side effects. These can include:

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

- swelling/tenderness of the underarm
- headache
- nausea
- vomiting
- muscle ache, joint aches, and stiffness
- pain or swelling at the injection site

[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 Service.

- feeling extremely tired
- chills
- fever

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

- rash
- redness or hives at the injection site (some of which may occur some time after the injection)

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

- itching at the injection site

Rare side effects (may affect up to 1 in 1000 people):

- temporary one sided facial drooping (Bell's palsy)
- swelling of the face (swelling of the face may occur in patients who have had facial cosmetic injections)
- dizziness
- decreased sense of touch or sensation

Not known (frequency cannot be estimated from the available data):

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

If you experience any possible side effects, even if not listed above, talk to your family 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 Spikevax contains

The active substance is a COVID-19 mRNA vaccine.

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