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mNexspike (*COVID-19 mRNA Vaccine*)

An overview of mNexspike and why it is authorised in the EU

What is mNexspike and what is it used for?

mNexspike is a vaccine for preventing coronavirus disease 2019 (COVID-19) in people aged 12 years and older.

mNexspike contains a molecule called messenger RNA (mRNA) with instructions for producing part of a protein from SARS-CoV-2, the virus that causes COVID-19.

mNexspike does not contain the virus itself and cannot cause COVID-19.

How is mNexspike used?

mNexspike is given as a single injection, preferably into the muscle of the upper arm. In people previously vaccinated against COVID-19, mNexspike should be given at least 3 months after the most recent dose of a COVID-19 vaccine.

The vaccine should be used according to official recommendations, issued at national level by public health bodies.

For more information about using mNexspike, see the package leaflet or consult a healthcare professional.

How does mNexspike work?

mNexspike works by preparing the body to defend itself against COVID-19. It contains a molecule called mRNA which has instructions for making part of the spike protein. This is a protein on the surface of SARS-CoV-2 which the virus needs to enter the body's cells.

When a person is given the vaccine, some of their cells will read the mRNA instructions and temporarily produce the spike protein fragment. The person's immune system will then recognise this fragment as foreign and produce antibodies and activate T cells (white blood cells) to attack it.

If, later on, the person comes into contact with the SARS-CoV-2 virus, their immune system will recognise it and be ready to defend the body against it.

The vaccine is contained in lipid nanoparticles (small fat particles) that help the mRNA enter the body's cells.

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The mRNA from the vaccine and the spike protein fragment are broken down after vaccination and removed from the body.

What benefits of mNexspike have been shown in studies?

A large main clinical trial in over 11,000 people showed that mNexspike is effective at protecting people from 12 years of age against COVID-19 and triggering the production of antibodies against SARS-CoV-2.

The study showed that mNexspike was as effective as the comparator vaccine, Spikevax bivalent Original/Omicron BA.4-5, at preventing COVID-19 and at stimulating the production of antibodies against the original SARS-CoV-2 and the SARS-CoV-2 BA.4/BA.5 strains. The safety of mNexspike was also shown to be comparable to that of the comparator vaccine.

Can children be vaccinated with mNexspike?

mNexspike is authorised for use in people from 12 years of age. EMA has agreed with the company on a plan to assess the vaccine in younger children at a later stage.

Can immunocompromised people be vaccinated with mNexspike?

There are no data on immunocompromised people (people with weakened immune systems). Although immunocompromised people may not respond as well to the vaccine, there are no particular safety concerns. Immunocompromised people can still be vaccinated as they may be at higher risk from COVID-19.

Can pregnant or breastfeeding women be vaccinated with mNexspike?

Animal studies do not show any harmful effects in pregnancy, however data on the use of mNexspike during pregnancy are very limited. As a precautionary measure, it is preferable to avoid using mNexspike during pregnancy.

No effects on the breastfed infant are expected, since the exposure of the breast-feeding woman to the active substance in mNexspike is negligible. Data collected from women who were breastfeeding after vaccination with another mRNA COVID-19 vaccine, elasomeran, do not shown a risk in breastfed infants. mNexspike can be used during breast-feeding.

Can people with allergies be vaccinated with mNexspike?

People who already know they have an allergy to one of the components of the vaccine listed in section 6 of the package leaflet should not receive the vaccine.

As for all vaccines, mNexspike should be given under close medical supervision, with the appropriate medical treatment available in case of allergic reactions.

How well does mNexspike work for people of different ethnicities and genders?

The main clinical trial included people of different ethnicities and genders. The efficacy was maintained across genders and ethnic groups.

What are the risks associated with mNexspike?

The most common side effects with mNexspike (affecting more than 1 in 10 people) include pain at the injection site, tiredness, headache, muscle pain, joint pain, chills, swollen or tender lymph nodes under the arm, nausea and vomiting.

The most common side effects in people younger than 18 years of age (affecting more than 1 in 10 people) include pain at the injection site, headache, muscle pain, swollen or tender lymph nodes under the arm, chills, nausea and vomiting.

Fever, redness and bruising at the injection site occurred in up to 1 in 10 people. Swollen or tender lymph nodes in the neck, hypoaesthesia (reduced sensation to touch, pain and temperature), diarrhoea, itching and bruising at the injection site may occur in up to 1 in 1,000 people. Rash may occur in up to 1 in 10,000 people.

Allergic reactions such as rash and urticaria (itchy rash) have occurred in people receiving the vaccine (in up to 1 in 100 people).

A very small number of cases of severe allergic reactions (anaphylaxis) have also occurred. As for all vaccines, mNexspike should be given under close supervision with appropriate medical treatment available.

Why is mNexspike authorised in the EU?

mNexspike was shown to be as effective as the comparator vaccine at protecting people from 12 years of age against COVID-19 and triggering the production of antibodies against SARS-CoV-2. Most side effects are mild to moderate in severity and are gone within a few days.

The European Medicines Agency therefore decided that mNexspike's benefits are greater than its risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of mNexspike?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of mNexspike have been included in the summary of product characteristics and the package leaflet.

A risk management plan (RMP) for mNexspike is also in place and contains important information about the vaccine's safety, how to collect further information and how to minimise any potential risks.

Safety measures will be implemented for mNexspike in line with the EU safety monitoring plan for COVID-19 vaccines to ensure that new safety information is rapidly collected and analysed. The company that markets mNexspike provides regular reports on the safety and efficacy of the vaccine.

As for all medicines, data on the use of mNexspike are continuously monitored. Suspected side effects reported with mNexspike are carefully evaluated and any necessary action taken to protect people.

Other information about mNexspike

mNexspike received a marketing authorisation valid throughout the EU on 12 February 2026.

Further information on mNexspike can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/mnexspike

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