swissmedic

Public Summary SwissPAR dated 11 January 2022

Spikevax® (active substance: CX-024414)

(previously Covid-19 Vaccine Moderna)

Temporary authorisation in Switzerland: 12 January 2021

Medicinal product (vaccine) for the prevention of COVID-19

About the medicinal product

The medicinal product (vaccine) Spikevax, with the active substance CX-024414, is a ready-to-use dispersion for injection[1].

The vaccine is designed to prevent COVID-19, which is caused by the SARS-CoV-2 virus (coronavirus).

SARS-CoV-2 is a new coronavirus that was discovered in China at the end of 2019. Owing to the rapid increase in case numbers in many countries and continents, the WHO (World Health Organisation) officially declared the outbreak to be a pandemic on 11 March 2020.

By the start of December 2021, in Switzerland over 1,000,000 people had contracted COVID-19, over 35,000 had been admitted to hospital and over 11,000 had died from the consequences of COVID-19 (Covid-19 Switzerland | Coronavirus | Dashboard (admin.ch))

Spikevax was authorised by Swissmedic on 12 January 2021 for use in adults.

Mode of action

The vaccine Spikevax causes the immune system (the body's natural defences) to produce antibodies and blood cells that work against the virus, thereby affording protection against COVID-19.

For a detailed explanation of the mode of action of mRNA vaccines, we recommend the Factsheet "How mRNA vaccines protect us from the coronavirus" or the Swissmedic videos on the vaccines generally.

[1] Dispersion for injection: liquid dosage form for injection

Use

The vaccine Spikevax is administered by a correspondingly trained healthcare professional in accordance with the current vaccination strategy.

Spikevax is injected into a muscle of the upper arm. Two doses of Spikevax are administered approximately 28 days apart for a complete basic immunisation course.

Efficacy

The efficacy of Spikevax in adults was compared with placebo (dummy drug) in a study in the USA with over 30,000 participants.

Healthy volunteers and study participants with stable chronic illnesses each received two doses of Spikevax or placebo roughly 28 days apart. At least 14 days after the second dose, the reliability of the vaccine Spikevax in preventing COVID-19 was investigated.

At the time of the main analysis, 28,207 participants had been followed up for a median[2] period of 2 months after the second dose. Of those who were exposed to the virus, those individuals vaccinated with Spikevax were 94.1% less likely to suffer from symptomatic COVID-19 than those who received a placebo vaccine.

In this study, none of the patients vaccinated with Spikevax suffered serious illness, indicating that Spikevax is beneficial in preventing serious COVID-19.

Precautions, undesirable effects & risks

Spikevax must not be used in those who are hypersensitive to the active substance or any of the excipients.

Like all vaccines, Spikevax can also produce side effects, although not necessarily in everyone. The most common adverse reactions are swelling of the underarm glands, headache, nausea, vomiting, muscle ache, joint aches and stiffness, pain and swelling at the injection site, severe tiredness, chills and fever.

Very rare cases of anaphylaxis (acute, allergic reactions) have also been reported after vaccination with Spikevax. Therefore, monitoring of patients for at least 15 minutes for hypersensitivity reactions and anaphylaxis is recommended following vaccination.

Very rare cases of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the membrane around the heart) were reported in the months following first authorisation. Cases generally occur within two weeks of vaccination, more frequently after the second dose and more frequently in younger men. Those who have received the vaccine should seek immediate medical attention if they develop signs of myocarditis or pericarditis such as shortness of breath, palpitations or chest pain.

All precautions, risks and other possible undesirable effects are listed in the Information for patients and the Information for healthcare professionals. (see link at the end of this document).

[2] Median: The value that lies exactly in the middle of a distribution of data is called the median or central value. Half of the data values are always smaller than the median, the other half are always greater.

Why the medicinal product has been authorised

The proven 94% efficacy of the vaccine Spikevax showed a high level of protection. Compared to non-vaccinated individuals, Spikevax lowered the risk of contracting COVID-19 by 94% (statistical range: 89.3% to 96.8%). This means that, out of 100 people exposed to the virus who would have contracted COVID-19 without vaccination, only 6 vaccinated individuals actually become ill. However, it does not mean that the probability of contracting COVID-19 after vaccination is 6%. The infection risk depends on the vaccination status (high protection against infection following exposure to the virus) but also on the frequency of the illness in the population, the precautions taken and individual behaviour. These factors determine the magnitude of the risk of coming into contact with the virus.

It was plausible, therefore, that the vaccine also afforded protection against severe COVID-19, and this was subsequently confirmed by epidemiological data.

Given the exceptional situation of the pandemic, taking account of all the risks and precautions, and on the basis of the available data, the benefit of Spikevax in reducing the risk of COVID-19 infection clearly outweighs its potential safety risks.

The medicinal product Spikevax was authorised in Switzerland on a temporary basis (in accordance with Art. 9a of the Therapeutic Products Act) since the clinical trials had not yet been concluded at the time of authorisation, and further data for the definitive evaluation of efficacy and safety will be submitted at a later date.

The temporary authorisation is contingent on the timely submission of the data requested by Swissmedic from ongoing clinical trials. Once these authorisation conditions have been met, the temporary authorisation can be converted into an ordinary authorisation.

Spikevax was authorised according to the "rolling submission" procedure. Rolling submission is a special form of authorisation for new active substances that has been adopted in the current pandemic situation and is intended to facilitate faster authorisation of urgently needed medicinal products. Using this procedure, Swissmedic can review data from ongoing clinical trials as soon as they become available.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Spikevax®
Information for patients (package leaflet): Information for patients Spikevax®

Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Public Summary SwissPAR.

Swissmedic monitors medicinal products authorised in Switzerland. Swissmedic initiates the necessary action in the event of newly discovered adverse drug reactions or other safety-relevant signals. New findings that could impair the quality, efficacy or safety of this medicinal product are recorded and published by Swissmedic. If necessary, the medicinal product information is adapted.