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Comirnaty® (active substance: tozinameran)

Temporary authorisation in Switzerland: 19 December 2020

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

About the medicinal product

The medicinal product Comirnaty, containing the active substance tozinameran, is a concentrate for dispersion for injection[1] of a COVID-19-mRNA vaccine.

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 outside China, and in many countries and continents, the WHO (World Health Organisation) officially declared the outbreak to be a pandemic on 11 March 2020.

Comirnaty is authorised for adults and adolescents aged 16 and older.

Mode of action

The vaccine Comirnaty 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 websites Factsheet - "How mRNA vaccines protect us from the coronavirus" or Swissmedic videos on the vaccines generally.

Use

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

Comirnaty is injected into a muscle of the upper arm. Two doses of Comirnaty are administered approximately 21 to 28 days apart for a complete vaccination course.

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

Efficacy

The efficacy of Comirnaty was compared with placebo (dummy drug) in a global study with over 43,000 participants.

Healthy volunteers and study participants with stable chronic illnesses each received two doses of Comirnaty or placebo 21 days apart. Seven days after the second dose, the reliability of the vaccine Comirnaty in preventing COVID-19 was investigated. The study participants were required to follow the specified local precautionary measures against COVID19 throughout the trial. Those who had been vaccinated with Comirnaty were 94.6% less likely to suffer from symptomatic COVID-19 than those who had received a placebo vaccine.

Subsequent efficacy analyses indicate that Comirnaty is beneficial in preventing severe episodes of COVID-19. It should be borne in mind, however, that the number of serious cases of the illness was very low in this study.

Precautions, undesirable effects & risks

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

Like all vaccines, Comirnaty can also produce side effects, although not necessarily in everyone. The most common adverse reactions are pain and swelling at the injection site, fatigue, headache, muscle pain, joint pain, chills and fever.

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

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).

Why the medicinal product has been authorised

The proven 95% efficacy of the vaccine Comirnaty affords a high level of protection. This means that, compared to non-vaccinated individuals, Comirnaty lowers the risk of contracting COVID-19 by 95% (statistical range: 89.6% to 97.6%). It is plausible that the vaccine also provides protection against severe episodes of COVID-19.

At the time Comirnaty was authorised, no other medicine had yet been authorised in Switzerland for the prevention of COVID-19. 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 Comirnaty in reducing the risk of COVID-19 infection clearly outweighs its potential safety risks.

The medicinal product Comirnaty 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.

Comirnaty 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: Fachinformation Comirnaty®
Information for patients (package leaflet): Patientinnen- und Patienteninformation Comirnaty®

Healthcare professionals (doctors, pharmacists and others) 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.