swissmedic

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Evusheld® (active substances: tixagevimab, cilgavimab)

Indication extension in Switzerland: 27 April 2023

Medicinal product (solutions for injection) for the prevention and treatment of COVID-19 in adolescents and adults

About the medicinal product

The medicinal product Evusheld contains the active substances tixagevimab and cilgavimab and is administered as solutions for injection into muscle.

Evusheld is an antiviral medicine (antiviral agent). It is indicated in adults and adolescents aged 12 years or older with a bodyweight of at least 40 kg.

The medicinal product Evusheld was already authorised temporarily by Swissmedic on 9 September 2022 for the prevention (pre-exposure prophylaxis) of COVID-19, which is caused by the SARS-CoV-2 coronavirus, if an adequate immune response to COVID-19 cannot be elicited.

The present indication extension means that Evusheld can now also be used for the treatment of mild to moderate COVID-19 if oxygen therapy or hospitalisation due to COVID-19 is not required and if there is an increased risk of progression to a severe form of the disease.

Evusheld is not intended as a replacement for vaccination against COVID-19. Nor is the medicinal product Evusheld authorised for post-exposure prophylaxis (following contact with an infected person) of COVID-19.

Mode of action

Evusheld is a combination product consisting of 2 active substances, tixagevimab and cilgavimab.

Tixagevimab and cilgavimab are monoclonal antibodies. Monoclonal antibodies are proteins that can bind to other specific proteins.

Both of the active substances in Evusheld bind to the spike protein of SARS-CoV-2, the pathogen that causes COVID-19. This prevents the virus from entering the body's cells. This can help the body to overcome the viral infection and avoid severe disease.

Administration

Evusheld, containing the active substances tixagevimab and cilgavimab, is a prescription-only medicine.

Both active substances are available as separate solutions for injection in doses of 150 mg per 1.5 mL.

The recommended dose for pre-exposure prophylaxis is 2 separate, sequential intramuscular injections of 1.5 mL in each case of tixagevimab and cilgavimab.

For the treatment of COVID-19, the recommended dose is 2 separate, sequential intramuscular injections of 3.0 mL in each case of tixagevimab and cilgavimab.

Evusheld should be administered as soon as possible after a positive viral test for SARS-CoV-2.

Evusheld should be used according to the official recommendations and taking into account the local epidemiological data and the available information on the sensitivity of the COVID-19 variants in circulation.

Efficacy

To assess the efficacy of Evusheld in pre-exposure prophylaxis, Swissmedic took account of the interim results of the ongoing PROVENT study. Data from the TACKLE study were also considered for the indication extension.

The ongoing TACKLE study investigated the efficacy and safety of Evusheld in 903 adult patients with a confirmed diagnosis of COVID-19. This study investigated individuals who were at risk of a severe course of the disease due in particular to obesity or high blood pressure. They had not been vaccinated against COVID-19 and had at least mild symptoms of COVID-19. The treatment was started within 7 days of the onset of symptoms. The patients received either Evusheld or a placebo in addition to the normal treatment.

The results showed that 4.4% of the patients who received Evusheld experienced severe COVID-19 or died, compared to 8.9% in the placebo group. In other words, Evusheld reduced the risk of severe forms of the disease by 50%. The study also showed that the earlier the patients were treated with Evusheld, the greater the benefit.

Precautions, undesirable effects, & risks

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

The most common undesirable effects (affecting 1-10 in 100 treated individuals) are hypersensitivity and injection site reactions (e.g. pain or itching).

All precautions, risks, and other possible undesirable effects are listed in the Information for healthcare professionals.

Why the medicinal product has been authorised

In at-risk patients who are unable to mount an adequate immune response after a COVID vaccination (e.g. immunocompromised individuals) or who cannot receive a vaccination, monoclonal antibodies such as

Evusheld can help prevent severe forms of COVID-19.

The present indication extension means that Evusheld can be used in patients with mild to moderate COVID-19 to substantially reduce the probability of severe forms of the disease or death.

Taking all the risks and precautions into account, and based on the available data, the benefit of Evusheld in preventing and treating COVID-19 outweighs its potential risks.

Swissmedic has authorised the medicinal product Evusheld temporarily in Switzerland (in accordance with Art. 9a TPA) since not all clinical trials were available or had been concluded at the time of authorisation and the indication extension. The temporary authorisation is contingent on the timely submission of the data requested by Swissmedic. Once these authorisation conditions have been met, the temporary authorisation can be converted into an authorisation without special conditions in the event of a positive benefit-risk assessment of the results.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Evusheld®

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.