swissmedic

Public Summary SwissPAR dated 30 June 2023

Evusheld® (active substances: tixagevimab, cilgavimab)

Temporary authorisation in Switzerland: 9 September 2022

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 consists of the active substances tixagevimab and cilgavimab and is administered as an intramuscular injection.

Evusheld is an antiviral medicine (antiviral agent). It is used in adults and adolescents aged 12 years and older weighing at least 40 kg for the prevention (pre-exposure prophylaxis) and treatment of COVID-19, which is caused by the SARS-CoV-2 coronavirus.

It is used for pre-exposure prophylaxis if an adequate immune response to COVID-19 cannot be elicited. At the time of prophylaxis, the patients are not infected with COVID-19 and had not recently come into contact with a person infected with COVID-19.

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

The symptoms of COVID-19 range from mild infections to severe disease. Certain characteristics (e.g. advanced age) increase the risk of the disease becoming severe.

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

Mode of action

Evusheld is a combination product consisting of two 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.

Use

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 two 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 two 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.

In this study, a group of participants with an increased risk for contracting COVID-19 was treated either with Evusheld or a placebo. Due to age, previous illnesses or other circumstances, the participants had a high probability of responding inadequately to a vaccination or contracting COVID-19.

The study results show that Evusheld reduces the risk of a SARS-CoV-2 infection by about 76% compared to placebo. However, since the number of investigated events was low, no clear influence on the course of the illness (hospital stay, severe forms of COVID-19, death) was demonstrated. The efficacy of Evusheld was observed in various participant groups, regardless of age, gender, ethnicity or previous illnesses. No cases of severe or critical COVID-19 occurred in those participants who received Evusheld, compared to several cases in the placebo participants.

The efficacy of Evusheld in treating patients with mild to moderate COVID-19 is being investigated in the still ongoing TACKLE study. This study enrolled individuals who had not been vaccinated against COVID-19, who were not hospitalised for COVID-19 treatment and who had at least one mild symptom. The treatment was initiated within 3 days of a positive test result and, at the latest, 7 days of symptom onset. 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.

In patients with mild to moderate COVID-19, Evusheld substantially reduced 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 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. 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 ordinary authorisation 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 in 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.