

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 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) 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.

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.

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.

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.

Taking all the risks and precautions into account, and based on the available data,

the benefit of Evusheld in preventing 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 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 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.