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Public Summary SwissPAR dated 19 December 2022

Xevudy® (active substance: sotrovimab)

Temporary authorisation in Switzerland: 14 January 2022

Infusion for the treatment of COVID-19

About the medicinal product

The medicinal product Xevudy, containing the active substance sotrovimab, can be used in adults and adolescents aged 12 years and older and weighing at least 40 kg who have been diagnosed with COVID-19 and in whom there is a risk of developing a severe form of COVID-19. The patients must not require supplemental oxygen or be hospitalised.

The national recommendations and the circulating coronavirus variants should be considered.

Mode of action

Sotrovimab, the active substance in Xevudy, is a monoclonal antibody. A monoclonal antibody is a protein that can bind to other specific proteins. Sotrovimab binds to the spike protein of SARS-CoV-2, the pathogen that causes COVID-19. This prevents the virus from entering the body's cells.

Use

Xevudy, containing the active substance sotrovimab, is a prescription-only medicine.

Xevudy is a concentrate for solution for infusion available in a vial containing 8 ml, corresponding to 500 mg sotrovimab (active substance). The recommended dose is a single administration of 500 mg sotrovimab and is administered as an infusion into a vein.

Efficacy

The efficacy of Xevudy was investigated in the COMET-ICE study with 1,057 patients. The patients were 18 years or older, were not hospitalised, had tested positive for SARS-CoV-2 and did not require supplemental oxygen. The onset of the COVID-19 symptoms was within the previous 5 days. The patients were at high risk of developing severe COVID-19. 528 people received a single infusion of sotrovimab and 529 people received a dummy drug (placebo). The hospitalisation and mortality rates were determined on day 29 post-infusion. These events (hospitalisation or death) occurred in 1% of

the Xevudy group (6 out of 528 people), compared with 6% of the placebo group (30 out of 529 people). This corresponds to a 79% reduction in the risk of severe COVID-19 with Xevudy. The majority of patients in this study were infected with the original strain of SARS-CoV-2. Laboratory studies suggest that Xevudy is also effective against other virus variants such as Omicron (B.1.1.529/BA.1).

Precautions, undesirable effects & risks

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

The most common undesirable effects in the clinical study were hypersensitivity reactions (2 in 100 patients) and infusion-related reactions (1 in 100 patients).

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

Why the medicinal product has been authorised

The COMET-ICE study found that Xevudy can reduce the risk of hospitalisation or death in patients infected with SARS-CoV-2 who are at increased risk of developing severe COVID-19. COMET-ICE was not conducted in patients who were infected with newer virus variants such as Omicron. The clinical efficacy of Xevudy as regards the new virus variants must therefore be actively monitored.

The safety profile of Xevudy is considered to be positive.

For these reasons, Xevudy, containing the active substance sotrovimab, has been temporarily authorised in Switzerland (Art. 9a TPA). 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 Xevudy®

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.