swissmedic

Public Summary SwissPAR dated 3 May 2024

Xofluza® (active substance: baloxavir marboxil)

Indication extension in Switzerland: 4 October 2023

Medicinal product (film-coated tablet) for the treatment of uncomplicated flu (influenza) in patients who have had flu symptoms for a maximum of 48 hours

About the medicinal product

Xofluza was first authorised by Swissmedic on 19 February 2020 for treatment of patients aged 12 years and older with uncomplicated flu (influenza).
An indication extension for Xofluza to prevent uncomplicated flu in patients aged 12 years and older following close contact with a person infected with flu was also approved on 19 November 2021.
The present indication extension means that Xofluza can now also be used to treat uncomplicated influenza in children aged 1 year and older as well as otherwise healthy adults, adolescents aged 12 years and older, and adults at increased risk of flu-related complications. It also means that Xofluza can be used for prevention of influenza in patients aged 1 year or older who have had close contact with a person infected with influenza.

Flu is caused by the influenza A and influenza B viruses, which have various subtypes and lines. The influenza virus is spread through direct or indirect contact with respiratory fluids containing the virus. In Switzerland, flu and related complications result in almost 275,000 doctor visits, several thousand hospitalisations, and several hundred deaths every year.

Mode of action

Xofluza contains the active substance baloxavir marboxil, which is able to reduce the growth of the virus.

It attacks the influenza virus by inhibiting "endonuclease", the virus-specific enzyme[1] involved in viral replication.

[1] Enzyme: enzymes are proteins that act as biocatalysts, controlling and accelerating biochemical reactions in the body.

Administration

Xofluza is a prescription only medication that is available in a range of dosage forms: 20 mg and 40 mg film-coated tablets, and granules for oral suspension.

The dosage of Xofluza depends on the patient's body weight. It is taken within 48 hours of the onset of flu symptoms or following close contact with an infected person.

Xofluza can be taken with or without food. It should not be taken with drinks containing calcium, certain laxatives, or food supplements. Where possible, dairy products should be avoided during treatment with Xofluza.

Efficacy

The efficacy of Xofluza for the indication extension was investigated in a number of studies. Two of the key studies were CP40563 and 1719T0834.

Study CP40563 (miniSTONE 2) investigated the efficacy of Xofluza in the treatment of influenza in children aged 1 year and older. Xofluza acts in a similar way to an authorised medicinal product containing the active substance oseltamivir. The frequency of influenza-related complications was also low and comparable in both patient groups.

Study 1719T0834 (BLOCKSTONE) demonstrated the efficacy of Xofluza in prevention of influenza in patients aged between 1 and 12 years following close contact with an infected person. Despite a limited number of very young patients (1 to 3 years), it may be assumed that the efficacy for this age group can be derived from the data for adolescents and adults.

Precautions, undesirable effects, & risks

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

Taking Xofluza can cause severe side effects, including allergic reactions such as breathing problems, severe rash, hives or blistering, swelling of the face, throat or mouth area, dizziness or drowsiness, through to shock.

All precautions, risks, and other possible undesirable effects are listed in the Information for patients (package leaflet) and the Information for healthcare professionals.

Why the medicinal product has been authorised

The present indication extension for the medicinal product Xofluza meets an important need in influenza treatment in otherwise healthy patients aged between 1 and 12 years, in high-risk patients aged 12 years and over, and for prevention of influenza in patients aged 1 year or older who have had close contact with a person infected with influenza.

Taking all the risks and precautions into account, and based on the available data, the benefits of the indication extension for Xofluza outweigh the risks. Swissmedic has

therefore authorised the indication extension described for the medicinal product Xofluza, containing the active substance baloxavir marboxil, in Switzerland.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Xofluza®

Information for patients (package leaflet): Information for patients Xofluza®

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.