swissmedic

Public Summary SwissPAR dated 14 April 2022

Xofluza® (active substance: baloxavir marboxil)

Indication extension in Switzerland: 19 November 2021

Medicinal product (film-coated tablet) to prevent uncomplicated influenza (flu) in patients aged 12 years and older following close contact with a person infected with flu.

About the medicinal product

Xofluza has been authorised to prevent uncomplicated influenza (flu) following close contact with a person infected with flu. It is used in patients aged 12 years and older.

Xofluza contains the active substance baloxavir marboxil, which inhibits a virus-specific enzyme[1], the "endonuclease", which is involved in the replication of the influenza virus.

In Switzerland, flu and related complications result in more than 275,000 doctor visits, several thousand hospitalisations and several hundred deaths every year. Study 1719T0834 demonstrated the efficacy of Xofluza in preventing flu in people who had had close contact with someone with flu. Significantly fewer confirmed flu infections were observed in these people following single administration of Xofluza than in those participants who had received a placebo (dummy drug).

Xofluza was first authorised by Swissmedic on 19 February 2020 for treatment of patients aged 12 years and older with uncomplicated influenza (flu).

In deciding whether to authorise an indication extension for the medicinal product Xofluza, Swissmedic took into account the assessments of the European Medicines Agency (EMA), the US Food and Drug Administration (FDA) and the corresponding product information.

Since the assessment of the clinical data was based on the assessment reports of the foreign partner authorities, the preconditions for a SwissPAR (Swiss Public Assessment Report) and a resulting Public Summary SwissPAR are not fully met. Swissmedic refers to the authorisation of the foreign comparator products.

www.ema.europa.eu
www.fda.gov

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

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Xofluza®

Healthcare professionals can answer any further questions.

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

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.