swissmedic

Public Summary SwissPAR dated 10.08.2020

Xofluza® (active substance: baloxavir marboxil)

First authorisation in Switzerland: 19.02.2020

Medicine (film-coated tablets) for the treatment of patients 12 years of age and older with uncomplicated influenza (flu), who have shown flu symptoms for no more than 48 hours and who are otherwise healthy or at high risk of developing flu-related complications.

Information on authorisation

The medicine Xofluza, containing the active substance baloxavir marboxil, was authorised in connection with the work-sharing initiative of the ACSS Consortium. This work-sharing initiative is a collaborative project between the drug regulatory authorities in Australia (Therapeutic Goods Administration, TGA), Canada (Health Canada, HC), Singapore (Health Sciences Authority, HSA) and Swissmedic and the pharmaceutical industry. The work-sharing initiative coordinates the assessment of authorisation applications for new active substances that have been submitted in at least two of the four countries.

The authorisation application for Xofluza was submitted for assessment to the regulatory authorities in Canada, Australia and Switzerland. Each country assessed a part of the application and then shared and discussed the results. At the end of the process, each authority decided on the application independently.
Accordingly, Swissmedic did not conduct a comprehensive scientific assessment, but considered, and in this case accepted, the results of the assessments by the foreign reference authorities. Accordingly, and since Swissmedic has not produced a complete SwissPAR (Swiss Public Assessment Report), it cannot issue a complete Public Summary SwissPAR. Swissmedic therefore refers to the publications issued by the authorities involved:

- Overview of the evaluation process by the Australian authority TGA: Australian prescription medicine decision summary for Xofluza
- Regulatory Decision Summary of the Canadian authority Health Canada: Regulatory Decision Summary - Xofluza - Health Canada

Further details of the ACSS work-sharing initiative are published on the Swissmedic website: Link to the work-sharing initiative

Why the medicine has been authorised

Various studies have shown that the medicine Xofluza with the active substance baloxavir marboxil alleviates flu symptoms faster than a placebo. Since the available data demonstrate a positive benefit-risk profile, Swissmedic has authorised the medicine Xofluza with the active substance baloxavir marboxil for use 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 (doctors, pharmacists and others) can answer any further questions.

This information is correct as at the date above. 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.