EMA/886617/2022
EMEA/H/C/004974

Xofluza (*baloxavir marboxil*)

An overview of Xofluza and why it is authorised in the EU

What is Xofluza and what is it used for?

Xofluza is an antiviral medicine for treating and preventing flu in adults and children from 1 year of age.

As a treatment, Xofluza is only used for uncomplicated flu (flu without serious effects that may require hospital care).

Xofluza contains the active substance baloxavir marboxil.

How is Xofluza used?

Xofluza is available as tablets and as granules to be dissolved into water; it is taken by mouth. To treat flu, patients should take a single dose by mouth within 48 hours of having symptoms. To prevent flu, the single dose is taken as soon as possible within 48 hours of being in contact with someone suspected of having flu.

The dose for treatment and prevention are the same: people weighing more than 20 but less than 80 kg should take 40 mg, while those weighing 80 kg and above should take 80 mg. In children and infants weighing less than 20 kg, the dose depends on body weight.

For more information about using Xofluza, see the package leaflet or contact your doctor or pharmacist.

How does Xofluza work?

The active substance in Xofluza, baloxavir marboxil, blocks an enzyme known as CEN, which the influenza virus uses to produce more copies of itself. By interfering with the activity of this enzyme, the medicine can treat the infection and prevent infection in patients exposed to the virus.

What benefits of Xofluza have been shown in studies?

Treating flu

A main study in 1,436 otherwise healthy patients from 12 years of age with uncomplicated flu showed that Xofluza was effective in speeding up recovery from flu symptoms. Patients who took a single dose

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of Xofluza recovered after an average of around 54 hours compared with 80 hours for patients taking placebo (a dummy treatment). Xofluza was as effective as a 5-day treatment with another flu medicine, oseltamivir, which also helped patients recover in around 54 hours.

Another study looked at 2,182 patients from 12 years of age with uncomplicated flu at high risk of complications. In this study, symptoms improved after an average of around 73 hours in patients taking Xofluza, compared with 81 and 102 hours in patients taking oseltamivir and placebo, respectively.

A third study involved 173 children between 1 and 11 years of age with flu-like symptoms. Patients took either a single dose of Xofluza or a 5-day course of oseltamivir. In the study, children given Xofluza recovered on average after 138 hours, compared with 150 hours for children who took oseltamivir.

Preventing flu

A study involving 752 people, including 142 children between 1 and 11 years of age, showed that taking Xofluza after being exposed to the virus from an infected person at home reduces the risk of a person getting the disease. In this study, around 2% of those who took Xofluza tested positive for flu and had symptoms compared with around 14% of those who took placebo.

What are the risks associated with Xofluza?

The most common side effect with Xofluza (which may affect up to 1 in 100 people) in people aged 12 years and above is itchy rash. In children younger than 12 years of age, the most common side effects (which may affect up to 1 in 10 people) are diarrhoea, vomiting and rash.

For the full list of side effects and restrictions of Xofluza, see the package leaflet.

Why is Xofluza authorised in the EU?

Studies have shown that Xofluza is effective in treating uncomplicated flu and preventing illness in people who have been exposed to the flu virus. The side effects of the medicines appear to be few and are manageable. The European Medicines Agency therefore decided that Xofluza's benefits are greater than its risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Xofluza?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Xofluza have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Xofluza are continuously monitored. Side effects reported with Xofluza are carefully evaluated and any necessary action taken to protect patients.

Other information about Xofluza

Xofluza received a marketing authorisation valid throughout the EU on 7 January 2021.

Further information on Xofluza can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/xofluza

This overview was last updated in 12-2022.