

Package leaflet: Information for the patient

Xofluza 40 mg film-coated tablets

Xofluza 80 mg film-coated tablets

baloxavir marboxil

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Xofluza is and what it is used for
2. What you need to know before you take Xofluza
3. How to take Xofluza
4. Possible side effects
5. How to store Xofluza
6. Contents of the pack and other information

1. What Xofluza is and what it is used for

What Xofluza is

Xofluza contains baloxavir marboxil. This is a type of antiviral medicine called a ‘cap-dependent endonuclease inhibitor’.

Xofluza is used for treating and preventing influenza. This medicine stops the influenza virus from spreading in the body and helps shorten the time to recovery from symptoms.

What Xofluza is used for

- Xofluza is used to treat influenza in patients aged 1 year and above who have had influenza symptoms for less than 48 hours.
- Xofluza is used to prevent influenza in individuals aged 1 year and above who have been in close contact with someone who is known or suspected to have influenza.

2. What you need to know before you take Xofluza

Do not take Xofluza if:

- you are allergic to baloxavir marboxil or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking Xofluza.

Infants and Children

Do not give this medicine to children below 1 year of age. This is because the effects of Xofluza in this age group are not known.

Other medicines and Xofluza

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Do not take Xofluza with:

- laxatives, antacids or oral supplements containing iron, zinc, selenium, calcium, or magnesium

The medicines listed above may decrease the effect of Xofluza.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, as a precautionary measure it is preferable to avoid the use of Xofluza. Ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Xofluza is not likely to change your ability to drive and to use machines.

Xofluza contains lactose

Xofluza contains lactose (a type of sugar). If you have been told by your doctor that you have an intolerance to some sugars, talk to your doctor before taking this medicine.

Xofluza contains sodium

This medicine contains less than 23 mg of sodium per tablet, that is to say essentially 'sodium-free'.

3. How to take Xofluza

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

When to take Xofluza

For treatment of influenza, take Xofluza as a single dose as soon as possible within 48 hours of your flu symptoms starting.

For prevention of influenza, take Xofluza as a single dose as soon as possible within 48 hours following exposure to an infected person.

How much Xofluza to take

Your dose of Xofluza depends on how much you weigh. Your doctor or pharmacist will tell you how much to take.

Your weight	Xofluza dose
< 20 kg	Refer to the Xofluza granules for oral suspension package leaflet
≥ 20 kg – < 80 kg	Single dose of 40 mg taken as - 1 x 40 mg tablet
80 kg or more	Single dose of 80 mg taken as - 1 x 80 mg tablet

Xofluza can be taken with or without food. Take the tablet with some water.

If you take more Xofluza than you should

If you accidentally take more of this medicine than you should, talk to your doctor or pharmacist for advice.

If you forget to take Xofluza

If you forget to take your dose, take it as soon as possible.

For the treatment of influenza, Xofluza should be taken within 48 hours of your flu symptoms starting.

For the prevention of influenza, Xofluza should be taken within 48 hours of close contact with someone who is known or suspected to have flu.

4. Possible side effects

Like all medicines, it is possible for this medicine to cause side effects, although not everybody gets them.

Adults, adolescents and children

Get medical help immediately if you get any of the following serious side effects:

- Severe allergic reaction (anaphylaxis), with signs such as swelling of the face or skin, itchy rashes, low blood pressure and difficulty breathing

The frequency of these side effects cannot be estimated from the available data.

Other possible side effects:

The following side effect is **uncommon** (this can affect up to 1 in every 100 patients):

- Itchy rash

Children (1 to < 12 years)

The following side effects are **common** (this can affect up to 1 in every 10 patients)

- Diarrhoea, rash and vomiting

Reporting of side effects

If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

5. How to store Xofluza

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the blister and carton after 'EXP'. The expiry date refers to the last day of that month.

This medicine does not need any special temperature storage conditions. Store in the original package in order to protect from moisture.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Xofluza contains

- The active substance is baloxavir marboxil.
- Each 40 mg film-coated tablet contains 40 mg baloxavir marboxil. Each 80 mg film-coated tablet contains 80 mg baloxavir marboxil.
- The other ingredients are lactose monohydrate (see Section 2 'Xofluza contains lactose'), croscarmellose sodium ((E468) (see Section 2 'Xofluza contains sodium')), povidone (K25) (E1201), microcrystalline cellulose (E460), sodium stearyl fumarate in the tablet core, and hypromellose (E464), talc (E553b) and titanium dioxide (E171) in the film-coating.

What Xofluza looks like and contents of the pack

Xofluza 40 mg tablets are white to light yellow, oblong shaped film-coated tablets with "BXM40" marked on one side.

Xofluza 40 mg film-coated tablets are available in blister packs of 1.

Xofluza 80 mg tablets are white to light yellow, oblong shaped film-coated tablets with "BXM80" marked on one side.

Xofluza 80 mg film-coated tablets are available in blister packs of 1.

Marketing Authorisation Holder and Manufacturer

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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

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