



This medicine is subject to additional monitoring in Australia. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

Xofluza[®]

Baloxavir marboxil

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Xofluza. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Xofluza against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Xofluza is used for

Xofluza is used to treat uncomplicated cases of the flu (influenza) in people 12 years of age and older who have had flu symptoms for no more than 48 hours.

This includes otherwise healthy people and people at high risk of complications from the flu, such as those who:

- are elderly or obese
- have other diseases, e.g. asthma, diabetes, heart failure, epilepsy
- have reduced immunity due to disease or medication

There is not enough information to recommend the use of Xofluza for children under the age of 12 years or weighing less than 40 kg.

Xofluza reduces the symptoms of the flu so that you feel better faster. It also reduces the amount of flu virus shed when you cough or sneeze.

You may also be less likely to develop complications of flu, such as bronchitis or sinusitis.

Xofluza is an antiviral medicine containing the active ingredient baloxavir marboxil. It belongs to a group of medicines called CAP endonuclease inhibitors. These medicines attack the flu virus and decrease its ability to reproduce.

Xofluza has no effect on the common cold or other respiratory virus infections.

Ask your doctor if you have any questions about why Xofluza has been prescribed for you.

Xofluza is available only with a doctor's prescription.

Before you take Xofluza

When you must not take it

Do not take Xofluza if you have an allergy to:

- any medicine containing baloxavir marboxil

- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should take Xofluza, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.

It is not known whether Xofluza is harmful to an unborn baby when taken by a pregnant woman or if it passes into breast milk. Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell them before you start taking Xofluza.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

In particular, tell your doctor or pharmacist if you are taking:

- laxatives (medicines that relieve constipation and promote regular bowel movements)
- antacids (medicines that relieve heartburn)
- oral supplements containing iron, zinc, selenium, calcium, magnesium

Some laxatives, antacids and oral supplements should not be taken at the same time as Xofluza as they may affect how well it works.

Your doctor and pharmacist can advise you.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take Xofluza

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to take

The recommended dose is 40 mg if you weigh between 40 kg to 80 kg.

The recommended dose is 80 mg if you weigh 80 kg or more.

You may need one or more tablets depending on the strength of the medicine.

Xofluza is not recommended for people who weigh less than 40 kg.

How to take it

Swallow the tablets whole with a full glass of water.

It does not matter whether you take Xofluza with food or not.

Do not take Xofluza with calcium-rich drinks or certain laxatives, antacids or oral supplements containing iron, zinc, selenium, calcium or magnesium. If possible, do not take Xofluza with dairy products, such as milk, cheese or yoghurt.

When to take it

Take Xofluza as soon as possible within the first 48 hours after the start of your flu symptoms.

Xofluza has only been shown to work if given in this timeframe. It is not approved to prevent infection with the flu.

You only need to take Xofluza on one occasion.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Xofluza. Do this even if there are no signs of discomfort or poisoning.

You may need medical attention.

While you are using Xofluza

Things you must do

Tell your doctor if your symptoms do not start to get better or if you feel worse or develop new symptoms after taking Xofluza.

Xofluza is not effective in treating infections other than the flu. Other kinds of infections can appear like flu

or occur along with flu and may need different kinds of treatment.

Things you must not do

Do not take Xofluza to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Things that would be helpful

When you are well again, ask your doctor about having the flu vaccine.

Vaccination every year is the best way to prevent the flu.

Talk to your doctor about your choice of flu vaccine if you have taken Xofluza.

Live flu vaccine available overseas as a nasal spray might not work as well if you have taken Xofluza.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Xofluza.

Xofluza helps most people with the flu but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Tell your doctor immediately, or go to Accident and Emergency at your nearest hospital, if you notice any of the following:

- wheezing, trouble breathing or swallowing
- skin rash, hives or blisters
- dizziness or feeling lightheaded
- feeling sick or vomiting

- swelling of face, throat or mouth
- swelling of hands, feet or genitals
- diarrhoea or dark bloody stool.

These are very serious side effects. If you have them, you may have had a serious reaction to Xofluza. You may need urgent medical attention or hospitalisation.

Allergic reactions are not common but they can occur.

Ask your doctor or pharmacist to answer any questions you may have.

Storage and disposal

Storage

Keep your tablets in the pack until it is time to take them.

If you take the tablets out of the pack they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 30°C.

Do not store Xofluza or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to not to take this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Xofluza film-coated tablets are available in strengths of 20 mg or 40 mg.

Xofluza 20 mg tablets are:

- oblong, white to light yellow, marked with "772" on one side and "20" on the other side.
- supplied in blister packs of 2 film-coated tablets

Xofluza 40 mg tablets are:

- oblong, white to light yellow, marked with "BXM40" on one side
- supplied in blister packs of 2 film-coated tablets

Ingredients

Xofluza contains 20 mg or 40 mg of baloxavir marboxil as the active ingredient. It also contains:

- lactose monohydrate
- croscarmellose sodium
- povidone
- microcrystalline cellulose
- sodium stearyl fumarate
- hypromellose
- purified talc
- titanium dioxide

This medicine does not contain sucrose, gluten, tartrazine or any other azo dyes.

Distributor

Xofluza is distributed in Australia by:

Roche Products Pty Ltd

ABN 70 000 132 865

Level 8, 30-34 Hickson Road

Sydney NSW 2000

Medical enquiries: 1800 233 950

Please check with your pharmacist for the latest Consumer Medicine Information.

Australian Registration Numbers:

- 20 mg: AUST R 317240
- 40 mg: AUST R 317241

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