

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

### 1. Why am I using Xofluza?

Xofluza contains the active ingredient baloxavir marboxil. Xofluza is used to treat flu (influenza) and prevent flu after exposure, in people 12 years of age and older.

For more information, see Section [1. Why am I using Xofluza?](#) in the full CMI.

### 2. What should I know before I use Xofluza?

Do not use if you have ever had an allergic reaction to Xofluza or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use Xofluza?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with Xofluza and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use Xofluza?

- For treatment of flu and prevention of flu, take as a single dose, within 48 hours after flu symptoms or exposure to an infection.
- The recommended dose is 40mg if you weigh between 40kg or more, and less than 80kg. This is one 40mg tablet or two 20mg tablets. The recommended dose is 80mg if you weigh 80kg or more. This is one 80mg tablet or two 40 mg tablets. Swallow the tablets whole with a full glass of water. If possible, do not take Xofluza with dairy products, such as milk, cheese or yoghurt.
- More instructions can be found in Section [4. How do I use Xofluza?](#) in the full CMI.

### 5. What should I know while using Xofluza?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Tell your doctor if your symptoms do not start to get better or if you feel worst or develop new symptoms while taking Xofluza.</li></ul>
<b>Things that would be helpful</b>	<ul style="list-style-type: none"><li>• See comments in the full CMI.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Keep your tablets in a cool dry place where the temperature stays below 30°C.</li></ul>

For more information, see Section [5. What should I know while using Xofluza?](#) in the full CMI.

### 6. Are there any side effects?

Tell your doctor immediately or go to emergency if you notice wheezing, trouble breathing or swallowing, skin rash, hives or blisters, dizziness, light headedness, feeling sick or vomiting, swelling of face, throat or mouth, swelling of hands, feet or dark bloody stools.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

- ▼ 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. You can report side effects to your doctor, or directly at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems).

# Xofluza®

Active ingredient: *baloxavir marboxil*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using Xofluza. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Xofluza.**

Where to find information in this leaflet:

- [1. Why am I using Xofluza?](#)
- [2. What should I know before I use Xofluza?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Xofluza?](#)
- [5. What should I know while using Xofluza?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

### 1. Why am I using Xofluza?

Xofluza is an antiviral medicine containing the active ingredient baloxavir marboxil. It attacks the flu virus and decreases its ability to reproduce.

Xofluza is used for treatment of the flu (influenza) in people over 12 years of age and older who have had flu symptoms for 48 hours or less and also used to prevent flu in patients aged 12 and above who have been in contact with someone who has confirmed flu.

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 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.

### 2. What should I know before I use Xofluza?

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.

#### Warnings

Do not use Xofluza if:

- you are allergic to baloxavir marboxil, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have any other medical conditions
- take any medicines for any other condition

- have allergies to any other medicines, foods, preservatives or dyes.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. [Are there any side effects?](#)

#### Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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.

### 3. What if I am taking other medicines?

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

Some medicines may interfere with Xofluza and affect how it works.

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 it works.

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.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Xofluza.**

### 4. How do I use Xofluza?

#### How much to take / use

- The recommended dose is 40mg if you weigh between 40kg or more, and less than 80kg. This is one 40mg or two 20mg tablets.
- Take Xofluza as a single dose. The recommended dose is 80mg if you weigh 80kg or more. This is one 80mg tablet or two 40mg tablets.
- You can take Xofluza with or without food.
- 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 yogurt.

- For treatment of flu, take Xofluza as a single dose 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 during this timeframe.
- For prevention of flu, take Xofluza as a single dose as soon as possible within 48 hours following exposure to a confirmed infected person.

#### If you use too much Xofluza

If you think that you have used too much Xofluza you may need urgent medical attention.

#### You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## 5. What should I know while using Xofluza?

#### Call your doctor straight away if you:

- do not start to get better
- feel worse or develop new symptoms

Xofluza is not effective in treating infections other than the flu. Other kinds of infections can appear like flu or occur along with the flu and may need different kinds of treatment.

#### 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.

#### Looking after your medicine

- 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 away from moisture or heat, where the temperature stays below 30°C. For example, do not store it in the bathroom or near a sink, or in the car or on window sills.

**Keep it where young children cannot reach it.**

#### When to discard your medicine

#### Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

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.

#### Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> <li>• wheezing, trouble breathing or swallowing</li> <li>• skin rash, hives or blisters</li> <li>• dizziness or feeling lightheadedness</li> <li>• feeling sick or vomiting</li> <li>• swelling of face, throat or mouth</li> <li>• diarrhoea</li> </ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

#### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

Xofluza is supplied in single dose packs.

#### What Xofluza contains

<b>Active ingredient (main ingredient)</b>	baloxavir marboxil
<b>Other ingredients (inactive ingredients)</b>	lactose monohydrate croscarmellose sodium povidone microcrystalline cellulose sodium stearyl fumarate hypromellose purified talc titanium dioxide
<b>Potential allergens</b>	Lactose  This medicine does not contain sucrose, gluten, tartrazine or any other azo dyes.

**Do not take this medicine if you are allergic to any of these ingredients.**

**What Xofluza looks like**

Xofluza film-coated tablets are available in strengths of 20mg, 40mg and 80mg.

Xofluza 20mg tablets (AUST R 317240) are: oblong, white to light yellow, marked with "debossed with a symbol and 772" on one side and "20" on the other side.

Xofluza 20mg tablets are supplied in blister packs of 2 film coated tablets.

Xofluza 40 mg tablets (AUST R 317241) are: oblong, white to light yellow, marked with "BXM40" on one side

Xofluza 40mg tablets are supplied in blister packs of 1 and 2 film-coated tablets.

Xofluza 80mg tablets (AUST R 388092) are: white to light yellow, oblong-shaped film-coated tablets debossed on one side with "BXM80".

Xofluza 80mg is supplied in blister packs of 1 film-coated tablet.

**Who distributes Xofluza**

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.

This leaflet was prepared in December 2023.