

SCHEDULING STATUS

S4

PROPRIETARY NAME AND DOSAGE FORM

Xofluza® 20 mg Film-coated tablets

Xofluza® 40 mg Film-coated tablets

Read all of this leaflet carefully before you start taking Xofluza

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your Pharmacist
- Xofluza has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

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

- Xofluza is used for treatment of influenza (flu) 12 years of age or older, who have experienced flu symptoms for no more than 48 hours and/or you are at high risk of developing influenza complications.
- Xofluza is used to prevent influenza in individuals aged 12 years and older who have been in close contact with someone who is known or suspected to have influenza.

2. What you need to know before you use Xofluza

You should not take Xofluza:

If you are hypersensitive (allergic) to baloxavir marboxil, or to any of the other ingredients of Xofluza.

Warnings and precautions

Take special care with Xofluza

Talk to your healthcare provider before you receive a live flu vaccine after you have taken Xofluza as no interaction studies with flu vaccines have been performed.

Children and adolescents

Do not take Xofluza if you are less than 12 years of age or weigh less than 40kg

Other medicines and Xofluza

Taking other medicines with Xofluza

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines).

Do not take Xofluza with calcium fortified beverages, laxatives, antacids or oral supplements containing iron, zinc, selenium, calcium or magnesium as they could interact with Xofluza and it will not work as well as it should.

Taking Xofluza with food and drink

Xofluza can be taken with or without food.

Do not take Xofluza with dairy products or calcium fortified beverages, as it may not work so well.

See “Taking other medicines with Xofluza” below.

Pregnancy and breastfeeding

Pregnancy

Tell your doctor If you are pregnant or plan to become pregnant. This is because it is not known if Xofluza can harm your inborn baby.

Breastfeeding

Tell your doctor if you are or are breastfeeding or plan to breastfeed your baby. This is because it is not known if Xofluza passes into your breast milk.

If you are pregnant or breastfeeding your baby, please consult your doctor pharmacist or other healthcare professional for advice before being taking Xofluza.

Driving and using machines

It is not known whether taking Xofluza will affect your ability to drive or use machines. However if you experience symptoms such as delirium or fever while you are taking Xofluza, do not drive or use machines until the symptoms disappear.

Important information about some of the ingredients of Xofluza

Xofluza contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Xofluza.

Xofluza contains lactose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

3. How to take Xofluza

Do not share medicines prescribed for you with any other person.

Always take Xofluza exactly as your doctor has instructed you. You should check with your doctor if you are unsure.

Your doctor will prescribe one dose of Xofluza and will tell you how many tablets to take depending on your weight. You can take Xofluza with or without food.

Your doctor will tell you how long your treatment with Xofluza will last. If you have the impression that the effect of Xofluza is too strong or too weak, tell your doctor or pharmacist.

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

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
Up to 80 kg	Single dose of 40 mg taken as - 2 x 20 mg tablets
80 kg or more	Single dose of 80 mg taken as - 2 x 40 mg tablets

If you take more Xofluza than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take Xofluza:

As Xofluza is taken as a single dose, take the dose as soon as you remember. If it is more than 48 hours after you showed flu symptoms, contact your doctor for advice.

If you stop taking Xofluza:

Xofluza is given as a single dose therefore no effects after stopping taking Xofluza are expected.

4. Possible side effects

Xofluza can have side effects

Not all side effects reported for Xofluza are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Xofluza, please consult your doctor, pharmacist or healthcare professional for advice.

The most frequent side effects of Xofluza include:

- Diarrhoea
- Bronchitis
- Common cold symptoms (nasopharyngitis)
- Headache
- Nausea

XOFLUZA is not effective in treating or preventing infections other than influenza.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are

asked to report any suspected adverse reactions to SAHPRA via the “6.04 Adverse Drug Reaction Report Form”, found online under SAHPRA’s publications:

<https://www.sahpra.org.za/Publications/Index/8>

5. How to store Xofluza

Store tablets at or below 30 C,

‘Store blister in outer carton until required for use, in order to protect from moisture and light’.

Store all medicines out of reach of children

Keep blister packs in outer container until required for use.

Do not use this medicine after the expiry date (EXP) stated on the outer carton.

Disposal of unused/expired medicine:

The release of pharmaceuticals in the environment should be minimised. Medicines should not be disposed of via wastewater and disposal through household waste should be avoided. Use established collection systems, if available in your location.

6. Contents of the pack and other information

What Xofluza contains

Each Xofluza 20 mg tablet contains 20 mg baloxavir marboxil.

Each Xofluza 40 mg tablet contains 40 mg baloxavir marboxil.

Excipients - Core: croscarmellose sodium, lactose monohydrate, microcrystalline cellulose, povidone K25 and sodium stearyl fumarate.

Excipients – Film coat: hypromellose, talc and titanium dioxide (E171). Contains sugar (77, 9 mg lactose monohydrate of the 20 mg and 155, 8 mg lactose monohydrate of the 40 mg)

What Xofluza looks like and contents of the pack

Xofluza 20 mg: White to light yellow, oblong shaped film-coated tablets debossed with “772” on the one side and “20” on the other side.

Xofluza 40 mg: White to light yellow, oblong shaped film-coated tablets debossed with “BXM40” on the one side.

20 mg tablets: Aluminium blister packs containing 2 or 4 tablets.

40 mg tablets: Aluminium blister packs containing 1 or 2 tablets.

Not all packs may be marketed.

7. Holder of Certificate of Registration

Roche Products (Pty) Ltd

24 Fricker Road

Illovo

Gauteng

South Africa

Roche Ethical Assistance Line (REAL) toll-free: 0800 21 21 25

8. Registration number(s)

Xofluza 20 mg: 55/20.2.8/0333

Xofluza 40 mg: 55/20.2.8/0334

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