

XOFLUZA® FILM-COATED TABLET

Baloxavir marboxil (40mg)

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What XOFLUZA is used for

XOFLUZA is a prescription medicine used to:

- treat the flu (influenza) in people 12 years of age and older who have had flu symptoms for no more than 48 hours.
- prevent the flu in people 12 years of age and older following contact with a person who has the flu.

It is not known if XOFLUZA is safe and effective in children less than 12 years of age.

XOFLUZA does not treat or prevent illness that is caused by infections other than the influenza virus.

XOFLUZA does not prevent bacterial infections that may happen with the flu.

How XOFLUZA works

XOFLUZA blocks part of the influenza virus that is instrumental in making proteins that are required to produce extra copies of the virus within a host cell. XOFLUZA interferes with the ability of the flu virus to multiply.

XOFLUZA is taken as a one-time dose.

Before you use XOFLUZA

- When you must not use it

Do not take XOFLUZA if:

1. **you are allergic to baloxavir marboxil or any of the ingredients in XOFLUZA. See the end of this leaflet for a**

complete list of ingredients in XOFLUZA.

2. the package is torn or shows signs of tampering
3. the expiry date (EXP) printed on the pack has passed. If you take this medicine after the expiry date has passed, it may not work as well.
4. if you are not sure if you should be taking XOFLUZA, talk to your doctor.

- Before you start to use it

Tell your doctor if:

1. you are pregnant or plan to become pregnant. It is not known whether XOFLUZA can harm your unborn baby.
2. you are breast-feeding or plan to breast-feed. It is not known if XOFLUZA passes into your breast milk.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Talk to your healthcare provider before you receive a live flu vaccine after taking XOFLUZA.

Do not take XOFLUZA with dairy products, calcium-fortified beverages, laxatives, antacids or oral supplements containing iron, zinc, selenium, calcium or magnesium.

Some medicines may interact with XOFLUZA and may affect how well it works. Your doctors and pharmacist may have more information on medicines to be careful with or avoid while taking XOFLUZA.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

Ask your doctor or pharmacist if you are not sure about any medicine.

How to use XOFLUZA

How much to use

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

Take XOFLUZA exactly as your doctor or pharmacist tells you to. Your healthcare provider will prescribe a single dose of XOFLUZA (which may be more than one tablet). Take XOFLUZA with or without food.

- When to use it

Treatment with XOFLUZA should be started as soon as possible, but no later than 48 hours after the first symptoms of influenza.

- How long to use it

XOFLUZA is taken as a single dose, initiated within 48 hours of symptoms onset.

- If you forget to use it

Take it as soon as you remember but no later than 48 hours after the first symptoms of influenza.

- If you use too much (overdose)

If you take too much XOFLUZA, go to the nearest emergency room right away.

While you are using it

- Things you must do

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed. Otherwise, your doctor may think that it was ineffective and change your treatment unnecessarily.

Tell your doctor if you feel your symptoms have worsened after taking XOFLUZA.

- Things you must not do

Do not stop taking XOFLUZA or change the dose without first checking with your doctor.

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

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Do not take any other medicines whether they require a prescription or not without first telling your doctor or consulting a pharmacist.

- **Things to be careful of**

Be careful while driving or operating machinery until you know how XOFLUZA affects you.

XOFLUZA is not expected to affect your ability to drive a car or operate machinery.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well after taking XOFLUZA.

XOFLUZA may cause serious side effects, including:

- Allergic reactions. Get emergency medical help right away if you develop any of these signs or symptoms of an allergic reaction:
 - Trouble breathing
 - Skin rash, hives or blisters
 - Swelling of your face, throat or mouth
 - Dizziness or lightheadedness

The most common side effects of XOFLUZA for treatment of the flu in adults and adolescents include:

- Diarrhea
- Bronchitis
- Nausea
- Sinusitis
- Headache

XOFLUZA is not effective in treating or preventing infections other than influenza. Other kinds of infections can appear like flu or occur along with flu and may need different kinds of treatment. Tell your healthcare provider if you feel worse or develop new symptoms during or after treatment with XOFLUZA or if your flu symptoms do not start to get better.

These are not all the possible side effects of XOFLUZA.
Call your doctor for medical advice about side effects.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers-> Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of XOFLUZA

- **Storage**

Keep XOFLUZA in its original package in order to protect from moisture, at temperature below 30°C.

- **Disposal**

If your doctor tells you to stop taking XOFLUZA, or the capsules have passed its expiry date, ask your pharmacist what to do with the rest of the tablets that is left over.

Product Description

- **What it looks like**

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

- **Ingredients**

- **Active ingredients:**
baloxavir marboxil

- **Inactive ingredients:**
croscarmellose sodium,
hypromellose,
lactose monohydrate,
microcrystalline cellulose,
povidone,
sodium stearyl fumarate,
talc, titanium dioxide.

- **MAL number**

MAL20046078ACRZ

Manufacturer

Shionogi Pharma Co., Ltd, Settsu Plant, Osaka, Japan.

Product Registration Holder

Roche (M) Sdn. Bhd.
Level 21, The Pinnacle,
Persiaran Lagoon, Bandar Sunway,
47500 Subang Jaya, Selangor,
Malaysia.

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