

PATIENT INFORMATION

XOFLUZA® (zoh-FLEW-zuh)
(baloxavir marboxil)
Tablets

XOFLUZA® (zoh-FLEW-zuh)
(baloxavir marboxil)
for oral suspension

What is XOFLUZA?

XOFLUZA is a prescription medicine used to:

- treat the flu (influenza) in people 5 years of age and older who have flu symptoms for no more than 48 hours and who are:
 - otherwise healthy **or**
 - at high risk of developing problems from the flu.
- prevent the flu in people 5 years of age and older following contact with a person who has the flu (post-exposure prophylaxis).

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.

It is not known if XOFLUZA is safe and effective for the treatment and prevention of the flu in children less than 5 years of age. XOFLUZA is not for use in children less than 5 years of age.

Do not take XOFLUZA if 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.

Before you take XOFLUZA, tell your healthcare provider about all of your medical conditions, including if you:

- are pregnant or plan to become pregnant. It is not known if XOFLUZA can harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if XOFLUZA passes into your breast milk.

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

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

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

How should I take XOFLUZA?

- Take XOFLUZA exactly as directed by your healthcare provider or pharmacist.
- Your healthcare provider will either prescribe:
 - XOFLUZA tablet as a single, one-time dose, **or**
 - XOFLUZA oral suspension provided with an oral syringe to be given as a single, one-time dose.
- XOFLUZA may be given through a feeding tube. Follow your healthcare provider's instructions for giving XOFLUZA through a feeding tube.
- Take XOFLUZA with or without food.
- Do not take XOFLUZA with dairy products, calcium-fortified beverages, laxatives, antacids or oral supplements containing iron, zinc, selenium, calcium or magnesium.
- If you take too much XOFLUZA, go to the nearest emergency room right away.

If you are taking XOFLUZA for oral suspension:

- The pharmacist will mix XOFLUZA for oral suspension before it is given to you. If XOFLUZA is not given to you as a liquid or an oral syringe was not provided, contact your pharmacist.
- **Take XOFLUZA before the expiration time and date** written by the pharmacist on the bottle label. **Do not** take XOFLUZA if the expiration time and date have passed. Throw away (discard) the bottle and contact your healthcare provider.
- Your healthcare provider will prescribe XOFLUZA based on your or your child's weight. The total prescribed dose of XOFLUZA for oral suspension may require less than one bottle, one bottle, or two bottles of XOFLUZA.
- The total prescribed dose of XOFLUZA for oral suspension may require more than one withdrawal from the bottle with the oral syringe.
- **Contact your healthcare provider or pharmacist if you have any questions on how to take or give the prescribed dose of XOFLUZA for oral suspension.**

Taking or giving a dose of XOFLUZA for oral suspension:

Step 1. Swirl the XOFLUZA for oral suspension bottle well before each use. **Do not shake.**

Step 2. Open the bottle by pushing downward on the child resistant bottle cap and twisting it in the direction of the arrow.

Step 3. Measure the oral suspension with the oral syringe provided by the pharmacist to be sure you give the prescribed dose. If the prescribed dose requires more than one withdrawal from the bottle, repeat **Steps 3 and 4** for each withdrawal until you take or give the prescribed dose.

Step 4. Take or give the full contents of the oral syringe.

Step 5. Close the bottle. Throw away any remaining oral suspension and the oral syringe.

What are the possible side effects of 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
 - swelling of your face, throat or mouth
 - skin rash, hives or blisters
 - dizziness or lightheadedness

The most common side effects of XOFLUZA for treatment of the flu in adults and adolescents (12 years of age and older) include:

- diarrhea
- sinusitis
- bronchitis
- headache
- nausea

The most common side effects of XOFLUZA for treatment of the flu in children (5 years of age to less than 12 years of age) include:

- vomiting
- diarrhea

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 side effects to FDA at 1-800-FDA-1088.

How should I store XOFLUZA?

XOFLUZA tablets:

- Store XOFLUZA tablet at room temperature between 68°F to 77°F (20°C to 25°C).
- Store XOFLUZA tablet in the blister package that it comes in.

XOFLUZA for oral suspension:

- Store XOFLUZA for oral suspension at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep XOFLUZA for oral suspension in the original container.
- Use XOFLUZA for oral suspension by the expiration time and date written on bottle label. Throw away any XOFLUZA for oral suspension not used by the time and date on the bottle label, or if it has been stored at a temperature above 77°F (25°C).

Keep XOFLUZA and all medicines out of the reach of children.

General information about the safe and effective use of XOFLUZA.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use XOFLUZA for a condition for which it was not prescribed. Do not give XOFLUZA to other people, even if they have the same symptoms that you have. It may harm them. You can ask for information about XOFLUZA that is written for health professionals.

What are the ingredients in XOFLUZA?

Active ingredient: baloxavir marboxil

XOFLUZA tablets inactive ingredients: croscarmellose sodium, hypromellose, lactose monohydrate, microcrystalline cellulose, povidone, sodium stearyl fumarate, talc, and titanium dioxide.

XOFLUZA for oral suspension inactive ingredients: colloidal silicon dioxide, hypromellose, maltitol, mannitol, povidone K25, sodium chloride, strawberry flavor, sucralose and talc.

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For more information, go to www.XOFLUZA.com or call 1-855-XOFLUZA (1-855-963-5892).