

PATIENT INFORMATION
XOFLUZA™ (zoh-FLEW-zuh)
(baloxavir marboxil)
tablets

What is XOFLUZA?

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.

It is not known if XOFLUZA is safe and effective in children less than 12 years of age or weighing less than 88 pounds (40 kg).

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.

Tell your healthcare provider about all the medicines you take, 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.

How should I take XOFLUZA?

- Take XOFLUZA exactly as your healthcare provider 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.
- 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.

What are the possible side effects of XOFLUZA?

The most common side effects of XOFLUZA in adults and adolescents include:

- diarrhea
- headache
- bronchitis
- nausea
- common cold symptoms (nasopharyngitis)

XOFLUZA is not effective in treating 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?

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

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

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

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

This Patient Information has been approved by the U.S. Food and Drug Administration.

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