# XOFLUZA™ (baloxavir marboxil) IN INFLUENZA (FLU)

Media Inquiries:
**(650) 467-6800**

xofluza™
(baloxavir marboxil) tablets 20mg 40mg

## About XOFLUZA

XOFLUZA™ is approved by the U.S. Food and Drug Administration (FDA) as a single-dose, oral treatment for acute, uncomplicated influenza, or flu, in people 12 years of age and older who have been symptomatic for no more than 48 hours and who are otherwise healthy or at high risk of developing flu-related complications. A single dose of XOFLUZA should be taken orally within 48 hours of symptom onset.[1]

### FIRST AND ONLY
single-dose, oral antiviral medicine to treat the flu[2,3]

### FIRST AND ONLY
antiviral medicine indicated specifically for patients at high risk of developing serious complications from the flu[1,3,6,7,8]

### FIRST
FDA-approved medicine with a novel proposed mechanism of action to treat the flu in nearly 20 years[2,3,6,7,8]

### FIRST
antiviral medicine designed to inhibit the cap-dependent endonuclease protein within the flu virus, preventing the formation of new viral particles by blocking viral replication early in the flu lifecycle[4,5]

### FIRST-IN-CLASS
medicine with demonstrated antiviral activity against a wide range of influenza viruses, including oseltamivir-resistant strains and avian strains (H7N9, H5N1) in non-clinical studies[1,2,3]

## About Influenza (Flu)

Influenza is a highly contagious illness caused by flu viruses that infect the nose, throat and sometimes the lungs. While flu viruses can be detected year-round in the U.S., they are most common during the fall and winter, with activity increasing in October and peaking between December and February.[9]

Some people are at higher risk for serious flu complications, including those who have conditions such as asthma, chronic lung disease, diabetes, heart disease, morbid obesity or adults 65 years of age or older. For these people, the flu can lead to hospitalization or even death.[10]

## Indication

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 and who are otherwise healthy or at high risk of developing flu-related complications.

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

XOFLUZA is contraindicated in patients with a history of hypersensitivity to baloxavir marboxil or any of its ingredients.

Genentech
*A Member of the Roche Group*

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# Flu Prevalence in the U.S.

Each year, up to 49 million people will be affected by the flu.[11,12] Since 2010, the Centers for Disease Control and Prevention (CDC) estimates that the flu has resulted annually in:[11]

**9.3 TO 49**
MILLION ILLNESSES

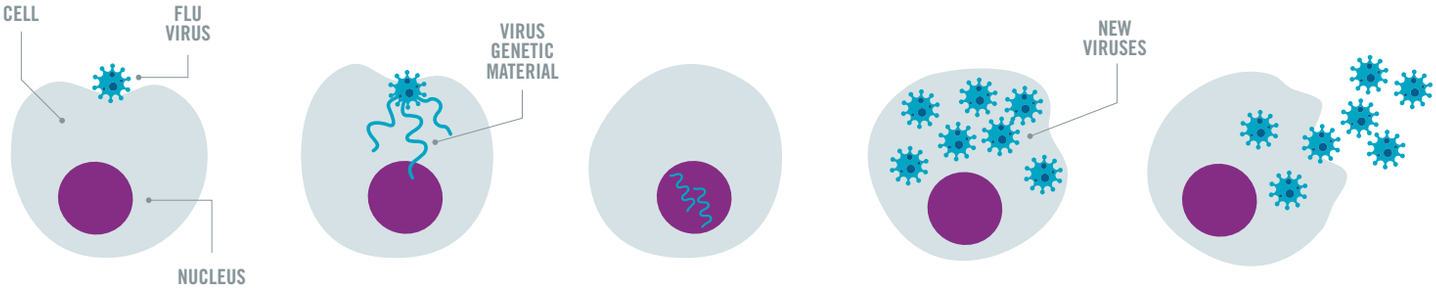
**140,000 TO 960,000**
HOSPITALIZATIONS

**12,000 TO 79,000**
DEATHS

# How XOFLUZA May Work (Proposed Mechanism of Action)

XOFLUZA is a first-in-class, single-dose, oral antiviral medicine that blocks an enzyme within the flu virus, stopping viral replication early in the influenza lifecycle.[1,13,14]

## THE FIVE STAGES OF THE FLU VIRUS LIFECYCLE



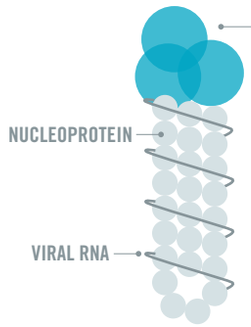

**1** Flu virus enters cell

**2** Virus genetic material and enzymes enter cell nucleus

**3** Virus replicates itself. **This is where XOFLUZA works**

**4** New viruses are assembled

**5** New viruses are released from the cell to infect other cells




### ENDONUCLEASE ENZYME

During this process, the endonuclease enzyme inside the flu virus "steals" part of the cell's genetic material to make more copies of itself.

XOFLUZA works by blocking this enzyme, stopping viral replication early in the influenza lifecycle.

# Important Safety Information

Do not take XOFLUZA if you are allergic to baloxavir marboxil or any of the ingredients in XOFLUZA.

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# Dosage

Based on results from clinical trials, **ONLY ONE DOSE** of XOFLUZA is needed to demonstrate benefit.[1,2]

| BODY WEIGHT | RECOMMENDED ORAL DOSE |
|---|---|
| 40 kg < 80 kg (88 lbs) < (176 lbs) | Two 20 mg tablets taken at the same time for a total single dose of 40 mg |
| ≥ 80 kg (176 lbs) | Two 40 mg tablets taken at the same time for a total dose of 80 mg |

# Efficacy

In October 2018, the FDA approved XOFLUZA for the treatment of acute, uncomplicated flu in people 12 years of age and older who have been symptomatic for no more than 48 hours. XOFLUZA was approved based on results from the Phase III CAPSTONE-1 study of a single dose of XOFLUZA compared with placebo or oseltamivir 75 mg, twice daily for five days, in otherwise healthy people with the flu, as well as results from a placebo-controlled Phase II study in otherwise healthy people with the flu.[1,2]

In October 2019, the FDA expanded the XOFLUZA label to include people who have been symptomatic for no more than 48 hours and who are at high risk of developing flu-related complications. This expanded indication was approved based on results from the Phase III CAPSTONE-2 study of a single dose of 40 mg or 80 mg of XOFLUZA compared to oseltamivir (75 mg twice daily for five days), or placebo in people 12 years of age or older who met CDC criteria for being at high risk of complications from the flu.[1,15]

## PRIMARY ENDPOINT FROM CAPSTONE-1 STUDY


XOFLUZA significantly reduced the duration of flu symptoms compared to placebo (median time 54 hours versus 80 hours; p<0.001).[1]

Similar efficacy results were seen between XOFLUZA and oseltamivir in relation to duration of symptoms (median time 54 hours versus 54 hours).

## PRIMARY ENDPOINT FROM CAPSTONE-2 STUDY


XOFLUZA significantly reduced the time to improvement of flu symptoms versus placebo in people at high risk of complications from flu (median time 73 hours versus 102 hours; p<0.001).[1]

Similar efficacy results were seen between XOFLUZA and oseltamivir in relation to duration of symptoms (median time 73 hours versus 81 hours).[1]

In subjects infected with type B virus, the median time to improvement of flu symptoms was shorter in the XOFLUZA group compared to the placebo group (75 hours versus 101 hours respectively).[1]

# Safety

Adverse events reported in at least 1% of adult and adolescent subjects treated with XOFLUZA included diarrhea (3%), bronchitis (3%), nausea (2%), sinusitis (2%) and headache (1%). XOFLUZA was well-tolerated and no new safety signals were identified.

# Important Safety Information (continued)

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.

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# Important Safety Information (continued)

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

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.

XOFLUZA may cause serious side effects, including allergic reactions.

Get emergency medical help right away if you develop any of these signs and 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 are diarrhea, bronchitis, sinusitis, headache, and nausea.

XOFLUZA is not effective in treating infections other than influenza. Other kinds of infections can have symptoms like those of the 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.

Please see the XOFLUZA full Prescribing Information for complete safety information.

**You are encouraged to report side effects to Genentech by calling 1-888-835-2555 or to the FDA by visiting http://www.fda.gov/medwatch or calling 1-800-FDA-1088.**


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