

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

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**xofluza**™  
(baloxavir marboxil) tablets <sup>20mg</sup>/<sub>40mg</sub>

## About XOFLUZA

XOFLUZA™ is approved by the U.S. Food and Drug Administration (FDA) as a single-dose, oral treatment for acute, uncomplicated influenza in people 12 years of age and older.<sup>1</sup> A single dose of XOFLUZA should be taken orally within 48 hours of symptom onset.<sup>1</sup>

### FIRST AND ONLY

single-dose, oral antiviral medicine to treat the flu<sup>2,3</sup>

### 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<sup>1,2,3</sup>



### FIRST

FDA-approved medicine with a novel proposed mechanism of action to treat the flu in nearly 20 years<sup>2,3,6,7,8</sup>

### FIRST

antiviral medicine designed to stop viral replication by inhibiting the endonuclease enzyme within the flu virus<sup>4,5</sup>

## About Influenza (Flu)

Influenza, or “flu,” is a highly contagious respiratory 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.<sup>9</sup>

## 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.

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).

## Limitations of Use

Influenza viruses change over time, and factors such as the virus type or subtype, emergence of resistance or changes in viral virulence could diminish the clinical benefit of antiviral drugs. Consider available information on drug susceptibility patterns for circulating influenza virus strains when deciding whether to use XOFLUZA.

# Flu Prevalence in the U.S.

Each year, up to 49 million people will be affected by the flu.<sup>10,11</sup> Since 2010, the Centers for Disease Control and Prevention (CDC) estimates that the flu has resulted annually in:<sup>10</sup>

9.3 TO  
49

MILLION ILLNESSES



140,000 TO  
960,000

HOSPITALIZATIONS



12,000 TO  
79,000

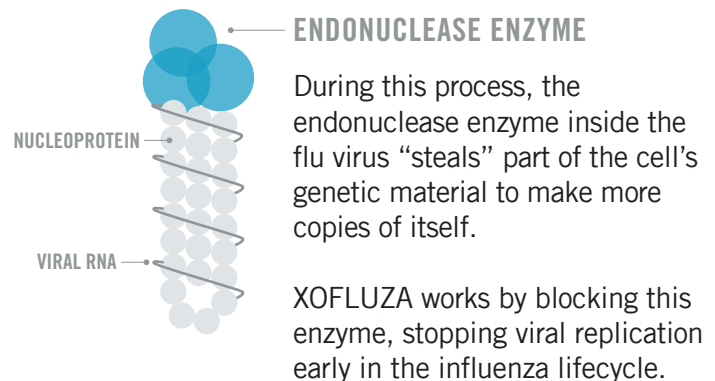
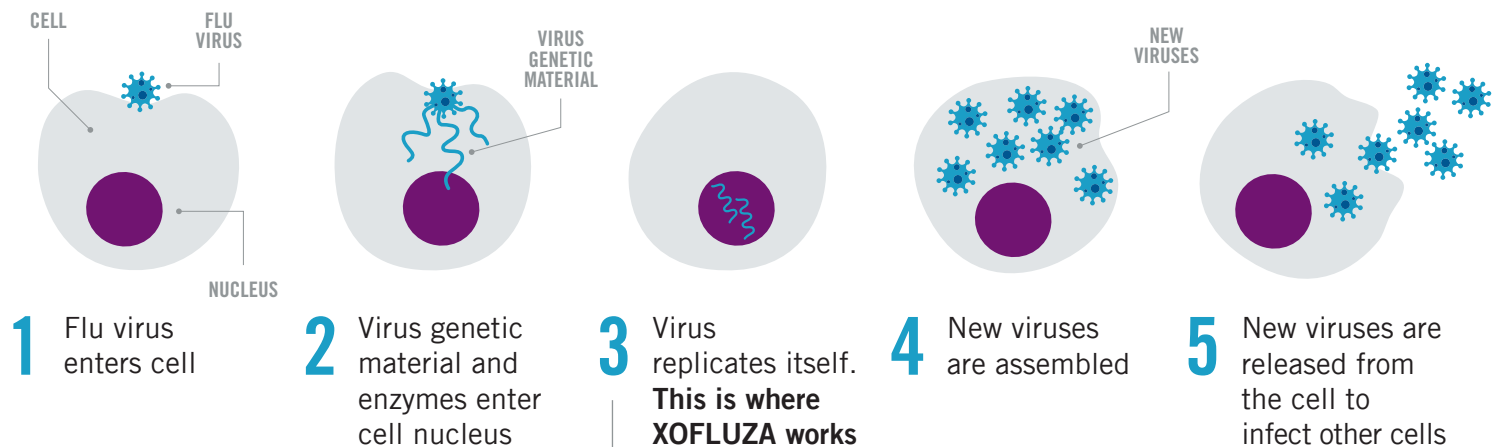
DEATHS



## 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.<sup>1,12,13</sup>

### THE FIVE STAGES OF THE FLU VIRUS 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.<sup>1,2</sup>

### BODY WEIGHT

40 kg to < 80 kg

≥ 80 kg

### RECOMMENDED ORAL DOSE

Single dose of 40 mg

Single dose of 80 mg

## XOFLUZA Efficacy

The FDA approval of XOFLUZA is 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.<sup>1,2</sup>

### PRIMARY ENDPOINT FROM CAPSTONE-1 STUDY



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

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

## Adverse Events

The most common adverse events reported in patients administered XOFLUZA were diarrhea (3%), bronchitis (2%), nasopharyngitis (1%), headache (1%) and nausea (1%), and all of these adverse events occurred at a lower or similar frequency than placebo.<sup>1</sup>

## 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.

**The most common side effects are** diarrhea, bronchitis, nausea, common cold symptoms (nasopharyngitis) and headache.

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 the 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.**

1. XOFLUZA™ Prescribing Information (Draft March 2018).
2. Hayden et al. Baloxavir Marboxil for Uncomplicated Influenza in Adults and Adolescents. *N Engl J Med*. 2018;379:913-23.
3. Centers for Disease Control and Prevention (2018, February 23). Influenza Antiviral Medications: Summary for Clinicians. Retrieved July 11, 2018, from: <https://www.cdc.gov/flu/professionals/antivirals/summary-clinicians.htm>.
4. Shi et al. Viral RNA polymerase: a promising antiviral target for influenza A virus. *Curr Med Chem*. 2013;20(31):3923-34.
5. Kawaguchi et al. Effects of S-033188, a cap-dependent endonuclease inhibitor, on influenza symptoms and viral titer: Results from a phase 2, randomized, double-blind, placebo-controlled study in otherwise healthy adults with seasonal influenza. Poster presented at ESWI 2017.
6. TAMIFLU Prescribing Information (1999).
7. RELENZA Prescribing Information (1999).
8. RAPIVAP Prescribing Information (2014).
9. Centers for Disease Control and Prevention (2016, July 26). The Flu Season. Retrieved June 20, 2018, from: <https://www.cdc.gov/flu/about/season/flu-season.htm>.
10. Centers for Disease Control and Prevention. Disease Burden of Influenza. Retrieved November 21, 2018, from: <https://www.cdc.gov/flu/about/burden/index.html>
11. Centers for Disease Control and Prevention. (2017, October 3). Key Facts About Influenza (Flu). Retrieved June 20, 2018, from: <https://www.cdc.gov/flu/keyfacts.htm>.
12. Yuan S, et al. A novel small-molecule inhibitor of influenza A virus acts by suppressing PA endonuclease activity of the viral polymerase. *Scientific Reports*. 2016; 6:22880.
13. Te Velthuis AJ, Fodor E. Influenza virus RNA polymerase: insights into the mechanisms of viral RNA synthesis. *Nature Reviews Microbiology*. 2016; 14(8):479-493.