Xofluza (baloxavir marboxil)

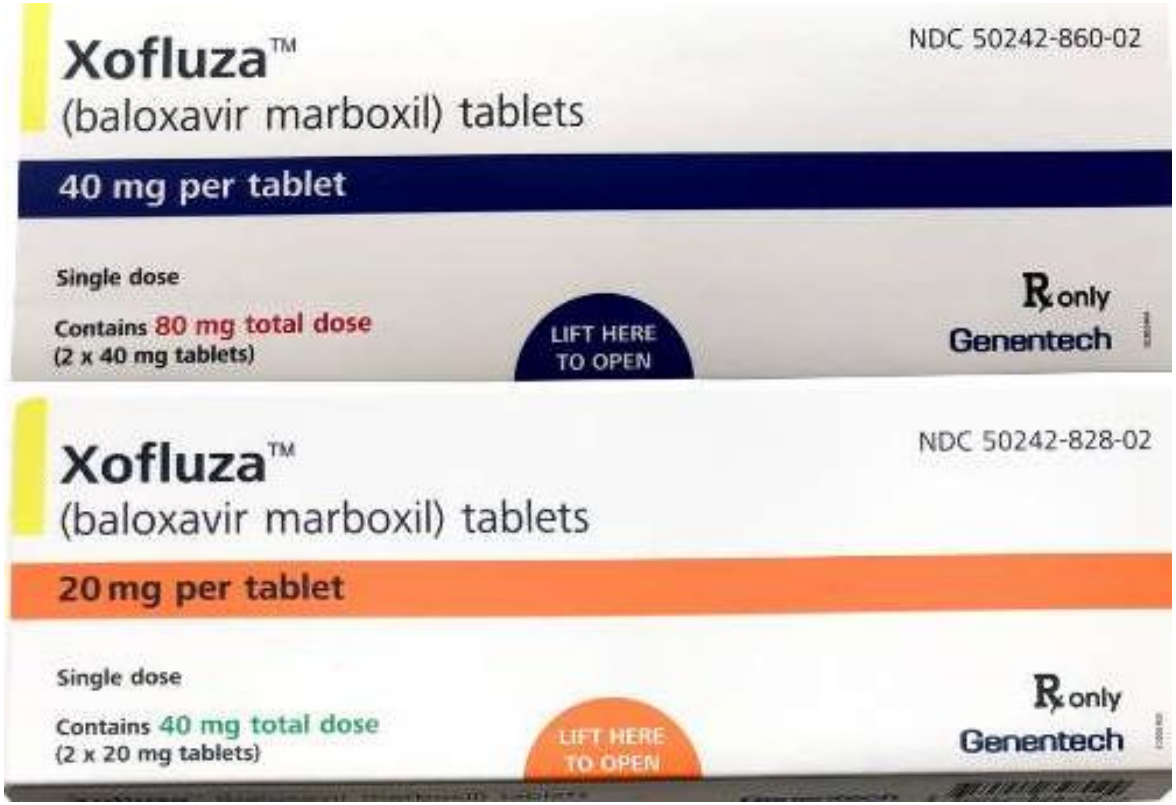
NEW PRODUCT SLIDESHOW

MPR

Introduction

- **Brand name:** Xofluza
- **Generic name:** Baloxavir marboxil
- **Pharmacological class:** Polymerase acidic (PA) endonuclease inhibitor
- **Strength and Formulation:** 20mg, 40mg; tabs
- **Manufacturer:** Genentech
- **How supplied:** Tabs—2
- **Legal Classification:** Rx

Xofluza


Xofluza™
(baloxavir marboxil) tablets
NDC 50242-860-02
40 mg per tablet
Single dose
Contains 80 mg total dose
(2 x 40 mg tablets)
LIFT HERE TO OPEN
℞ only
Genentech
Xofluza™
(baloxavir marboxil) tablets
NDC 50242-828-02
20 mg per tablet
Single dose
Contains 40 mg total dose
(2 x 20 mg tablets)
LIFT HERE TO OPEN
℞ only
Genentech

Indication

- Treatment of **acute uncomplicated influenza** in patients who have been symptomatic for no more than 48hrs

Limitations of Use

- Consider available information on drug susceptibility patterns for circulating influenza strains when deciding whether to use

Dosage & Administration

- Start within 48 hours of symptom onset
- ≥12 years:
  - **(40–<80kg):** 40mg as a single dose
  - **(≥80kg):** 80mg as a single dose

Considerations for Special Populations

- **Pregnancy:** No adequate data on developmental risks in pregnant women
- **Nursing mothers:** Consider mother's clinical need and potential adverse effects on breastfed infant
- **Pediatric:** <12yrs (or <40kg): not established
- **Elderly:** Insufficient number of patients studied

Warnings/Precautions

- Potential secondary **bacterial infections**; treat appropriately

Interactions

- **Avoid** co-administration with dairy products, calcium-fortified beverages, polyvalent cation-containing laxatives, antacids, or oral supplements (eg, calcium, iron, magnesium, selenium, or zinc)
- **May reduce efficacy** of live attenuated influenza vaccines

Adverse Reactions

- Diarrhea
- Bronchitis
- Nasopharyngitis
- Headache
- Nausea

Mechanism of Action

- Baloxavir marboxil is a prodrug that is converted to the active metabolite baloxavir via hydrolysis
- Baloxavir inhibits the endonuclease activity of the polymerase acidic protein, an influenza virus-specific enzyme in the viral RNA polymerase complex required for viral gene transcription, resulting in the inhibition of influenza virus replication

Clinical Studies

- The efficacy and safety of Xofluza were evaluated in 2 randomized, controlled, double-blind clinical trials **(Trials 1 and 2)** in otherwise healthy patients with acute uncomplicated influenza

Clinical Studies

- **Trial 1** was a placebo-controlled phase 2 dose-finding study comparing a single oral dose of Xofluza with placebo in 400 adults aged 20−64 years in Japan
- The predominant strain in patients who had influenza virus and received Xofluza was influenza A/H1N1 (63%), followed by influenza B (25%), and influenza A/H3N2 (12%)

Clinical Studies

- **Trial 2** was a phase 3 active- and placebo-controlled study in 1,436 adults and adolescents aged ≥12 years in the US and Japan
- Adults aged 20−64 years received Xofluza or placebo as a single oral dose on Day 1 or oseltamivir twice daily for 5 days

Clinical Studies

- Patients in the Xofluza and placebo arms received a placebo for the duration of oseltamivir dosing after their Xofluza or placebo dose
- Eligible patients had:
  - Axillary temperature of at least 38˚C
  - At least 1 moderate or severe respiratory symptom (cough, nasal congestion, or sore throat)
  - At least 1 moderate or severe systemic symptom (headache, feverishness or chills, muscle or joint pain, or fatigue)

Clinical Studies

- The **primary efficacy population** was defined as those with a positive rapid influenza diagnostic test (Trial 1) or positive influenza RT-PCR (Trial 2) at study entry

Clinical Studies

- The **primary endpoint** for both trials was time to alleviation of symptoms, defined as the time when all 7 symptoms (cough, sore throat, nasal congestion, headache, feverishness, myalgia, and fatigue) had been assessed by the patient as **“none”** or **“mild”** for a duration of at least 21.5 hours

Clinical Studies

- Treatment with Xofluza at the recommended dose in Trials 1 and 2 resulted in a **statistically significant shorter time** to symptom alleviation compared to placebo in the primary efficacy population

Clinical Studies

- In **Trial 1**, the median time to symptom alleviation for Xofluza 40mg was 50 hours vs 78 hours in the placebo arm (*P* =0.014)
- In **Trial 2**, the median time to symptom alleviation for Xofluza 40mg or 80mg in adults was 54 hours vs 80 hours for placebo (*P* <0.001)
- In adolescents, the median time was 54 hours for Xofluza vs 93 hours in the placebo arm

Clinical Studies

- No difference in the median time to symptom alleviation was found between Xofluza and oseltamivir-treated patients (both at 54 hours) in Trial 2

- For more clinical trial data, see full labeling

New Product Monograph

- For more information view the product monograph available at:

  https://www.empr.com/xofluza/drug/34893/