Oseltamivir Oral Suspension and Capsules – Drug Unavailability

Issue

The U.S. is experiencing an interruption in the dependable availability of **oseltamivir oral suspension and capsules** – a neuraminidase inhibitor antiviral agent used for **prophylaxis** and **treatment** of **influenza**. This supply disruption may affect all available NDCs of oseltamivir, with variable anticipated dates of market availability. The FDA does not yet note a widespread drug shortage; rather, acutely high demand is overwhelming supply from primary manufacturers.

Products Affected

All NDCs of oseltamivir are being affected.

Reason for Shortage

Manufacturers have not provided explicit reasons for shortage. Industry wide, increased market demand during this period of seasonal flu activity has sporadically overwhelmed supply.

Estimated Resupply Date(s)

- Alvogen has oseltamivir 6 mg/mL powder for oral suspension in 60 mL bottles on allocation. The 30 mg and 45 mg capsules are on back order with a release date in late-November 2022 for the 30 mg capsules and mid-November 2022 for the 45 mg capsules.
- Amneal has oseltamivir 30 mg and 45 mg capsules on back order and cannot estimate a release date.
- Avkare has oseltamivir 6 mg/mL powder for suspension in 60 mL bottles on back order and estimates a release date in early-November 2022.
- Camber has oseltamivir 30 mg, 45 mg, and 75 mg capsules on allocation.
- Macleod's has oseltamivir 30 mg capsules on back order and estimates a release date in early-December 2022. The 75 mg capsules are also on back order and estimates a release date in late-November 2022.
- Teva has oseltamivir 6 mg/mL powder for suspension in 60 mL bottles on back order and estimates a release date of late-November to early-December 2022.
- Zydus has oseltamivir 6 mg/mL powder for suspension in 60 mL bottles on allocation.

Action Steps

PharMerica Pharmacies

- Monitor for availability of product and complete orders when possible.
- Proactively notify serviced facilities of ongoing local supply status, as influenza antivirals are time-sensitive for efficacy (oseltamivir [and alternative – baloxavir] should be initiated within 48 hours of symptom onset).
- Notify serviced facilities when prescription orders are unable to be fulfilled due to drug unavailability.
- Order alternative influenza antivirals as needed for serviced facilities demand.

Facilities

- Solicit recommendations from prescribers and obtain orders for alternative therapy to switch patients to for influenza treatment or prophylaxis when notified of oseltamivir unavailability by PharMerica pharmacies.
- Continue to educate and provide residents with influenza vaccination as a primary preventative health step.
- Refer to CDC Guidance on Influenza Outbreak Management in LTPAC Facilities

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Alternative Therapy

BALOXAVIR (XOFLUZA®)

Indication

1. **Treatment** of acute uncomplicated influenza in patients who have been symptomatic for ≤ 48 hours and who are:
    a. Otherwise healthy adults and pediatric patients ≥ 5 y.o., OR
    b. Adults and pediatric patients ≥12 y.o. who are at high risk of developing influenza-related complications.
2. **Post-exposure prophylaxis** of influenza in patients ≥5 y.o. following contact with an individual who has influenza.

Dosage and Administration

- Take as a single dose as soon as possible and within 48 hours of influenza symptom onset for treatment of acute uncomplicated influenza or following contact with an individual who has influenza.

****Note: Dosing for both treatment and prophylaxis are the SAME weight-based recommendations****

Patient Body Weight (kg)	Recommended Single Oral Dose in Patients 5 Years of Age and Older (Tablets)
20 kg to less than 80 kg	One 40 mg tablet (blister card contains one 40 mg tablet)
At least 80 kg	One 80 mg tablet (blister card contains one 80 mg tablet)

Dietary Considerations

Avoid co-administration with dairy products, calcium-fortified beverages, polyvalent cation-containing laxatives, antacids, or oral supplements (e.g., calcium, iron, magnesium, selenium, or zinc).

Available Dosage Form and Strengths

Oral Tablets: 40 mg and 80 mg

Contraindications

Contraindicated in patients with a history of hypersensitivity to baloxavir marboxil or any of its ingredients.

Facility outbreaks

In the case of an outbreak, LTC residents potentially exposed to influenza (those in affected wards or units) should receive antiviral chemoprophylaxis as soon as possible; however, guidelines have not been updated to include baloxavir as no data is available on use of baloxavir to control LTCF influenza outbreaks (*only* oseltamivir is recommended for this indication at this time).

Geriatric/Nursing Considerations

The safety and effectiveness of XOFLUZA in subjects 65 years of age and older has been established and is supported by one randomized, double-blind, controlled trial [see Clinical Studies (14.2)]. In Trial T0832, of 730 XOFLUZA-treated subjects at high risk of influenza-related complications, 209 (29%) subjects were 65 years of age and older. The median time to improvement of influenza symptoms in subjects 65 years of age and older was 70 hours in subjects who received XOFLUZA (N=112) and 88 hours in those who received placebo (N=102). The safety profile observed for this population was similar to that reported in the overall trial population except for nausea, which was reported in 6% of elderly subjects compared to 1% of subjects from 18 to 64 years of age.