Generic Name:
Baloxavir marboxil
Trade Name:
Xofluza
Company:
Shionogi & Co., Ltd.
Notes:

FDA has approved a new antiviral drug, baloxavir marboxil, to treat acute uncomplicated influenza (flu) in patients aged 12 years and older who have been symptomatic for no more than 48 hours.

According to FDA Commissioner Scott Gottlieb, MD, the polymerase acidic (PA) endonuclease inhibitor is the first new antiviral flu treatment with a novel mechanism of action approved by FDA in nearly 20 years.

Safety and efficacy of baloxavir marboxil taken as a single oral dose was demonstrated in two randomized controlled clinical trials of 1,832 patients in which participants were assigned to receive either baloxavir marboxil, a placebo, or another antiviral flu treatment within 48 hours of experiencing flu symptoms.

In both trials, patients treated with baloxavir marboxil had a shorter time to alleviation of symptoms compared with patients who took the placebo. In the second trial, there was no difference in the time to alleviation of symptoms between participants who received baloxavir marboxil and those who received the other flu treatment.

Within 48 hours of symptom onset, patients weighing 40 kg to less than 80 kg take a single oral dose of 40 mg, and patients weighing at least 80 kg take a single oral dose of 80 mg, with or without food. Avoid coadministration with dairy products, calcium-fortified beverages, polyvalent cation-containing laxatives, antacids, or oral supplements (e.g., calcium, iron, magnesium, selenium, or zinc).

Common adverse reactions in clinical trials were diarrhea and bronchitis.

Medication Monitor Categories:
New Drug Approvals