

Baloxavir (Xofluza): A new antiviral drug for the flu

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A new drug for the treatment of [influenza](#) was approved by the US Food and Drug Administration (FDA) in October 2018, just in time for the 2018–19 flu season. Baloxavir marboxil (Xofluza) works against the two types of influenza virus that cause disease in humans, influenza A and B.

This new drug works differently than currently available drugs, including oseltamivir (Tamiflu), zanamivir (Relenza), and peramivir (Rapivab). These older drugs inhibit the virus by blocking a viral enzyme called neuraminidase. In contrast, baloxavir inhibits a subunit of the viral polymerase, the enzyme responsible for influenza virus replication. Put more simply, baloxavir interferes with the ability of the flu virus to multiply, while the older drugs interfere with the ability of the flu virus to spread within the body.

This different mechanism of action means baloxavir may be effective against strains of influenza A that are resistant to oseltamivir, the drug used most widely for treatment of influenza. Baloxavir is also active against strains of avian influenza (“bird flu”).

Baloxavir reduces duration of flu-like symptoms

Baloxavir marboxil is taken by mouth. In the gastrointestinal tract, the marboxil component gives way to reveal the active drug, baloxavir acid. A phase 3 randomized, double-blind [trial](#) called CAPSTONE-1, published in the *New England Journal of Medicine*, compared baloxavir to oseltamivir and to placebo for the treatment of influenza-like illness. In this multicenter study (supported by the manufacturer of baloxavir), otherwise healthy patients, ages 20 to 64, received either a single dose of baloxavir (40 or 80 milligrams, depending on the weight of the patient); a twice-daily 75-mg dose of oseltamivir for five days; or placebo. In addition, children and adolescents ages 12 to 19 were randomized to receive either baloxavir or placebo.

CAPSTONE-1 showed that baloxavir reduced the duration of flu-like symptoms by about one day, from an average of 80.2 hours to 53.7 hours. Of note, patients who started baloxavir within 24 hours of symptom onset had a greater benefit from the drug compared to those who started later. Baloxavir rapidly reduced the concentration of influenza virus in respiratory secretions, and did so more rapidly than oseltamivir (one day versus three days, respectively). Nevertheless, both baloxavir and oseltamivir were similarly effective in shortening the duration of flu-like symptoms. Baloxavir was generally well tolerated.

For now, generic oseltamivir is still a good option

Given the results of CAPSTONE-1, when should baloxavir be used, and should it be used in place of oseltamivir? Baloxavir is approved for the treatment of influenza in patients 12 and older who have been symptomatic for no more than 48 hours. The main advantage of baloxavir is that a single oral dose is effective, whereas oseltamivir needs to be taken twice daily for five days. However, both drugs reduce the duration of flu-like symptoms. Oseltamivir is now available generically, and may be less expensive than baloxavir. Therefore, unless a doctor suspects that someone is unable or unlikely to complete a five-day course of medication, oseltamivir remains an appropriate choice for the majority of people with influenza, pending additional data or prescribing guidelines.

