

Brand Name: Xofluza

Generic: baloxavir marboxil

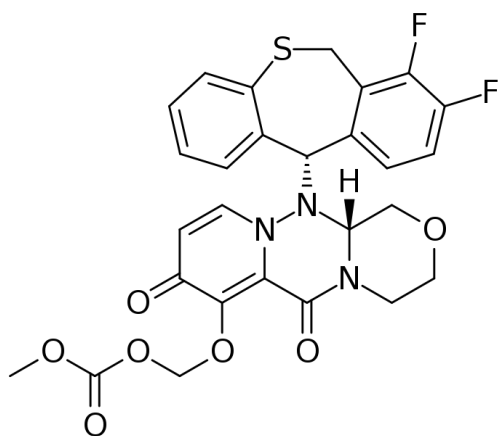
Type: small molecule

Year Accepted/Phase: 2018

Mechanism:

Baloxavir marboxil inhibits the cap-dependent endonuclease enzyme within the influenza virus, which is essential for viral replication.

Chemical Structure:



Indication:

Xofluza is indicated for the treatment of acute uncomplicated influenza in patients 12 years of age and older who have been symptomatic for no more than 48 hours, and for post-exposure prophylaxis of influenza in individuals 12 years of age and older.

Clinical trials:

Phase III Trials for Influenza Treatment

Pubmed: <https://pubmed.ncbi.nlm.nih.gov/30675086/>

Purpose: Evaluate the efficacy and safety of baloxavir marboxil compared to placebo or oseltamivir in patients with acute uncomplicated influenza.

Dates: Conducted from 2016 to 2017.

Results: The Phase III trials demonstrated that baloxavir marboxil significantly reduced the duration of flu symptoms compared to placebo and oseltamivir. It also significantly reduced viral shedding and the time to alleviation of symptoms.

Impact: These results supported the approval of Xofluza for the treatment of acute uncomplicated influenza in 2018.

Phase III Trials for Influenza Prophylaxis

Pubmed: <https://pubmed.ncbi.nlm.nih.gov/32640124/>

Purpose: Evaluate the efficacy and safety of baloxavir marboxil for post-exposure prophylaxis of influenza in household contacts of an index case.

Dates: Conducted from 2016 to 2018.

Results: The Phase III trials showed that baloxavir marboxil significantly reduced the risk of developing influenza compared to placebo. It also reduced the duration of viral shedding in those who did develop influenza.

Impact: These findings supported the approval of Xofluza for post-exposure prophylaxis of influenza in 2019.