

FDA APPROVALS

FDA approves first generic of Tamiflu for influenza A, B

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The FDA recently approved the first generic version of Tamiflu for the treatment and prevention of influenza A and B in patients aged 2 weeks and older, according to an agency announcement.

Tamiflu (oseltamivir phosphate, Roche) is used to treat influenza and was approved in 1999. According to the statement, the generic version is approved for treatment in patients aged 2 weeks and older who exhibit influenza-like symptoms for no more than 48 hours, and also in patients aged 1 year and older for the prevention of influenza.

The FDA said it “does not know if oseltamivir phosphate is effective in people who start treatment after 2 days of developing symptoms, or have weakened immune systems.”

Clinical trial data indicated common side effects experienced by patients who use oseltamivir phosphate include nausea and vomiting.

Oseltamivir phosphate should not take the place of routine influenza vaccination. The announcement also indicated oseltamivir phosphate does not treat or prevent illness caused by infections other than the influenza virus and does not prevent bacterial infections that may accompany influenza.

Patients and health care providers may find more information on oseltamivir phosphate in the drug label, according to the FDA.

Reference: FDA. http://www.accessdata.fda.gov/drugsatfda_docs/label/2016/021087s068,021246s051lbl.pdf?source=govdelivery&utm_medium=email&utm_source=govdelivery. Accessed August 4, 2016.