

ATTENTION: HIV-infected children are at risk for potentially serious disease due to influenza viruses. The Food and Drug Administration has issued an alert regarding use of the antivirals Tamiflu and Relenza in children, including HIV-infected children. The alert and tables with pediatric dosing of these drugs relevant to HIV-infected children follows:

On April 26, the Acting Secretary of HHS declared a public health emergency related to the current outbreak of "swine flu" (now designated "novel 2009 H1N1"). In response to this public health emergency, the CDC requested Emergency Use Authorization (EUA) for the use of Tamiflu and Relenza for treatment and prophylaxis of influenza for broader populations than are currently included in the product labeling, including pediatric populations, and others who fall outside of the indicated uses.

Influenza viruses cause serious, sometimes fatal, disease in immunocompromised patients, including HIV infected infants, toddlers, and young children.

Currently, Relenza is approved to treat acute uncomplicated illnesses due to influenza in adults and children 7 years and older who have been symptomatic for less than two days, and for the prevention of influenza in adults and children 5 years and older. Tamiflu is approved for the treatment and prevention of influenza in patients 1 year and older.

The EUAs allow for Tamiflu also to be used to treat and prevent influenza in children under 1 year, and to provide alternative dosing recommendations for children older than 1 year. In addition, under the EUAs, both medications may be distributed to large segments of the population without complying with the label requirements otherwise applicable to dispensed drugs, and accompanied by written information pertaining to the emergency use. They may also be distributed by a broader range of health care workers, including some public health officials and volunteers, in accordance with applicable state and local laws and/or public health emergency responses.

These temporary extensions of the indication, which will terminate when the emergency no longer exists, are summarized below:

1. *Use of Tamiflu for treatment and prophylaxis of influenza in infants <1 year of age.* Tamiflu is currently approved for use in patients 1 year of age and older. New dosing recommendations in infants <1 year were based on expedited review of safety and pharmacokinetic data submitted by Roche and the Collaborative Antiviral Study Group of NIAID/NIH. In addition, age-based dose recommendations in older children were included in these new recommendations. These EUA recommendations are intended for use with Tamiflu for Oral Suspension and are shown here:

Expanded EUA Tamiflu Dose Recommendations for Treatment of Influenza in Pediatric Patients			
Body Weight (kg)	Body Weight (lbs)	Dose by Age	Recommended Treatment Dose for 5 Days
>40 kg	>88 lbs	>10 years	75 mg twice daily
>23 kg to 40 kg	>51 lbs to 88 lbs	6-9 years	60 mg twice daily
>15 kg to 23 kg	>33 lbs to 51 lbs	3-5 years	45 mg twice daily
≤15 kb	<33 lbs	1-2 years	30 mg twice daily
Dosing for infants younger than 1 year not based on weight		6-11 months	25 mg twice daily
		3-5 months	20 mg twice daily
		<3 months	12 mg twice daily

The Tamiflu Oral Suspension bottle comes with a dispenser marked for 30, 45, or 60 mg. For children who weigh more than 40 kg (or 88 lbs) or adults who can't swallow capsules, you will need to measure out a dose of 30 mg plus another dose of 45 mg. For infants less than 1 year old, a different measuring device must be used that will dispense 2 mL (about 25 mg), 1.6 mL (about 20 mg) or 1 mL (12 mg).

There is an approved process for compounding a Tamiflu suspension from 75 mg capsules in the event of a shortage of the suspension; see page 19 of the Tamiflu package insert:

http://www.accessdata.fda.gov/drugsatfda_docs/label/2008/021087s047,%20021246s033lbl.pdf. Also see: <http://www.fda.gov/cder/drug/antivirals/influenza/default.htm>.

Doses for prevention of the novel 2009 H1N1 are the same for each weight group, but doses are administered only once per day rather than twice. Prevention dosages should be taken for 10 days following close contact with an infected person or during a community outbreak.

2. *Use of Tamiflu and Relenza in patients not included in the current labeling.* These drugs are currently indicated for use in patients with acute, uncomplicated influenza who have had symptoms for <48 hours. The EUA allows for use of Tamiflu and Relenza in patients who have more severe influenza disease or who have been ill for longer than 48 hours based on limited published data and the understanding that the novel 2009 H1N1 may have different presentations. Depending on available products and susceptibility data, clinicians may wish to make individual risk-benefit assessments regarding the appropriate use of the products.

More detailed information about Influenza Antiviral Drugs is available on the FDA web site at <http://www.fda.gov/cder/drug/antivirals/influenza/default.htm>

The [TAMIFLU® FACT SHEET FOR HEALTH CARE PROVIDERS](#) contains information specific to the expanded pediatric dosing recommendations for Tamiflu.

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