

Pharmacy Guidance for Tamiflu

CDC RECOMMENDATIONS FOR USE

- Early empiric treatment with oseltamivir or zanamivir should be considered for persons with suspected or confirmed influenza who are at higher risk for complications including:
 - Children younger than 2 years old;
 - Persons aged 65 years or older
 - Pregnant women
 - Persons of any age with certain chronic medical or immunosuppressive conditions (see page 3); and,
 - Persons younger than 19 years of age who are receiving long-term aspirin therapy

<http://www.cdc.gov/h1n1flu/recommendations.htm>

BEYOND USE EXPIRATION DATE

FDA is authorizing the use of certain lots of expired Tamiflu for Oral Suspension as part of the federal government's response to the 2009 H1N1 Influenza public health emergency.

The lots of Tamiflu for Oral Suspension that are being authorized are part of the Strategic National Stockpile and have been tested through the federal government's Shelf-Life Extension Program (SLEP). Be aware that specific lots of Tamiflu for Oral Suspension have been authorized for use beyond their expiration dates. Please see the table below for the exact lot numbers and extended dates for product distributed within Arizona.

| | | |
|-------|-------------------|-------------------|
| B1045 | May 31, 2005 | February 28, 2010 |
| B1047 | November 30, 2005 | February 28, 2010 |
| B1048 | January 31, 2006 | August 31, 2010 |

For any Tamiflu that is beyond its expiration date, you may verify if it has been authorized for use through the following website: <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm154962.htm>

The lots of Tamiflu for Oral Suspension now authorized by FDA for use beyond their expiration dates are not required to be relabeled with information about the use of the products beyond their expiration dates.

- CDC recommends placing the prescription label over the expiration date
- Arizona State Board of Pharmacy recommends the use of auxiliary labels to communicate the extended expiration dates
- **NOTE:** There is an expiration date on the box as well as the bottle. Do not dispense the box with the bottle.
- Emergency Use Authorizaton (**EUA**) fact sheets for both patients and healthcare professionals will be made available by public health officials. These fact sheets will contain information about the authorized use of these products beyond their expiration dates and **must accompany each and every Tamiflu prescription.**

DOSING CONCERNS

- The compounded suspension is a different concentration (15 mg/mL) compared to commercially available Tamiflu for Oral Suspension, which has a concentration of 12 mg/mL.
- Please provide an appropriate dispensing device (**i.e., one that measures volume in mL**) is provided with the compounded suspension of Tamiflu.
- If a prescription specifies the dose in teaspoons, only a syringe calibrated in fractions of a teaspoon should be dispensed and the instructions adjusted accordingly; if a prescription specifies the dose in milliliters, only a syringe calibrated in milliliters should be used.

Total Volume of Suspension Needed for Correct Dosing

| Body Weight (kg) | Body Weight (lbs) | Total Volume to Compound per patient (mL) |
|------------------|-------------------|---|
| ≤ 15 kg | ≤ 33 lbs | 30 mL |
| 16 to 23 kg | 34 to 51 lbs | 40 mL |
| 24 to 40 kg | 52 to 88 lbs | 50 mL |
| ≥ 41 kg | & ≥ 89 lbs | 60 mL |

Dosing Chart for Pharmacy-compounded Tamiflu

| Body Weight (kg) | Body Weight (lbs) | Dose (mg) | Volume per Dose (15 mg/mL) | Treatment Dose Required (for 5 days) | Prophylaxis Dose Required (for 10 days) |
|------------------|-------------------|-----------|----------------------------|--------------------------------------|---|
| ≤ 15 kg | ≤ 33 lbs | 30 mg | 2 mL | 2 mL twice daily | 2 mL once daily |
| 16 to 23 kg | 34 to 51 lbs | 45 mg | 3 mL | 3 mL twice daily | 3 mL once daily |
| 24 to 40 kg | 52 to 88 lbs | 60 mg | 4 mL | 4 mL twice daily | 4 mL once daily |
| ≥ 41 kg | ≥ 89 lbs | 75 mg | 5 mL | 5 mL twice daily | 5 mL once daily |

PRESCRIPTION CLARIFICATION

Call backs to the prescriber do not need to be made if prepared according to method on pg 19 of the Roche Tamiflu package insert, no additional authorization is required.

COST

The oral suspension Tamiflu from the stockpile is free for all patients, but a dispensing fee may be charged. However, a patient has a right to deny paying anything for their Tamiflu prescription.

For more detailed information, visit the Arizona State Board of Pharmacy website at www.azpharmacy.gov/faqs.asp or Arizona Pharmacy Alliance website H1N1Connection at www.azpharmacy.org