EMERGENCY USE AUTHORIZATION of TAMIFLU®: FACT SHEET FOR HEALTH CARE PROVIDERS[1]

You have been asked as a health care provider to give TAMIFLU® (oseltamivir phosphate) to people, as appropriate, for the treatment or prevention of 2009 H1N1 flu (previously known as Swine Influenza A or Swine Flu). TAMIFLU® is approved by the U.S. Food and Drug Administration (FDA) to treat and prevent influenza. Certain aspects of the emergency use are not part of the approved drug applications, such as use in pediatric patients less than 1 year old, use in patients who are symptomatic for more than 2 days, and use in patients who have complicated illness requiring hospitalization. **For more information,** refer to http://www.cdc.gov/h1n1flu/eua/tamiflu.htm or www.fda.gov.

Recommended Treatment Dosage

Adults and Adolescents 13 years and older: 75 mg twice daily for 5 days. Treatment should begin as soon as possible after symptom onset.

Pediatric Patients 1 to 12 years old: Dosage is shown in the following table. For pediatric patients who cannot swallow capsules, TAMIFLU® for Oral Suspension (12 mg/mL) is the preferred formulation. If the commercially-manufactured oral suspension product is not available, TAMIFLU® Capsules that provide the correct dose for the patient (30 mg, 45 mg, or 75 mg) may be opened and mixed with sweetened liquids such as regular or sugar-free chocolate syrup. Another option is for pharmacists to compound an oral suspension from TAMIFLU® Capsules following the directions in the FDA-approved TAMIFLU Package Insert under "Emergency Compounding of an Oral Suspension from TAMIFLU Capsules (final concentration 15 mg/mL)."

Body Weight (kg)	Body Weight (lbs)	Age (years)	Dose for 5 Days	# Bottles of Oral Suspension Needed for the 5 Day Regimen	# of Capsules Needed for the 5 Day Regimen
≤ 15 kg	≤ 33 lbs	1–2	30 mg twice daily	1	10 capsules (30 mg)
> 15–23 kg	> 33–51 lbs	3–5	45 mg twice daily	2	10 capsules (45 mg)
> 23–40 kg	> 51–88 lbs	6–9	60 mg twice daily	2	20 capsules (30 mg)
> 40 kg	> 88 lbs	10–12	75 mg twice daily	3	10 capsules (75 mg)

Pediatric Patients (full-term infants) less than 1 year old

Age	Recommended Treatment Dose for 5 Days (weight-based dose)*
< 12 months	3 mg/kg/dose twice daily

* Weight-based dosing is preferred, however, if weight is not known, dosing by age for treatment of influenza in full-term infants younger than 1 year of age may be necessary (birth-2 months = 12 mg (1 mL) twice daily; 3-5 months = 20 mg (1.6 mL) twice daily, 6-11 months = 25 mg (2 mL) twice daily)

For infants less than 1 year old, a measuring device other than the one provided with the packaging, must be used to correctly measure the dose. Instead, a 3 mL or 5 mL oral syringe should be used to measure the dose. The dose recommended in the table is not intended for premature infants (those < 37 weeks of gestational age at birth who have not reached their expected due date), and may lead to high drug concentrations in this age group due to immature renal function. Very limited data from a cohort of premature infants receiving a mean dose of 1.7 mg/kg BID demonstrated drug concentrations higher than those observed with the recommended dose in term infants (3 mg/kg). Observed drug concentrations were highly variable among premature infants. These data are insufficient to recommend a specific dose of TAMIFLU® for premature infants.

Recommended Prophylaxis Dosage

Adults and Adolescents 13 years and older: 75 mg once daily for at least 10 days following close contact with an infected person. Therapy should begin as soon as possible after exposure. The recommended dose for prophylaxis during a community outbreak of influenza is 75 mg once daily. Safety and efficacy have been demonstrated for up to 6 weeks. The duration of protection lasts for as long as dosing is continued.

Pediatric Patients 1 to 12 years old: Dosage following close contact with an infected individual is shown in the following table. For pediatric patients who cannot swallow capsules, TAMIFLU® for Oral Suspension (12 mg/mL) is the preferred formulation. If the commercially-manufactured oral suspension product is not available, TAMIFLU® Capsules that provide the correct dose for the patient (30 mg, 45 mg, or 75 mg) may be opened and mixed with sweetened liquids such as regular or sugar-free chocolate syrup. Another option is for pharmacists to compound an oral suspension from TAMIFLU® Capsules following the directions in the FDA-approved TAMIFLU® Package Insert under "Emergency Compounding of an Oral Suspension from TAMIFLU Capsules (final concentration 15 mg/mL)."

[1] In the event of an emergency, it is possible that public health officials or other volunteers might distribute TAMIFLU® products to recipients as authorized. In this fact sheet, the term "health care provider(s)" includes these individuals and is used for brevity here.

Body Weight (kg)	Body Weight (lbs)	Age (years)	Dose for 10 Days	# Bottles of Oral Suspension Needed for the 10 Day Regimen	# of Capsules Needed for the 10 Day Regimen
≤ 15 kg	≤ 33 lbs	1–2	30 mg once daily	1	10 capsules (30 mg)
> 15–23 kg	> 33–51 lbs	3–5	45 mg once daily	2	10 capsules (45 mg)
> 23–40 kg	> 51–88 lbs	6–9	60 mg once daily	2	20 capsules (30 mg)
> 40 kg	> 88 lbs	10–12	75 mg once daily	3	10 capsules (75 mg)

Prophylaxis in pediatric patients following close contact with an infected individual is recommended for 10 days. Prophylaxis in patients 1 to 12 years of age has not been evaluated for longer than 10 days duration. Therapy should begin as soon as possible after exposure.

Pediatric Patients (full-term infants) less than 1 year old*

Age	Recommended Prophylaxis Dose for 10 Days (weight-based dose)**
3 to < 12 months	3 mg/kg/dose once daily
Younger than 3 months	Not recommended unless situation judged critical due to limited data on use in this age group

** Weight-based dosing is preferred, however, if weight is not known, dosing by age for prophylaxis of influenza in full-term infants younger than 1 year of age may be necessary (3-5 months = 20 mg once daily (1.6 mL), 6-11 months = 25 mg (2 mL) once daily).

For infants less than 1 year old, a measuring device other than the one provided with the packaging must be used to correctly measure the dose. Instead, a 3 mL or 5 mL oral syringe should be used to correctly measure the dose. For infants younger than 3 months old and premature infants (those < 37 weeks of gestational age at birth who have not reached their expected due date), prophylaxis is not recommended unless the situation is judged critical due to limited data on use in these groups.

Special Dosage Instructions

No dose adjustment is recommended for patients with mild or moderate hepatic impairment (Child-Pugh score ≤ 9). No dose adjustment is required for geriatric patients.

Renal Impairment, Recommended Treatment Dosage: Dose adjustment is recommended for patients with creatinine clearance between 10 and 30 mL/min. Treatment dose should be reduced to 75 mg once daily for 5 days. No recommended dosing regimens are available for patients undergoing routine hemodialysis and continuous peritoneal dialysis treatment with end-stage renal disease.

Renal Impairment, Recommended Prophylaxis Dosage: Dose adjustment is recommended for patients with creatinine clearance between 10 and 30 mL/min receiving TAMIFLU®. In these patients it is recommended that the dose be reduced to 75 mg of TAMIFLU® every other day or 30 mg TAMIFLU® every day. No recommended dosing regimens are available for patients undergoing routine hemodialysis and continuous peritoneal dialysis treatment with end-stage renal disease.

Preparation and Administration of Commercially-Manufactured TAMIFLU® for Oral Suspension (final concentration 12 mg/mL)

TAMIFLU® for Oral Suspension may be constituted by a pharmacist or health care provider.

1. Tap the closed bottle several times to loosen the powder.
2. Measure **23 mL** of water in a graduated cylinder.
3. Add the total amount of water for constitution to the bottle and shake the closed bottle well for 15 seconds.
4. Remove the child-resistant cap and push bottle adapter into the neck of the bottle.
5. Close bottle with child-resistant cap tightly. This will assure the proper seating of the bottle adapter in the bottle and child-resistant status of the cap.

NOTE: SHAKE THE TAMIFLU® FOR ORAL SUSPENSION WELL BEFORE EACH USE.

Store constituted suspension under refrigeration at 2-8°C (36-46°F). Do not freeze. The constituted TAMIFLU® for Oral Suspension (12 mg/mL) should be used within 10 days of preparation; the pharmacist, health care official, patient, or patient's parent or guardian should write the date of expiration of the constituted suspension on the label. The Fact Sheet for Patients and Parent/Caregivers and oral dispenser should be dispensed to the patient.

An oral dosing dispenser with 30 mg, 45 mg, and 60 mg graduations is provided with TAMIFLU® for Oral Suspension; the 75 mg dose can be measured using a combination of 30 mg and 45 mg. Patients should use the manufacturer's dispenser. In the event that the dispenser provided is lost or damaged, another dosing syringe or other device may be used to deliver the following volumes: 2.5 mL (1/2 tsp) for children ≤ 15 kg, 3.8 mL (3/4 tsp) for > 15 kg to 23 kg, 5 mL (1 tsp) for > 23 kg to 40 kg, and 6.2 mL (1 ¼ tsp) for > 40 kg.

Health care providers and pharmacists should be aware of potential dosing errors with TAMIFLU® for Oral Suspension. Health care providers and pharmacists should include doses in mg if the dosing dispenser with the drug is in mg. Pharmacists and health care providers should ensure that the units of measure in the dosing instructions match the dosing device provided with the drug.

Expired TAMIFLU®

If you have been asked to distribute/dispense TAMIFLU® that is past its expiration date, please be aware that based on scientific review and analysis of available data, FDA has authorized the use of certain lots of expired TAMIFLU® during this public health emergency. Some of these data may have been generated as part of the federal government's Shelf Life Extension Program (SLEP). Under SLEP, FDA conducts scientific testing to determine if specific lots of TAMIFLU® can be used beyond their expiration dates. If analysis of the available data indicates the product is still acceptable for use, FDA can authorize its use beyond its expiration date. **For any TAMIFLU® that is past its expiration date, you should look up the lot number at the following website to determine if FDA has authorized its use beyond the expiry date: http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm154962.htm. If the lot number for expired TAMIFLU® appears on this website, you may inform recipients of the expired TAMIFLU that it has been authorized for use beyond its expiration date.**

What are the Possible Side Effects of TAMIFLU®?

The side effects reported most often in those people who took this drug were gastrointestinal (i.e., nausea and vomiting). Nausea and vomiting may be less severe if TAMIFLU® is taken with food.

Rare cases of anaphylaxis and serious skin reactions including toxic epidermal necrolysis, Stevens-Johnson Syndrome, and erythema multiforme have been reported in post marketing experience with TAMIFLU®. TAMIFLU® should be stopped and appropriate treatment instituted if an allergic-like reaction occurs or is suspected.

There have been postmarketing reports of delirium and abnormal behavior leading to injury, and in some cases resulting in fatal outcomes, in patients with influenza who were receiving TAMIFLU®. These events may occur in the setting of encephalitis or encephalopathy but can occur without obvious severe disease. Because these events were reported voluntarily during clinical practice, estimates of frequency cannot be made but they appear to be uncommon based on TAMIFLU® usage data. These events were reported primarily among pediatric patients and often had an abrupt onset and rapid resolution. The contribution of TAMIFLU® to these events has not been established. Patients with influenza should be closely monitored for signs of abnormal behavior.

Refer to the Package Insert for more safety information.

Make available to recipients the information in the Fact Sheet for Patients and Parents

Reporting And Monitoring Adverse Events

Health care providers and recipients that experience adverse events or medication errors are encouraged to report to MedWatch at www.fda.gov/medwatch, by submitting a MedWatch Form 3500 (available at http://www.fda.gov/medwatch/safety/FDA-3500_fillable.pdf) or by calling 1-800-FDA-1088.