

**EMERGENCY USE AUTHORIZATION of TAMIFLU®:
FACT SHEET FOR HEALTH CARE PROVIDERS¹**

You have been asked as a health care provider to give TAMIFLU® (oseltamivir phosphate) to people who have been exposed to novel Influenza A (H1N1) (Swine Influenza A). 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> 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 is the preferred formulation. If the oral suspension product is not available, TAMIFLU® Capsules may be opened and mixed with sweetened liquids such as regular or sugar-free chocolate syrup.

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	≤ 33	1-2	30 mg twice daily	1	10 capsules (30 mg)
> 15-23	> 33-51	3-5	45 mg twice daily	2	10 capsules (45 mg)
> 23-40	> 51-88	6-9	60 mg twice daily	2	20 capsules (30 mg)
> 40	> 88	10-12	75 mg twice daily	3	10 capsules (75 mg)

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. It is recommended that patients use this dispenser. In the event that the dispenser provided is lost or damaged, another

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.

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.

Pediatric Patients less than 1 year old*

Body Weight (kg)	Dose by Age	Recommended Treatment Dose for 5 Days (Dose in volume is based on the concentration (12 mg/mL) of commercially-manufactured TAMIFLU® Oral Suspension)
Dosing for infants younger than 1 year not based on weight	< 3 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 more information regarding the basis for dose recommendations, see FDA's "Tamiflu Technical Review Document for H1N1 Influenza A" on www.cdc.gov/h1n1flu or www.fda.gov.

For infants less than 1 year old, a different measuring device (such as a 5-mL oral syringe) must be used to correctly measure the dose.

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 is the preferred formulation. If the oral suspension product is not available, TAMIFLU® Capsules may be opened and mixed with sweetened liquids such as regular or sugar-free chocolate syrup.

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

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. It is recommended that patients use this 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.

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 soon as possible.

Pediatric Patients less than 1 year old*

Body Weight (kg)	Dose by Age	Recommended Prophylaxis Dose for 10 Days (Dose in volume is based on the concentration (12 mg/mL) of commercially-manufactured TAMIFLU® for Oral Suspension)
Dosing for infants younger than 1 year not based on weight	< 3 months	Not recommended unless situation judged critical
	3-5 months	20 mg (1.6 mL) once daily
	6-11 months	25 mg (2 mL) once daily

*For more information regarding the basis for dose recommendations, see FDA's "Tamiflu Technical Review Document for H1N1 Influenza A" on www.cdc.gov/h1n1flu or <http://www.fda.gov>.

For infants less than 1 year old, a different measuring device (such as a 5-mL oral syringe) must be used to correctly measure the dose.

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 of TAMIFLU® for Oral Suspension

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 Parents and oral dispenser should be dispensed to the patient.

Expired TAMIFLU® for Oral Suspension

If you have been asked to distribute/dispense TAMIFLU® for Oral Suspension that is past its original labeled expiration date, please be aware that the expiration date may have been extended as part of the federal government's Shelf Life Extension Program (SLEP). Under SLEP, FDA conducts scientific testing to see if specific lots of TAMIFLU® can be used beyond the expiration dates originally printed on the label by the manufacturer. If the product passes testing, FDA determines that the shelf life of the product can be extended beyond the expiration dates originally printed on the label. **For any TAMIFLU® for Oral Suspension that is past its original labeled expiration date, you may look up the lot number at the following website to determine if the expiry date for this lot has been extended and for how long: www.cdc.gov/h1n1flu/eua. For TAMIFLU® for Oral Suspension whose expiration date has been extended, you may inform recipients of the new 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.