

## Announcing the new strength of TAMIFLU for Oral Suspension 6mg/mL

TAMIFLU is indicated in patients 1 year and older for the treatment of uncomplicated influenza in those who have been symptomatic for no more than 2 days and for the prophylaxis of influenza. We are changing the concentration from 12 mg/mL to 6 mg/mL and the dispenser from mgs to mLs. The new 6 mg/mL TAMIFLU for Oral Suspension (NDC 0004-0820-09) coupled with a new oral dispenser in mLs will help simplify prescribing and dosing.

The 12 mg/mL concentration is no longer being manufactured.

### Important Prescribing Information (Revised March 2011)

Please prescribe TAMIFLU for appropriate patients as follows:

**Formulation and Concentration or Strength:**

- Oral Suspension (6 mg/mL) or capsules (30 mg, 45 mg or 75 mg)

**Dose:**

- mL (preferred for oral suspension) or mg (preferred for capsules), based on patient's weight (please refer to the Dosing Table for more information)

**Frequency and Duration:**

- Treatment: twice daily for 5 days
- Prophylaxis: once daily, typically for 10 days for post-exposure prophylaxis or for up to 6 weeks during a community outbreak

### Dosage and Administration

TAMIFLU may be taken with or without food. However, when taken with food, tolerability may be enhanced in some patients. The recommended oral treatment and prophylaxis dose of TAMIFLU for patients 1 year of age and older is shown in the table below.

#### Treatment and Prophylaxis Dosing of Oral TAMIFLU for Influenza for Patients 1 Year of Age and Older Based on Body Weight†

Table 1 in TAMIFLU Prescribing Information

Weight (kg)	Weight (lbs)	Treatment Dosing for 5 days	Prophylaxis Dosing for 10 days‡	Volume of Oral Suspension (6 mg/mL) for each Dose*	Number of Bottles of Oral Suspension to Dispense	Number of Capsules and Strength to Dispense
15 kg or less	33 lbs or less	30 mg <b>twice</b> daily	30 mg <b>once</b> daily	5 mL	1 bottle	10 Capsules, 30 mg
16 kg thru 23 kg	34 lbs thru 51 lbs	45 mg <b>twice</b> daily	45 mg <b>once</b> daily	7.5 mL	2 bottles	10 Capsules, 45 mg
24 kg thru 40 kg	52 lbs thru 88 lbs	60 mg <b>twice</b> daily	60 mg <b>once</b> daily	10 mL	2 bottles	20 Capsules, 30 mg
41 kg or more	89 lbs or more	75 mg <b>twice</b> daily	75 mg <b>once</b> daily	12.5 mL**	3 bottles	10 Capsules, 75 mg

† Treatment should begin within 2 days of onset of symptoms and prophylaxis should begin within 2 days of exposure to an infected individual. Please see the Prescribing Information for dosing in patients with renal impairment.

‡ Prophylaxis for adults following close contact with an infected individual for at least 10 days. Duration of prophylaxis in both adults and pediatric patients during a community outbreak is up to 6 weeks in immunocompetent patients.

\* A 10 mL oral dosing dispenser is provided with the oral suspension. In the event that the dispenser provided is lost or damaged, another dosing dispenser may be used to deliver the volumes.

\*\* Delivery of this TAMIFLU for Oral Suspension dose requires administering 10 mL followed by another 2.5 mL.

Please see accompanying full Prescribing Information and inside for additional important safety information.

## COMMONLY ASKED QUESTIONS BY HEALTHCARE PROFESSIONALS

### What has changed with the new TAMIFLU® (oseltamivir phosphate) for Oral Suspension (OS)?

- The concentration of the constituted OS product has changed from 12 mg/mL to 6 mg/mL.
- The new oral dispenser is labeled in mLs, rather than mgs.
- Usable bottle volume has changed from 25 mLs to 60 mLs.
- The drug product / formulation has not changed.

### Why are these changes being made?

- The new strength of TAMIFLU for Oral Suspension will help to reduce the potential for prescribing and dosing confusion through the following:
  - Including a new oral dispenser labeled in mLs to align with how prescriptions are commonly written
  - Lowering the OS concentration can simplify administration for caregivers
    - Previous: 15 mg/mL for pharmacist-compounded and 12 mg/mL for pre-manufactured OS
    - New: 6mg/mL harmonizes concentration for both emergency compounding and pre-manufactured concentration
    - Lower concentration results in less foaming, which can affect oral suspension dosing and accuracy

### What if the local pharmacy does not have any TAMIFLU for Oral Suspension in stock?

- Genentech expects the supply of TAMIFLU for Oral Suspension and all other formulations, including the 75 mg capsules for adults and the 30 mg and 45 mg capsules for children, to be ample to meet demands of the 2011-2012 season.
- TAMIFLU provides the flexibility for healthcare professionals to treat and prevent influenza with alternatives to oral suspension:
  - TAMIFLU 30 mg or 45 mg capsules depending on the weight of the child; for patients with difficulty swallowing capsules, contents can be mixed into sweetened liquids, such as chocolate syrup by a caregiver.
  - In emergency situations if commercially manufactured TAMIFLU for OS is not readily available from wholesalers or Genentech, a liquid suspension can be compounded by a Pharmacist using the TAMIFLU 75 mg capsules – instructions for dosing and compounding may be found in the TAMIFLU Prescribing Information or at [www.Tamiflu.com/HCP](http://www.Tamiflu.com/HCP).
- Pharmacists: We encourage you to order TAMIFLU for Oral Suspension 6 mg/ml and other formulations of the capsules for appropriate stocking of antiviral therapy to meet influenza patient needs.

## Indications and Limitations of Use

TAMIFLU is indicated in patients 1 year and older for the treatment of uncomplicated influenza caused by viruses types A and B who have been symptomatic for no more than 2 days and for the prophylaxis of influenza.

Efficacy of TAMIFLU in patients who begin treatment after 48 hours of symptoms has not been established.

TAMIFLU is not a substitute for early and annual vaccination as recommended by the Centers for Disease Control's Advisory Committee on Immunization Practices (ACIP).

There is no evidence for efficacy of TAMIFLU in any illness caused by agents other than influenza viruses Types A and B.

Influenza viruses change over time. Emergence of resistance mutations could decrease drug effectiveness. Other factors (for example, changes in viral virulence) might also diminish clinical benefits of antiviral drugs. Consider available information on influenza drug susceptibility patterns and treatment effects when deciding whether to use TAMIFLU.

## Important Safety Information

TAMIFLU is contraindicated in patients who have had severe allergic reactions such as anaphylaxis or serious skin reactions such as toxic epidermal necrolysis, Stevens-Johnson syndrome, or erythema multiforme to any component of TAMIFLU. Cases of these events have been reported in postmarketing 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 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. If neuropsychiatric symptoms occur, the risks and benefits of continuing treatment should be evaluated for each patient.

Serious bacterial infections may begin with influenza-like symptoms or may co-exist with or occur as complications during the course of influenza. TAMIFLU has not been shown to prevent such complications.

Efficacy in subjects with chronic cardiac and/or respiratory disease or in immunocompromised patients has not been established. No information is available regarding treatment of influenza in patients at imminent risk of requiring hospitalization.

The concurrent use of TAMIFLU with live attenuated influenza vaccine (LAIV) intranasal has not been evaluated. However, because of the potential for interference between these products, LAIV should not be administered within 2 weeks before or 48 hours after administration of TAMIFLU, unless medically indicated.

Adverse events that occurred more frequently in patients treated with TAMIFLU than in patients taking placebo and occurred in  $\geq 2\%$  of patients were (TAMIFLU%, placebo %):

- Treatment in adults – nausea (10%, 6%), vomiting (9%, 3%), bronchitis (2%, 2%)
- Treatment in pediatrics – vomiting (15%, 9%), abdominal pain (5%, 4%), epistaxis (3%, 3%), ear disorder (2%, 1%)
- Prophylaxis of adults – headache (18%, 18%), nausea (7%, 3%), diarrhea (3%, 2%), vomiting (2%, 1%), abdominal pain (2%, 1%)
- Prophylaxis of pediatrics – vomiting (10%, 2%), abdominal pain (3%, 0%), nausea (4%, 1%)

**TAMIFLU® (oseltamivir phosphate)**

**HIGHLIGHTS OF PRESCRIBING INFORMATION**  
These highlights do not include all the information needed to use TAMIFLU safely and effectively. See full prescribing information for TAMIFLU.

TAMIFLU® (oseltamivir phosphate) capsules  
TAMIFLU® (oseltamivir phosphate) for oral suspension  
Initial U.S. Approval: 1999

**RECENT MAJOR CHANGES**

Indications and Usage (1.3)	2/2016
Dosage and Administration (2.3, 2.4, 2.7)	2/2016
Warnings and Precautions (5.3, 5.4)	2/2016

**INDICATIONS AND USAGE**

TAMIFLU is an influenza neuraminidase inhibitor indicated for:

- Treatment of influenza in patients 1 year and older who have been symptomatic for more than 2 days. (1.1)
- Prophylaxis of influenza in patients 1 year and older. (1.2)

**Important Limitations of Use:**

- Efficacy not established in patients who begin therapy after 48 hours of symptoms. (1.1)
- Not a substitute for annual influenza vaccination. (1.3)
- No evidence of efficacy for illness from agents other than influenza viruses Type A and B. (1.3)
- Consider available information on influenza drug susceptibility patterns and treatment effectiveness when deciding whether to use TAMIFLU. (1.3)

Dosing Forms		NDC Numbers
Oral suspension		NDC 0004- <b>0820</b> -09
How Supplied/Wholesaler Minimum Order		
<p>Supplied as a white powder blend in a glass bottle. After constitution, the powder blend produces a white tutti-frutti-flavored oral suspension. After constitution with 55 mL of water, each bottle delivers a usable volume of 60 mL of oral suspension equivalent to 360 mg oseltamivir base (6 mg/mL). Each bottle is supplied with a bottle adapter and a 10 mL oral dispenser (NDC 0004-0820-09).</p> <p><b>Minimum order:</b> 6mg/mL: 1 carton</p>		
Weight	Dimensions	Storage Information
Case Quantity: 18 Case Weight: 5.6lb approx Cases per Pallet: 80	SKU Dimension: 2.75 x 2.06 x 4.88" Case Dimensions: 12.8 x 8.8 x 6.2"	Store dry powder at 25°C (77°F); excursions permitted to 15° - 30°C (59° - 86°F). Store constituted suspension under refrigeration for up to 17 days at 2° - 8°C (36° - 46°F). Do not freeze. Alternatively, store constituted suspension for up to 10 days at 25°C (77°F); excursions permitted to 15° - 30°C (59° - 86°F). [See USP Controlled Room Temperature]. See full prescribing information.


## Contact Information

Drug Safety/Adverse Events	6:00 AM – 4 PM (PT) M-F, Voice mail available 24/7	888-835-2555
Product Order Fulfillment and Support	6 AM - 5PM (PST) M-F	800-551-2231

## Online Resources

For further information on TAMIFLU, please visit <http://www.tamiflu.com/hcp>

To contact us by phone, please visit <http://www.gene.com/gene/contact/telephone.html> for relevant contact numbers



**Tamiflu**<sup>®</sup>  
oseltamivir phosphate  
*treat. prevent. protect.*

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