

**Subject: Announcing a new strength of TAMIFLU<sup>®</sup> (oseltamivir phosphate) for Oral Suspension and new Emergency Compounding Instructions**

Dear Pharmacist,

**Genentech is pleased to introduce a new strength of TAMIFLU for Oral Suspension 6 mg/mL.** We have changed the concentration from 12 mg/mL to 6 mg/mL and the dispenser from mgs to mLs to help reduce the potential for prescribing and dosing confusion. New emergency compounding instructions to make the 6 mg/mL Oral Suspension concentration from 75 mg capsules are available.

The 12 mg/mL concentration is no longer being manufactured. There are no quality issues with the 12 mg/mL concentration. However, to help reduce overlap between the two different products, Genentech has established a voluntary Take Back Program for unsold Oral Suspension 12 mg/mL (NDC# 0004-0810-95) from July 11 to August 31, 2011. Please contact your distributor for detailed instructions on returning unsold 12 mg/mL TAMIFLU for Oral Suspension and qualifying for the associated credits.

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.

**Important Dispersion Information**

Please verify all TAMIFLU for Oral Suspension prescriptions include the following:

- Dosage (in mL, preferred)
- Concentration (mg/mL): If prescribed concentration differs from available product, please contact the healthcare provider to adjust
- Pharmacists should ensure the units of measure on the prescription instructions match the dosing device

**Updated Dosing Table (Revised March 2011) <sup>1</sup>**

**Treatment and Prophylaxis Dosing of Oral TAMIFLU for Influenza  
For Patients 1 Year of Age and Older Based on Body Weight<sup>†</sup>**

Weight (kg)	Weight (lbs)	Treatment Dosing for 5 days	Prophylaxis Dosing for 10 days <sup>‡</sup>	Volume of Oral Suspension (6 mg/mL) for Each Dose <sup>*</sup>	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 <sup>**</sup>	3 bottles	10 Capsules, 75 mg

<sup>†</sup> 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.

<sup>‡</sup> 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.

<sup>\*</sup> 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.

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

<sup>1</sup> Please see Prescribing Information (enclosed or available at [www.Tamiflu.com/HCP](http://www.Tamiflu.com/HCP))

## New Product Information



**TAMIFLU for Oral Suspension is now only manufactured in a 6 mg/mL concentration.**

This change is accompanied by the following:

- Redesigned carton, including **New Strength** highlighted in a red box and Genentech branding
- New NDC number (0004-0820-09)
- New Oral Dispenser graduated in mLs
- Larger bottle and new closure
- Revised package insert and patient package insert
- New 6 mg/mL emergency compounding instructions<sup>1</sup>

### TAMIFLU in Multiple Formulations<sup>1</sup>

Multiple formulations and mixing options of TAMIFLU provide healthcare providers with options to treat influenza patients:

- For pediatric and adult patients who **can** swallow capsules, the following options are available:
  - 30 mg, 45 mg or 75 mg capsules
- For pediatric and adult patients who **cannot** swallow capsules, the following options are available:
  - TAMIFLU for Oral Suspension 6 mg/mL (commercially manufactured), TAMIFLU 30 mg, 45 mg or 75 mg capsules, opened and mixed with a liquid by caregiver<sup>1</sup>

### Emergency Compounding

If TAMIFLU for Oral Suspension is unavailable, TAMIFLU 75 mg capsules can be compounded into a 6 mg/mL oral suspension by a pharmacist.<sup>1</sup> Compounding is for emergency situations only when the FDA-approved, commercially manufactured TAMIFLU for Oral Suspension is not readily available. The Prescribing Information has been updated with new compounding instructions. Genentech recommends pharmacists / pharmacies ensure they are using the correct Prescribing Information if compounding, and to also update their references with new Prescribing Information.

Please see the enclosed full prescribing information for Tamiflu. Genentech encourages you to become familiar with these prescribing instructions. If you have any questions or require additional information concerning TAMIFLU, please refer to these resources for further details:

- TAMIFLU.com Website:
  - [www.Tamiflu.com/HCP](http://www.Tamiflu.com/HCP) (general information for healthcare providers)
  - [www.Tamiflu.com/OS](http://www.Tamiflu.com/OS) (detailed information on the Oral Suspension)
- Genentech Medical Information/Communications Department: 1-800-821-8590

Genentech will continue to monitor the safety of TAMIFLU through established reporting mechanisms and notify regulatory authorities of any serious adverse events for evaluation. We will continue to provide you with the most current product information for TAMIFLU moving forward. You can assist us in monitoring the safety of TAMIFLU by reporting adverse reactions to us at 1-888-835-2555, by FAX at 1-800-532-3931, or to FDA at [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or by mail to MedWatch, FDA Federal Safety Information and Adverse Event Reporting Program, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852-9787.

Sincerely,

A handwritten signature in black ink, appearing to read 'Hal Barron', with a stylized flourish at the end.

**Hal Barron, MD**

**Executive Vice President, Global Development and Chief Medical Officer  
Genentech, A Member of the Roche Group**

<sup>1</sup> Please see Prescribing Information (enclosed or available at [www.Tamiflu.com/HCP](http://www.Tamiflu.com/HCP))

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## 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. Prescribers should 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%)