

## **EMERGENCY USE AUTHORIZATION of TAMIFLU®: FACT SHEET FOR PATIENTS AND PARENTS**

You have been given TAMIFLU® (oseltamivir phosphate) for either treatment or prevention of novel H1N1 flu virus (Swine Influenza A). You can decide whether to take this drug. Taking TAMIFLU® may help you/your child recover more quickly if you/your child have novel H1N1 flu or help keep you/your child from getting sick if you/your child have been exposed to novel H1N1 flu virus.

### **What is novel H1N1 flu?**

Novel H1N1 (referred to as “swine flu” early on) is a new flu virus causing illness in people. This new virus was first detected in people in the United States in April 2009. Other countries, including Mexico and Canada, have reported people sick with this new virus. This virus is spreading from person-to-person, probably in much the same way that regular seasonal flu viruses spread.

### **What are the symptoms of novel H1N1 flu in humans?**

The symptoms are similar to the symptoms of regular seasonal flu and include fever, cough, sore throat, runny or stuffy nose, body aches, headache, chills and fatigue. Some people, especially children, have reported diarrhea and vomiting associated with novel H1N1 flu. In the past, severe illness (pneumonia and trouble breathing) and deaths have been reported with novel H1N1 flu infection in people. Like seasonal flu, novel H1N1 flu may cause worsening of underlying chronic medical conditions.

### **What is TAMIFLU®?**

TAMIFLU® is a medicine that is approved by the U.S. Food and Drug Administration (FDA) to prevent and treat influenza.

### **Why is TAMIFLU® being used under an Emergency Use Authorization (EUA)?**

An EUA is issued by the FDA to allow certain aspects of TAMIFLU® use during this emergency involving novel H1N1 flu. **For more information**, visit <http://www.cdc.gov/h1n1flu/eua> or <http://www.fda.gov>.

### **How much TAMIFLU® should my child or I take if my child or I have novel H1N1 flu?**

The dose for adults and teenagers 13 years of age and older is 75 mg twice daily for 5 days. For infants and children 1 to 12 years old, dosing by weight is best, but if your child’s weight is not known, age can be used as shown in the table below. Treatment should start as soon as possible after the onset of symptoms and should be taken for 5 days.

<b>Body Weight (kg)</b>	<b>Body Weight (lbs)</b>	<b>Age</b>	<b>Recommended Treatment Dose for 5 Days</b>
Dosing for infants younger than 1 year is not based on weight. Use TAMIFLU® for Oral Suspension (12 mg per mL).		< 3 months	12 mg twice daily
		3-5 months	20 mg twice daily
		6-11 months	25 mg twice daily
≤ 15 kg	≤ 33 lbs	1-2 year	30 mg twice daily
> 15 kg to 23 kg	> 33 lbs to 51 lbs	3-5 years	45 mg twice daily
> 23 kg to 40 kg	> 51 lbs to 88 lbs	6-9 years	60 mg twice daily
> 40 kg	> 88 lbs	10-12 years	75 mg twice daily
Dosing for adults and teenagers 13 years and older is not based on weight.		13 years and older	75 mg twice daily

Tamiflu® for Oral Suspension that is made by Roche Laboratories, Inc., comes with an oral dispenser marked for 30 mg, 45 mg, or 60 mg. For children who weigh more than 40 kg (or 88 lbs) or adults who can’t swallow capsules, you will need to measure out a dose of 30 mg plus another dose of 45 mg. For infants less than 1 year old, a different measuring device must be used that will dispense 2 mL (about 25 mg), 1.6 mL (about 20 mg) or 1 mL (12 mg). If you have any questions about the correct dose for you or your child, please contact your healthcare provider.

**How much TAMIFLU<sup>®</sup> should my child or I take if my child or I have been exposed to novel H1N1 flu?**

Doses for prevention of novel H1N1 flu are the same as those used for treatment as described in the above section, but are given only once a day rather than twice a day. Also, you should continue the medication for 10 days instead of 5 days. If you have any questions about correct doses for you or your child, please contact your healthcare provider.

**What if my child or I cannot swallow capsules?**

For pediatric patients who cannot swallow capsules, especially children less than 1 year old, TAMIFLU<sup>®</sup> for Oral Suspension is preferred. For children 1 year of age or older and adults who cannot swallow capsules, if the oral suspension is not available, the recommended dose of TAMIFLU<sup>®</sup> Capsule may be given by opening the capsule and mixing the powder with sweetened liquids such as regular or sugar-free chocolate syrup.

**What are the possible benefits of taking TAMIFLU<sup>®</sup>?**

If used for treatment, TAMIFLU<sup>®</sup> can benefit by stopping the flu virus from spreading inside the body. This can lead to improved symptoms of flu and quicker recovery. If you have been exposed to someone with the flu, taking TAMIFLU<sup>®</sup> can help keep the virus from making you sick.

**What are the possible side effects from taking TAMIFLU<sup>®</sup>?**

The most common side effects of TAMIFLU<sup>®</sup> are nausea and vomiting. These are not usually severe and usually happen in the first 2 days of treatment. Taking TAMIFLU<sup>®</sup> with food may reduce the chance of getting these side effects. Other events reported commonly by children treated with TAMIFLU<sup>®</sup> included abdominal pain, nosebleeds, ear problems, and pink eye. Side effects for children less than 1 year of age are not known, because there is little information on TAMIFLU<sup>®</sup> use in this age group.

If you develop an allergic reaction or severe rash, stop taking TAMIFLU<sup>®</sup> and contact your healthcare provider.

Children and teenagers with the flu may be at an increased risk of seizures, confusion, or abnormal behavior early during their illness. These events may occur shortly after beginning TAMIFLU<sup>®</sup> or may occur even when flu is not treated. These events are uncommon but may result in accidental injury to the patient. Therefore, children should be observed for signs of unusual behavior and a healthcare provider should be contacted immediately if the patient shows any signs of unusual behavior.

**Is there an alternative treatment?**

Yes. At this time, the Centers for Disease Control and Prevention (CDC) recommends the use of TAMIFLU<sup>®</sup> or RELENZA<sup>®</sup> (zanamivir) for the treatment and/or prevention of infection with novel H1N1 flu.

**What if I decide not to treat myself or my child with TAMIFLU<sup>®</sup>?**

It is your choice whether you or your child are treated with TAMIFLU<sup>®</sup>. You can decide not to take or stop taking it any time. It will not change your regular medical care.

**What if my TAMIFLU<sup>®</sup> for Oral Suspension bottle shows it is expired?**

If you were given a TAMIFLU<sup>®</sup> for Oral Suspension bottle that shows an expired date, you should know that the expiration date may have been extended based on scientific testing done by FDA. If the medicine passes FDA's tests, the expiration date of the medicine can be extended beyond the date originally printed on the bottle. To check on a specific bottle's expiration date, you may look up the lot number at the following website to determine if the lot has been extended and for how long: [www.cdc.gov/h1n1flu/eua](http://www.cdc.gov/h1n1flu/eua). If you have questions or wish to obtain further information, please contact the public health authority who gave you the TAMIFLU<sup>®</sup> for Oral Suspension.

**How do I report side effects with TAMIFLU<sup>®</sup>?**

Call your healthcare provider if you or your child experience side effects that bother you or your child or that do not go away. Report side effects to **FDA MedWatch** at [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.

**How can I learn more?**

If you have questions about your treatment, please refer to [www.cdc.gov/h1n1flu](http://www.cdc.gov/h1n1flu)