

EMERGENCY USE AUTHORIZATION of TAMIFLU®: FACT SHEET FOR PATIENTS AND PARENTS/CAREGIVERS

You have been given TAMIFLU® (oseltamivir phosphate) for either treatment or prevention of 2009 H1N1 flu (used to be called Swine Influenza A or Swine Flu). You can decide whether or not to take this drug. Taking TAMIFLU® may help you or your child recover more quickly if you or your child have 2009 H1N1 flu or help keep you or your child from getting sick if you or your child have been exposed to the 2009 H1N1 flu virus.

What is 2009 H1N1 flu?

The 2009 H1N1 flu is a new flu virus causing illness in people. This new virus was first detected in people in the United States in April 2009. This virus is spreading from person-to-person worldwide, probably in much the same way that regular seasonal flu viruses spread.

What are the signs and symptoms of 2009 H1N1 flu virus in people?

The symptoms include fever, cough, sore throat, runny or stuffy nose, body aches, headache, chills and fatigue. Some people may have diarrhea and vomiting. People may be infected with the flu, including 2009 H1N1 flu, and have respiratory symptoms without a fever. Like seasonal flu, 2009 H1N1 flu may cause worsening of underlying chronic medical conditions like asthma and heart disease. Severe illnesses and death associated with this virus have been reported.

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 TAMIFLU® to be used in more ways during this emergency involving 2009 H1N1 flu. **For more information**, visit www.cdc.gov/h1n1flu/eua/tamiflu.htm or <http://www.fda.gov>.

How much TAMIFLU® should my child or I take if my child or I have 2009 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. For infants less than 1 year old, dosing is based on weight and should be calculated by your health care provider. Treatment should start as soon as possible after the onset of symptoms and should be taken for 5 days.

| Body Weight (kg) | Body Weight (lbs) | Age | Recommended Treatment Dose for 5 Days |
|--|--------------------------|--------------------|--|
| Dosing for infants younger than 1 year is preferred to be based on weight. | | < 1 year | Talk to your health care provider. |
| ≤ 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 patients who are prescribed 75 mg per dose and who cannot swallow capsules, you will need to measure out a dose of 30 mg plus another dose of 45 mg using the oral dispenser. TAMIFLU® Capsules also come in child sizes (30 mg and 45 mg) in addition to the adult size (75 mg). If you have any questions about the correct dose for you or your child, please contact your health care provider.

How much TAMIFLU® should my child or I take if my child or I have been exposed to 2009 H1N1 flu?

Doses for prevention of 2009 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 health care 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® for Oral Suspension is preferred. For children less than 1 year old, talk to your health care provider. For children 1 year of age or older and adults who cannot swallow capsules, if the oral suspension is not available, the recommended size TAMIFLU® Capsules may be given by opening the capsule and mixing the powder with sweetened liquids such as regular or sugar-free chocolate syrup. If none of the size Tamiflu capsules recommended for your child are available, a pharmacist can mix up a TAMIFLU® liquid from adult size capsules and show you how to give the correct dose.

What are the possible benefits of taking TAMIFLU®?

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

What are the possible side effects from taking TAMIFLU®?

The most common side effects of TAMIFLU® are nausea and vomiting. These are not usually severe and usually happen in the first 2 days of treatment. Taking TAMIFLU® with food may reduce the chance of getting these side effects. Other events reported commonly by children treated with TAMIFLU® 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® use in this age group.

If you develop an allergic reaction or severe rash, stop taking TAMIFLU® and contact your health care 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® 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 health care 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 either TAMIFLU® or RELENZA® (zanamivir) for the treatment and/or prevention of infection with 2009 H1N1 flu.

What if I decide not to treat myself or my child with TAMIFLU®?

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

What if my TAMIFLU® is expired?

If you were given TAMIFLU® that has an expired date, you should know that FDA has authorized the use of certain lots of expired TAMIFLU®. Based on scientific review, FDA found that some TAMIFLU® may be used past the expiration date printed on the package. If you want to look up the lot number for your TAMIFLU to see if it has been authorized for use past its expiration date, go to <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm154962.htm>. If you have questions or want more information, please contact the public health authority or health care provider who gave you the TAMIFLU®.

How do I report side effects with TAMIFLU®?

Call your health care 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 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/eua/tamiflu.htm.