

Pandemic Influenza: How to Take Oseltamivir to Prevent or Treat Influenza Emergency Use Instructions for Recipients

This document provides instructions on how to use the medicine called **oseltamivir** (pronounced 'osel-TAM-i-veer', also called Tamiflu®) during the current influenza or 'flu' public health emergency. You (or your child) are being offered oseltamivir to prevent or treat the flu. If you are experiencing flu symptoms, the medicine may help you recover more quickly and may reduce the chance of serious illness from flu. Taking this medicine may help prevent you from getting sick if you are exposed to the flu virus. It is your choice whether or not to take the medicine. Read this document to learn the risks and benefits of taking oseltamivir. If you have questions, talk to a doctor or healthcare provider about taking oseltamivir.

What is an influenza pandemic?

An influenza pandemic is the spread of a new influenza A virus worldwide that is very different from current and recently circulating human seasonal influenza A viruses. H7N9 flu is a new flu virus causing severe illness in people. Like seasonal flu, H7N9 spreads from person-to-person and can cause worsening of chronic medical conditions.

What are the signs and symptoms of H7N9 flu virus in people?

People infected with flu, including H7N9 flu, can have symptoms that include fever, cough, sore throat, runny or stuffy nose, body aches, headache, chills and fatigue. Some people may have diarrhea and vomiting. Severe illnesses and death have occurred as a result of illness associated with this virus.

What is oseltamivir?

Oseltamivir is a prescription drug approved by the Food and Drug Administration (FDA) to prevent and treat acute, uncomplicated influenza.

This fact sheet describes how to use oseltamivir for the following:

- Treatment of adults and children of all ages with acute, uncomplicated influenza, including those who have had flu symptoms for more than 48 hours
- Treatment of adults and children of all ages who have complicated illness and/or are hospitalized
- Prevention of influenza in adults and children aged 3 months and older who have been exposed to H7N9 virus, as appropriate

Who should **NOT** take oseltamivir?

Do not take oseltamivir if you or your child have had a previous severe allergic reaction to oseltamivir or any of its ingredients. Tell the healthcare provider if you or your child have kidney problems. Oseltamivir is not recommended for patients with end-stage kidney disease not undergoing dialysis.

How do I take oseltamivir?

Oseltamivir is taken by mouth either as a pill (capsule) or as a liquid (oral suspension) once or twice each day. Follow the instructions from your healthcare provider for how much medicine to take or give your child and for how many days to take the medicine. Oseltamivir is usually taken for 5 days for treatment, but your healthcare provider may recommend taking it longer depending on your or your child's situation. For treatment, start taking the medicine as soon as possible after your symptoms begin.

What is the recommended dose of oseltamivir?

- The dose for adults and teenagers aged 13 years and older is 75 mg twice daily.
- 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. See **Table 1** below for dosing.
- For infants less than 1 year old, dosing is based on weight that will be calculated by your health care provider. If you child's weight is not known, your provider may use the doses as shown in **Table 2** for age-based doses.

Oseltamivir capsules come in 30 mg, 45 mg, 75 mg strength doses, so different members of your family may require different strengths. Do not share capsules with family members. If you have any questions about the correct dose, please contact your healthcare provider.

Dosing Tables for Children:

TABLE 1. Dosages for Children 1–12 years of age (weight-based dosing preferred)

| Child's Weight (lbs) | Age (years) | Treatment Dose for 5 days | Prevention Dose for 5 or 10 days* | Amount of Suspension given for each Dose | |
|----------------------|-------------|---------------------------|-----------------------------------|--|----------------|
| | | | | Milliliters (mL) | Teaspoon (tsp) |
| ≤33 lbs | 1–2 | 30 mg twice daily | 30 mg twice daily | 5 mL | 1 tsp |
| >33–51 lbs | 3–5 | 45 mg twice daily | 45 mg twice daily | 7.5 mL | 1.5 tsp |
| >51–88 lbs | 6–9 | 60 mg twice daily | 60 mg twice daily | 10 mL | 2 tsp |
| > 88 lbs | 10–12 | 75 mg twice daily | 75 mg twice daily | 12.5 mL | 2.5 tsp |

*The number of days to take oseltamivir for prevention of flu will be determined by your doctor or healthcare provider based on your or your child's exposure to flu; you may be instructed to take it for 5 or 10 days.

TABLE 2. Dosages for Infants less than 1 year of age (weight-based dosing preferred)

| Age (months) | Treatment Dose | Prevention Dose | Amount of Suspension given for each Dose | |
|---------------------------------------|-----------------------------|--|---|----------------|
| | | | Milliliters (mL) | Teaspoon (tsp) |
| If child's weight is known | | | | |
| Birth – 2 months | 3 mg/kg dose twice daily | Based on healthcare provider's clinical decision | Follow instructions from your healthcare provider | |
| 3 – 11 months | 3 mg/kg dose twice daily | 3 mg/kg dose twice daily | Follow instructions from your healthcare provider | |
| If child's weight is not known | | | | |
| Birth – 2 months | 12 mg twice daily | Based on healthcare provider's clinical decision | 2 mL | ½ tsp |
| 3 – 5 months | 20 mg twice daily | 20 mg twice daily | 3.3 mL | ⅔ tsp |
| 6 – 11 months | 25 mg twice daily | 25 mg twice daily | 4.1 mL | 1 tsp |

What if my child or I have problems swallowing capsules?

For younger children and adults who cannot swallow capsules, especially children less than 1 year of age, oseltamivir in liquid form (oral suspension) is available. Oseltamivir oral suspension comes with an oral dispenser marked for 30 mg, 45 mg, or 60 mg. For a 75 mg dose, you will need to measure out a dose of 30 mg plus another dose of 45 mg using the oral dispenser. If oseltamivir oral suspensions are not readily available, a pharmacist or healthcare provider can mix up an oseltamivir liquid from adult size capsules. Follow the dosing in the tables below.

For older children and adults who cannot swallow capsules, if the oral suspension is not available, oseltamivir capsule may be given by opening the capsule and mixing the capsule contents with sweetened liquids such as regular or sugar-free chocolate syrup.

What are common side effects of oseltamivir?

The most common side effects of oseltamivir are nausea and vomiting. Nausea and vomiting may be less severe if oseltamivir is taken with food.

What are possible serious side effects of oseltamivir?

Rare cases of allergic reaction and serious skin reactions have occurred. If you develop an allergic reaction or rash, **stop** taking oseltamivir and contact your healthcare provider. Additionally, people with influenza may be at an increased risk for confused thinking, hallucinations, or significant changes in behavior such as irritability, anxiety or reduced awareness of your environment. Talk to your healthcare provider if these symptoms develop. Seek medical care right away (go to the emergency room or call 911) if you experience:

- Closing of the throat or trouble breathing
- Swelling of the lips, tongue or face
- Severe itching or rash, especially hives and wheals (red, swollen bumps on the skin)

What if I am taking other medicines?

Tell your doctor or healthcare provider about any medications you are taking.

What else do I need to know about oseltamivir?

If you are given oseltamivir that has an expired date, please note that FDA is allowing the use of certain lots of oseltamivir beyond the expiration date on the container based on FDA's scientific review. For more information, go to the FDA website at www.fda.gov (search for "oseltamivir expiration").

What other medicines can I take instead of oseltamivir?

There are other FDA-approved medicines like inhaled zanamivir (Relenza®) and peramivir (Rapivab®) to help treat H7N9 flu and a vaccine to help prevent H7N9 flu. Public health officials will tell you if other medicines are available. The risks and benefits of those medicines will be explained in separate instructions.

What if I decide not to take oseltamivir?

It is your choice whether or not to take oseltamivir. The flu can become severe and lead to serious complications such as pneumonia or respiratory failure. Some people have died from the current flu virus. If you choose not to take oseltamivir, your symptoms may last longer and may lead to a more serious illness. Even if you take oseltamivir, there is still a chance that you may get sicker and develop complications from the flu.

What is the overall risk-benefit statement?

Although oseltamivir has some potential and serious side effects, the expected benefit of oseltamivir in helping to treat influenza and reduce the risk of serious complications or death associated with influenza virus A exposure outweighs these risks.

How do I report side effects or medication errors?

Tell your doctor or healthcare provider right away of any side effects or medication errors and report the side effect or error to MedWatch at www.fda.gov/medwatch or 1-800-FDA-1088.

A federal program called the Countermeasures Injury Compensation Program (CICP) may help pay for costs of medical care and other specific expenses of certain people who have been seriously injured by some medicines or vaccines. If you have been injured by oseltamivir used to treat influenza during this emergency, you can learn more about this Program by visiting www.hrsa.gov/cicp or by calling 1-855-266-2427 (toll-free).

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