

Emergency Use Instructions (EUI) Fact Sheet for Recipients and Caregivers: Oseltamivir to Prevent or Treat Novel Influenza A

You are being given a medicine called **oseltamivir** (pronounced 'osel-TAM-i-veer'), also called Tamiflu®, to prevent or treat illness caused by a novel flu. In this fact sheet, novel flu means an infection with a pandemic influenza A virus or novel influenza A virus with pandemic potential. It is your choice whether or not to take oseltamivir. Taking this medicine may help prevent you or your child from getting sick if exposed to a novel flu virus or recover more quickly if experiencing flu symptoms. If you have questions, talk to a doctor or healthcare provider about receiving oseltamivir. This fact sheet provides instructions for the use of oseltamivir for novel flu that go beyond its labeling ([Package Insert](#)) approved by the U.S. Food and Drug Administration (FDA).

What are Emergency Use Instructions (EUI)?

EUI are issued by the Centers for Disease Control and Prevention (CDC) to provide information about certain emergency uses of FDA-approved medical products that may not be included in or that differ in some way from the information provided in the FDA-approved labeling ([Package Insert](#)). EUI consist of a Fact Sheet for Healthcare Providers and a Fact Sheet for Recipients and Caregivers.

Why is CDC issuing EUI for oseltamivir?

Oseltamivir is approved by U.S. FDA for the treatment of acute, uncomplicated illness due to influenza A and B infection in patients 2 weeks of age and older who have been symptomatic for no more than 48 hours. It is also FDA-approved for prophylaxis (prevention) of influenza A and B infection in patients 1 year and older. CDC is issuing EUI to provide information about oseltamivir for treating and preventing novel flu that extend beyond its FDA-approved use, which includes some patients, dosages and durations of oseltamivir use not described in FDA-approved labeling.

What is novel flu?

In this fact sheet, novel flu refers to infection caused by a flu A virus that is different from current and recently circulating human seasonal flu viruses. Novel flu viruses usually circulate among animals. Novel flu viruses, however, can change in such a way that they can infect people more easily and then have the potential to cause a pandemic in certain circumstances. Novel flu has the potential to cause severe illness in people. For more information on novel flu, refer to [H5N1 Bird Flu: Current Situation Summary](#).

What are the signs and symptoms of novel flu in people?

People with novel flu can have symptoms similar to seasonal flu that include fever, cough, sore throat, runny or stuffy nose, body aches, headache, chills, and fatigue. Eye discomfort, redness, and eye discharge can also occur. Some people may have diarrhea and vomiting. Severe illness and death may occur as a result of illness associated with novel flu.

What is oseltamivir and who can receive it?

Oseltamivir is a prescription drug approved by the U.S. FDA as described above under "Why is CDC issuing EUI for oseltamivir". CDC recommends* the following uses of oseltamivir that differ from or go beyond its FDA-approved labeling:

- Initiation of treatment beyond 48 hours after symptom onset.
- Treatment of severely ill hospitalized patients, including longer courses of treatment (such as 10 days) based on clinical judgment.
- Higher total daily dose and flexible duration for post-exposure prophylaxis (PEP). The EUI-recommended dosing regimen, in most cases, is twice daily for 5 or 10 days in people who have had close contact with a patient or animal with novel flu.
- Treatment of newborns under 2 weeks of age.

* The term "recommend" under EUI refers to CDC recommendations that may or may not be the same as the information in the FDA-approved labeling ([Package Insert](#)) for oseltamivir.

- PEP in newborns and infants less than 1 year of age.
- Treatment and PEP dosing regimens for preterm newborns and infants.

Who should NOT take oseltamivir?

Do not take oseltamivir if you have had a previous severe allergic reaction to oseltamivir or any of its ingredients. Oseltamivir is not recommended for patients with end-stage kidney disease who are NOT undergoing dialysis.

What should I tell my healthcare provider before taking oseltamivir?

Before you take oseltamivir, tell your healthcare provider if you:

- have problems swallowing capsules
- have kidney problems
- have any other medical conditions
- are pregnant or plan to become pregnant (available information indicate that oseltamivir does not increase the risk of birth defects)
- are breastfeeding or plan to breastfeed. Oseltamivir can pass into breast milk in small amounts

Tell your healthcare provider about all the medicines you take, including prescription or over-the-counter medicines, vitamins, and herbal supplements.

How do I take oseltamivir?

- Take oseltamivir exactly as your healthcare provider tells you.
- Oseltamivir is taken by mouth either as a pill (capsule) or as a liquid (oral suspension). Under this EUI, oseltamivir should be taken twice each day. Follow the instructions from your healthcare provider for how much medicine to take or to give your child and for how many days.
- Start taking the medicine as soon as possible.
- Oseltamivir capsules come in several dosage strengths, so different members of your family may require different strengths. Do not share capsules with family members, and if you have questions about the correct dose, contact your healthcare provider.
- Take oseltamivir with food or without food. There is less chance of stomach upset if you take oseltamivir with food.
- If you miss a dose of oseltamivir, take it as soon as you remember. If it is 2 hours or less before your next dose, do not take the missed dose. Take your next dose of oseltamivir at your scheduled time. Do not take 2 doses at the same time.

Children and adults unable to swallow capsules:

For children and adults who cannot swallow capsules, especially children less than 1 year of age, oseltamivir oral suspension may be available. Oseltamivir oral suspension comes with an oral dispenser marked for 30 mg, 45 mg, or 60 mg. For 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 the oral suspension is not available, you or a pharmacist or healthcare provider can mix up an oseltamivir liquid using adult-size capsules by opening the capsule and mixing the capsule contents with thick, sweet liquids such as regular or sugar-free chocolate syrup. Refer to [CDC's webpage on Opening and Mixing Oseltamivir Capsules with Liquids if Child Cannot Swallow Capsules](#) and [video instructions on Mixing Tamiflu in Sweet Liquid](#) for more information.

What are common side effects of oseltamivir?

The most common side effects of oseltamivir are nausea, vomiting, headache, and pain. Nausea and vomiting may be less severe if oseltamivir is taken with food. For more information, refer to the FDA-approved labeling ([Package Insert](#)).

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 flu may be at an increased risk of confused thinking, hallucinations, or significant changes in behavior such as irritability, anxiety, or reduced awareness of their environment. Talk to your healthcare provider if these symptoms develop. For more information, refer to the FDA-approved labeling ([Package Insert](#)).

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)

How should I store oseltamivir?

- Keep oseltamivir capsules dry and store at room temperature between 68°F to 77°F (20°C to 25°C). Oseltamivir for oral suspension may be kept in the refrigerator for up to 17 days between 36°F to 46°F (2°C to 8°C) or at room temperature between 68°F to 77°F (20°C to 25°C) for 10 days. Do not freeze.
- Keep oseltamivir out of the reach of children and pets. Call the poison control center if children or pets consume the medicine by accident (1-800-222-1222).

How do I report side effects or medication errors?

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

What is the Countermeasures Injury Compensation Program?

The Countermeasures Injury Compensation Program (CICP) is a federal program that may help pay for costs of medical care and other specific expenses of certain people who have been seriously injured by certain medicines or vaccines, which may include certain oseltamivir products. Generally, a claim must be submitted to the CICP within one (1) year from the date of receiving the medicine. To learn more about this program, visit www.hrsa.gov/cicp or call 1-855-266-2427.

What if the Tamiflu I was given has an expired date?

If you are given Tamiflu (brand name for oseltamivir) that has an expired date, you should know that FDA has determined that certain lots of Tamiflu can be used for up to 20 years beyond their original manufacture date. To see if the Tamiflu that you received is included, look up the lot number for your Tamiflu by going to <https://aspr.hhs.gov/SNS/Pages/Access-to-Influenza-Countermeasure.aspx>. If you have questions or want more information, please contact the public health authority or healthcare provider who gave you the Tamiflu.

What other medicines can I take instead of oseltamivir?

Ask your healthcare provider about FDA-approved alternative medicines that may be available and appropriate for you.

How can I learn more?

- Contact your healthcare provider
- Visit CDC at <https://www.cdc.gov/bird-flu/>
- Contact your local, state, territorial or tribal health department