

Advise the patient to read the FDA-approved patient labeling (Patient Information and Instructions for Use).

Serious Skin/Hypersensitivity Reactions

Advise patients and/or caregivers of the risk of severe allergic reactions (including anaphylaxis) or serious skin reactions. Instruct patients and/or caregiver to stop oseltamivir phosphate and seek immediate medical attention if an allergic-like reaction occurs or is suspected [see *Warnings and Precautions (5.1)*].

Neuropsychiatric Events

Advise patients and/or caregivers of the risk of neuropsychiatric events in oseltamivir phosphate - treated patients with influenza and instruct patients to contact their physician if they experience signs of abnormal behavior while receiving oseltamivir phosphate [see *Warnings and Precautions (5.2)*].

Important Dosing Information

Instruct patients to begin treatment with oseltamivir phosphate as soon as possible from the first appearance of flu symptoms, within 48 hours of onset of symptoms. Similarly, instruct patients to start taking oseltamivir phosphate for prevention as soon as possible after exposure [see *Dosage and Administration (2)*]. Instruct patients to take any missed doses as soon as they remember, except if it is near the next scheduled dose (within 2 hours), and then continue to take oseltamivir phosphate at the usual times.

Influenza Vaccines

Instruct patients that oseltamivir phosphate is not a substitute for receiving an annual flu vaccination. Patients should continue receiving an annual flu vaccination according to guidelines on immunization practices. Because of the potential for oseltamivir phosphate to inhibit replication of live attenuated influenza vaccine (LAIV) and possibly reduce efficacy of LAIV, avoid administration of LAIV within 2 weeks or 48 hours after oseltamivir phosphate administration, unless medically necessary [see *Drug Interactions (7.1)*].

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Manufactured for:

Lupin Pharmaceuticals, Inc.

Baltimore, Maryland 21202

United States

MADE IN INDIA

Revised: August 2020

PATIENT INFORMATION

Oseltamivir Phosphate Capsules USP, for oral use

(OH-sel-TAM-i-vir FOS-fate)

What is oseltamivir phosphate capsule?

Oseltamivir phosphate capsule is a prescription medicine used to:

- treat the flu (influenza) in people 2 weeks of age and older who have had flu symptoms for no more than two days.
- prevent the flu in people who are 1 year of age and older.

It is not known if oseltamivir phosphate capsule is:

- effective in people who start treatment after 2 days of developing flu symptoms.
- effective for the treatment of the flu in people with long-time (chronic) heart problems or breathing problems.
- effective for the treatment or prevention of flu in people who have weakened immune systems (immunocompromised).
- safe and effective for the treatment of the flu in children less than 2 weeks of age.
- safe and effective in the prevention of the flu in children less than 1 year of age.

Oseltamivir phosphate capsule does not treat or prevent illness that is caused by infections other than the influenza virus. Oseltamivir phosphate capsule does not prevent bacterial infections that may happen with the flu.

Oseltamivir phosphate capsule is not recommended for people with end-stage renal disease (ESRD) who are not receiving dialysis.

Oseltamivir phosphate capsule does not take the place of receiving a flu vaccination. Talk to your healthcare provider about when you should receive an annual flu vaccination.

Who should not take oseltamivir phosphate capsule?

Do not take oseltamivir phosphate capsule if you are allergic to oseltamivir phosphate or any of the ingredients in oseltamivir phosphate capsule. **See the end of this leaflet for a complete list of ingredients in oseltamivir phosphate capsule.**

What should I tell my healthcare provider before taking oseltamivir phosphate capsule? Before you take oseltamivir phosphate capsule, tell your healthcare provider if you:

- have problems swallowing oseltamivir phosphate capsule
- have kidney problems
- have any other medical conditions
- are pregnant or plan to become pregnant. Available information indicate that oseltamivir phosphate capsule does not increase the risk of birth defects.
- are breastfeeding or plan to breastfeed. Oseltamivir phosphate 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.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I take oseltamivir phosphate capsule?

- Take oseltamivir phosphate capsule exactly as your healthcare provider tells you to.
- Take oseltamivir phosphate capsule with food or without food. There is less chance of stomach upset if you take oseltamivir phosphate capsule with food.
- If you miss a dose of oseltamivir phosphate capsule, 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 phosphate capsule at your scheduled time. Do not take 2 doses at the same time.
- If oseltamivir phosphate for oral suspension is not available or you cannot swallow oseltamivir phosphate capsules, your healthcare provider or pharmacist may instruct you to open oseltamivir phosphate capsules and mix the capsules contents with sweetened liquids such as chocolate syrup (regular or sugar-free), corn syrup, caramel topping, or light brown sugar (dissolved in water).

If your healthcare provider or pharmacist has instructed you to take oseltamivir phosphate for oral suspension or open your oseltamivir phosphate capsules, read the detailed Instructions for Use at the end of this leaflet. Ask your pharmacist if you have any questions.

What are the possible side effects of oseltamivir phosphate capsule?

Oseltamivir phosphate capsule may cause serious side effects, including:

- **Serious skin and allergic reactions** . Oseltamivir phosphate capsule can cause serious skin and allergic reactions. Stop taking oseltamivir phosphate capsules and get medical help right away if you get any of the following symptoms:
 - skin rash or hives
 - your skin blisters and peels
 - blisters or sores in your mouth
 - itching
 - swelling of your face, eyes, lips, tongue, or throat
 - trouble breathing
 - chest pain or tightness
- **Change in behavior.** People, especially children, who have the flu can develop nervous system problems and abnormal behavior that can lead to death. During treatment with oseltamivir phosphate capsule, tell your healthcare provider right away if you or your child have confusion, speech problems, shaky movements, seizures, or start hearing voices or seeing things that are not really there (hallucinations).

The most common side effects of oseltamivir phosphate capsule when used for treatment of the flu include nausea, vomiting, and headache. The most common side effect of oseltamivir phosphate capsule when used for prevention of the flu include nausea, vomiting, headache, and pain.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all of the possible side effects of oseltamivir phosphate capsule.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. You may also report side effect to Lupin Pharmaceuticals, Inc. at 1-800-399-2561.

How should I store oseltamivir phosphate capsule?

- Store oseltamivir phosphate capsules at room temperature between 68°F to 77°F (20°C to 25°C).
- Safely throw away any unused oseltamivir phosphate capsules that are out of date or no longer needed.

Keep oseltamivir phosphate capsules and all medicines out of the reach of children.

General information about the safe and effective use of oseltamivir phosphate capsules.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use oseltamivir phosphate capsules for a condition for which it was not prescribed. Do not give oseltamivir phosphate capsules to other people, even if they have the same symptoms you have. It may harm them.

If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about oseltamivir phosphate capsules that is written for health professionals.

For more information, go to www.lupinpharmaceuticals.com.

What are the ingredients in oseltamivir phosphate capsules?

Active ingredient: oseltamivir phosphate

Inactive ingredients :

Oseltamivir phosphate capsules: croscarmellose sodium, povidone, pregelatinized starch, sodium stearyl fumarate and talc

30 mg capsule shell: gelatin, iron oxide yellow and titanium dioxide

45 mg capsules shell: gelatin, iron oxide black and titanium dioxide

75 mg capsules shell: gelatin, iron oxide black, iron oxide yellow and titanium dioxide

Imprinting ink: FD & C Blue # 2 Aluminum Lake, propylene glycol and shellac.

This Patient Information has been approved by the U.S. Food and Drug Administration.

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INSTRUCTIONS FOR USE

Oseltamivir Phosphate Capsules USP, for oral use

(OH-sel-TAM-i-vir FOS-fate)

How do I mix the contents of oseltamivir phosphate capsules with sweetened liquids, if directed by my healthcare provider or pharmacist?

You will need:

- the prescribed dose of oseltamivir phosphate capsules
- a small bowl
- sweetened liquid, such as chocolate syrup (regular or sugar-free), corn syrup, caramel topping, or light brown sugar (dissolved in water)

Step 1. Open the contents of the prescribed dose of oseltamivir phosphate capsules into a small bowl.

Step 2. Add a small amount of the sweetened liquid to the capsule contents.

Step 3. Stir the mixture and give the entire dose of oseltamivir phosphate capsules.

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ID#: 264976

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 68180-675-10

Oseltamivir Phosphate Capsules USP

30 mg

Rx only

Bottle of 10 Capsules