

PRODUCT MONOGRAPH

PrTAMIFLU®

oseltamivir capsule

30 mg, 45 mg and 75 mg oseltamivir (as oseltamivir phosphate)

oseltamivir powder for oral suspension

6 mg/mL oseltamivir (as oseltamivir phosphate) when reconstituted

Antiviral Agent

Hoffmann-La Roche Limited
7070 Mississauga Road
Mississauga, Ontario
L5N 5M8

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www.rochecanada.com

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PrTAMIFLU®
oseltamivir phosphate

This leaflet is part III of a three-part "Product Monograph" published when TAMIFLU was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about TAMIFLU. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION**What the flu is:**

The flu, or influenza, is an infection caused by influenza viruses. It is most common in the fall and winter. The flu is highly contagious. The virus usually enters the body through the mouth, nose or eyes. When a person with the flu coughs or sneezes, the virus becomes airborne and can be inhaled by anyone nearby.

Flu occurs in local outbreaks which happen once or twice per year, usually in the winter.

What the difference is between the flu and a cold:

Both the flu and a cold are viral infections and can cause symptoms such as coughing and sore throat. A cold is a minor viral infection of the nose and throat. The flu however is usually more severe, has rapid onset of symptoms, and is associated with higher fever and aches and pains.

What the medication is used for:

TAMIFLU is a prescription medication (a viral neuraminidase inhibitor) used to treat or prevent the onset of flu.

What it does:

TAMIFLU works by inhibiting an enzyme necessary for the flu virus to spread through your body.

In two large clinical treatment trials, flu patients who took TAMIFLU recovered 1.3 days (30%) faster than flu patients who did not take TAMIFLU. TAMIFLU should also alleviate your symptoms, and help you feel better soon.

In a large clinical trial for prevention of flu in families with children 13 years and older, TAMIFLU,

started within 2 days of the first family member getting sick and taken for 7 days, prevented over 90% of the flu illnesses in the rest of the family.

When TAMIFLU should not be used:

- Do not use TAMIFLU if you are allergic or sensitive to oseltamivir phosphate or any ingredient in this formulation (See "What the non-medicinal ingredients are")
- TAMIFLU should not be used in children under 1 year of age.

What the medicinal ingredient is:

TAMIFLU is available as capsules containing 30 mg, 45 mg or 75 mg of the active ingredient oseltamivir as oseltamivir phosphate.

The oral suspension contains 6 mg/mL of the active ingredient oseltamivir as oseltamivir phosphate.

What the non-medicinal ingredients are:

TAMIFLU capsules contain the following non-medicinal ingredients: corn starch, croscarmellose sodium, gelatin, iron oxides, povidone K 30, sodium stearyl fumarate, talc, titanium dioxide and FD&C Blue No. 2.

TAMIFLU oral suspension contains the following non-medicinal ingredients: monosodium citrate, saccharin sodium, sodium benzoate, sorbitol, titanium dioxide, tutti-frutti flavoring and xanthan gum.

What dosage forms it comes in:*30 mg, 45 mg and 75 mg capsules*

TAMIFLU 30 mg capsules are available as light yellow capsules with "Roche" printed in blue ink on one side and "30 mg" printed in blue ink on the other.

TAMIFLU 45 mg capsules are available as grey capsules with "Roche" printed in blue ink on one side and "45 mg" printed in blue ink on the other.

TAMIFLU 75 mg capsules are available as a grey/light-yellow capsule with "Roche" printed in blue ink on one side and "75 mg" printed in blue ink on the other.

6 mg/mL suspension

TAMIFLU is also available as a liquid suspension (liquid form with a dosing dispenser called oral suspension). The suspension will be prepared by your pharmacist and will be a thick white fruit-flavored liquid.

WARNINGS AND PRECAUTIONS

BEFORE you use TAMIFLU talk to your doctor or pharmacist if:

- you ever had a bad reaction to oseltamivir phosphate (TAMIFLU) or any of the inactive ingredients
- you have hereditary fructose intolerance, as the TAMIFLU oral suspension contains sorbitol and you should not use the suspension if you have this condition
- you are allergic to other medicines, food and dyes
- you are taking any other medicines, including those not prescribed by your doctor
- you have any type of kidney disease
- you are pregnant, plan on becoming pregnant, breast-feeding or planning to breast-feed.

This information will help your doctor and you decide whether you should use TAMIFLU and what extra care may need to be taken while you are on the medicine.

INTERACTIONS WITH THIS MEDICATION

Tell your doctor about all medications (prescription and non-prescription) that you are taking, or plan on taking.

PROPER USE OF THIS MEDICATION

Your doctor has prescribed TAMIFLU after diagnosing your flu condition. Other people may not benefit from taking this medicine, even though their problems may seem similar to yours. Do not give your TAMIFLU to anyone else.

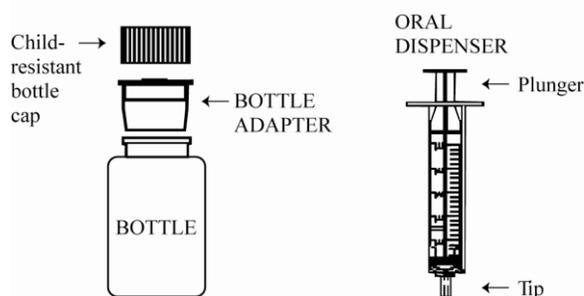
TAMIFLU is not a substitute for the flu shot. If you are at high risk of developing complications, you should continue to get your flu shot as recommended by your doctor. You might be surprised to find that you are still susceptible to flu even though you got your annual flu shot.

Treatment with TAMIFLU (adults, adolescents and children (≥ 1 year))

Treatment with TAMIFLU should begin **no more than two days** after flu symptoms have started to appear. Typical symptoms of flu include sudden onset of fever, headache, tiredness, muscular weakness, runny or stuffy nose, sore throat and cough.

Usual dose:

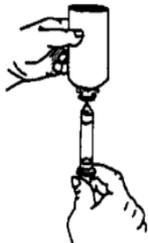
- TAMIFLU should be taken twice daily (once in the morning and once in the evening) for five days.
- It is important that you begin your treatment with TAMIFLU as soon as possible from the first appearance of your flu symptoms. If flu symptoms, most notably fever, do not begin to improve in the first day or two after you start your treatment with TAMIFLU, speak with your doctor.
- TAMIFLU can be taken with food. As with many medicines, if taken with a light snack, milk, or a meal, possible stomach upset may be reduced.
- You must complete the entire treatment recommended by your doctor, even if you are feeling better.
- Take this medicine only as directed by your doctor. Do not take more of it, do not take it more often, and do not take it for a longer time than prescribed by your doctor. Never share TAMIFLU with anyone, even if they have the same symptoms.
- If your doctor has prescribed TAMIFLU liquid suspension, follow the directions below to ensure proper dosing.



1. Shake closed bottle well for about 5 seconds before each use.
2. Remove child-resistant cap.
3. Before inserting the tip of the dispenser into bottle adapter, push

the plunger completely down toward the tip of the dispenser. Insert tip firmly into opening of the bottle adapter.

4. Turn the entire unit (bottle and dispenser) upside down.
5. Pull the plunger out slowly until the desired amount of medication is withdrawn into the dispenser (see figure).



6. Turn the entire unit right side up and remove the oral dispenser slowly from the bottle.
7. Dispense directly into mouth.
8. Close bottle with child-resistant cap after each use.
9. Disassemble oral dispenser, rinse under running tap water and air dry prior to next use.

Emergency Home Preparation of an Oral Suspension from TAMIFLU Capsules:

When TAMIFLU oral suspension is not available, and if directed by your doctor or pharmacist, you may mix the contents of TAMIFLU capsules with sweetened liquids to prepare an oral suspension for children, immediately before dosing.

Please follow your doctor's (pharmacist's) instructions carefully to ensure proper dosing:

- Holding one capsule over a small bowl, carefully pull the capsule open and pour the complete contents of the capsule into the bowl.
- Add a small amount of a sweetened liquid such as chocolate syrup (regular or sugar-free) that the child will consume completely.
- Stir the mixture and give the entire dose to the child.

- Rinse the bowl with a bit of sweetened liquid and administer the rinse to the child.

Prevention with TAMIFLU (adults, adolescents and children (≥ 1 year))

Therapy should begin **within 2 days** after coming into contact with someone with flu symptoms. Typically, about one in ten get the flu during an outbreak, although this varies. If someone close to you (like someone living in your home) has the flu your chance of getting it yourself is higher (around one in five).

Usual dose:

- TAMIFLU should be taken once daily for 10 days or longer as recommended by your doctor if you have contacted someone who has flu. It is important that you begin your treatment with TAMIFLU as soon as possible after you are exposed.
- TAMIFLU can be taken with food. As with many medicines, if taken with a light snack, milk, or a meal, possible stomach upset may be reduced.
- The duration of dosing was tailored by your doctor. You must complete the entire course of therapy that your doctor has prescribed for you.
- Take this medicine only as directed by your doctor. Do not take more of it, do not take it more often, and do not take it for a longer time than prescribed by your doctor.

Overdose:

In case of overdose, contact a healthcare practitioner, hospital emergency department or regional poison control centre, even if there are no symptoms.

Missed Dose:

If you forget to take a dose of TAMIFLU take it as soon as possible, then just carry on with the regular times you take your medication. Do not take double the amount if you miss one dose.

If you have missed several doses, inform your doctor and follow the advice given to you. Do not change your dose of TAMIFLU unless instructed to do so by your doctor.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Unwanted effects are possible with all medicines. Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking TAMIFLU.

TAMIFLU is generally well tolerated. The most common/possible unwanted effects are:

- nausea
- vomiting
- abdominal pain
- headache

Taking TAMIFLU with food may reduce possible stomach upset.

Severe skin and hypersensitivity reactions have been reported since the marketing of TAMIFLU. Symptoms of skin reactions include flushing, rash, itching or swelling. Symptoms of hypersensitivity reactions include dizziness or breathing problems.

Cases of liver toxicity have also been reported, symptoms of which include, yellowing of skin or eyes and dark urine.

People with the flu, particularly children and adolescents, may be at an increased risk of seizures, confusion, delirium, hallucinations, agitation, anxiety or other abnormal behaviour early during their illness. These events may occur shortly after beginning TAMIFLU or may occur when flu is not treated. These events are uncommon but may result in self-injury to the patient, sometimes fatal. Therefore, patients should be observed for signs of unusual behaviour and a healthcare professional should be contacted immediately if the patient shows any signs of unusual behaviour.

Some unwanted effects may go away during treatment as your body adjusts to the medicine. If you are concerned about these or any other unexpected effects while on TAMIFLU, talk with your doctor or pharmacist.

This is not a complete list of side effects. For any unexpected effects while taking TAMIFLU, contact your doctor or pharmacist.

HOW TO STORE IT

- Keep this medication out of the reach of children.
- Store away from heat.
- Keep TAMIFLU capsules in their original labeled container at room temperature at 15-25°C and keep them in a dry place.
- Keep TAMIFLU liquid suspension in its original labeled container in a refrigerator at 2-8°C. Do not freeze. The pharmacist will write the date of expiration on the bottle label.
- Do not use this medicine after the expiry date on the package.

This leaflet does not provide all known information about TAMIFLU. If you have any questions or concerns about your treatment, please speak with your doctor or pharmacist.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: **Canada Vigilance Program
Health Canada
Postal Locator 1908C
Ottawa, Ontario
K1A 0K9**

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at: www.rochecanada.com or by contacting the sponsor, Hoffmann-La Roche Limited, at 1-888-762-4388 (Drug Information).

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Oral dosing dispenser manufactured by F. Hoffmann-La Roche Ltd., 4070 Basel, Switzerland (supplied by Baxa Corporation, owned and operated by Baxter Healthcare Corporation).



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