

### **PART III: CONSUMER INFORMATION**

**PrNAT-OSELTAMIVIR**  
oseltamivir phosphate  
30 mg , 45 mg and 75 mg

**This leaflet is part III of a three-part "Product Monograph" published when NAT-OSELTAMIVIR was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about NAT-OSELTAMIVIR. 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:**

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

##### **What it does:**

NAT-OSELTAMIVIR 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 oseltamivir phosphate recovered 1.3 days (30%) faster than flu patients who did not take oseltamivir phosphate. NAT-OSELTAMIVIR 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, oseltamivir phosphate, 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 NAT-OSELTAMIVIR should not be used:**

- Do not use NAT-OSELTAMIVIR if you are allergic or sensitive to oseltamivir phosphate or any ingredient in this formulation (See "What the non-medicinal ingredients are")
- NAT-OSELTAMIVIR should not be used in children < 13 years of age
- NAT-OSELTAMIVIR should not be used for emergency compounding or home preparation of an Oral Suspension.

##### **What the medicinal ingredient is:**

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

##### **What the non-medicinal ingredients are:**

NAT-OSELTAMIVIR capsules contain the following non- medicinal ingredients: pregelatinized starch, croscarmellose sodium, gelatin, iron oxides (red, black and yellow), povidone K 30, sodium stearyl fumarate, talc,

titanium dioxide, shellac, propylene glycol and FD&C Blue No. 2 Aluminum lake.

**What dosage forms it comes in:**

*30 mg, 45 mg and 75 mg capsules*

NAT-OSELTAMIVIR 30 mg capsules are available as white to off white powder filled in size '4' capsules with yellow colour cap imprinted with '30 mg' with blue colour ink and yellow colour body imprinted with 'NAT' with blue colour ink.

NAT-OSELTAMIVIR 45 mg capsules are available as white to off white powder filled in size '4' capsules with grey colour cap imprinted with '45 mg' with blue colour ink and grey colour body imprinted with 'NAT' with blue colour ink.

NAT-OSELTAMIVIR 75 mg capsules are available as white to off white powder filled in size '2' capsules with yellow colour cap imprinted with "75 mg" with blue colour ink and grey colour body imprinted with "NAT" with blue colour ink.

**WARNINGS AND PRECAUTIONS**

**BEFORE you use NAT-OSELTAMIVIR talk to your doctor or pharmacist if:**

- you ever had a bad reaction to oseltamivir phosphate (NAT-OSELTAMIVIR) or any of the non-medicinal ingredients
- 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 NAT-OSELTAMIVIR 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 NAT-OSELTAMIVIR 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 NAT-OSELTAMIVIR to anyone else.

NAT-OSELTAMIVIR 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.

**Note: NAT-OSELTAMIVIR is only available as a 30 mg, 45 mg and 75 mg capsule. NAT-OSELTAMIVIR should not be used for emergency compounding or home preparation of an Oral Suspension.**

**Treatment with NAT-OSELTAMIVIR (adults, adolescents (≥ 13 years))**

Treatment with NAT-OSELTAMIVIR 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:

- NAT-OSELTAMIVIR 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 NAT-OSELTAMIVIR 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 NAT-OSELTAMIVIR, speak with your doctor.
- NAT-OSELTAMIVIR 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 NAT-OSELTAMIVIR with anyone, even if they have the same symptoms.

**Prevention with NAT-OSELTAMIVIR (adults, adolescents (≥ 13 years))**

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:

- NAT-OSELTAMIVIR 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 NAT-OSELTAMIVIR as soon as possible after you are exposed.
- NAT-OSELTAMIVIR 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 NAT-OSELTAMIVIR 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 NAT-OSELTAMIVIR 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 NAT-OSELTAMIVIR.

NAT-OSELTAMIVIR is generally well tolerated. The most common/possible unwanted effects are:

- nausea
- vomiting
- abdominal pain
- headache

Taking NAT-OSELTAMIVIR with food may reduce possible stomach upset.

Severe skin and hypersensitivity reactions have been reported since the marketing of oseltamivir phosphate. 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 NAT-OSELTAMIVIR 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

NAT-OSELTAMIVIR, talk with your doctor or pharmacist.

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

#### **HOW TO STORE IT**

- Keep this medication out of the reach and sight of children.
- Store away from heat.
- Keep NAT-OSELTAMIVIR capsules in their original labeled container at room temperature at 15- 25°C and keep them in a dry place.
- Do not use this medicine after the expiry date on the package

This leaflet does not provide all known information about NAT-OSELTAMIVIR. 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**  
<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>
- **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, ON K1A 0K9**

**Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at <https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>.**

*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 obtained by contacting the sponsor, Natco Pharma (Canada) Inc.: By phone: 1-800-296-9329.

This leaflet was prepared by Natco Pharma (Canada) Inc.

Last revised: January 18, 2018.