

PACKAGE LEAFLET: INFORMATION FOR THE USER

Oseltamivir Capsules 75 mg*
Oseltamivir

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Oseltamivir Capsules 75 mg is and what it is used for
2. Before you take Oseltamivir Capsules 75 mg
3. How to take Oseltamivir Capsules 75 mg
4. Possible side effects
5. How to store Oseltamivir Capsules 75 mg
6. Further information

1. WHAT OSELTAMIVIR CAPSULES 75 MG IS AND WHAT IT IS USED FOR

- Oseltamivir Capsules 75 mg is prescribed to you for treating or preventing influenza.
- Oseltamivir Capsules 75 mg contains oseltamivir, which belongs to a group of medicines named "neuraminidase inhibitors". These medicines prevent the influenza virus from spreading inside the body and so help to ease the symptoms arising from the influenza virus infection, or to prevent infection.
- Influenza is an infection caused by the influenza virus. The signs (symptoms) of influenza include the sudden onset of fever (more than 37.8°C), cough, runny or stuffy nose, headache, muscle ache and – often extreme - fatigue. These symptoms may also be caused by infections other than influenza. True influenza infection primarily occurs during annual outbreaks (epidemics) at times when influenza viruses are spreading in the local community. Outside of the epidemic period, these symptoms will mainly be caused by other infections or illnesses.

2. BEFORE YOU TAKE OSELTAMIVIR CAPSULES 75 MG

Do not take Oseltamivir Capsules 75 mg

- if you are allergic (hypersensitive) to oseltamivir or any of the other ingredients of Oseltamivir Capsules 75 mg.

Take special care with Oseltamivir Capsules 75 mg

Before you take Oseltamivir Capsules 75 mg, make sure your prescribing doctor knows if you

- are allergic to other medicines
- have problems with your kidneys.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Oseltamivir Capsules 75 mg can be taken with paracetamol, ibuprofen or acetylsalicylic acid (Aspirin). Oseltamivir Capsules 75 mg is not expected to alter the effect of any other medicines.

* *Trade names are not prequalified by WHO. This is under local DRA responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

Oseltamivir capsules 75 mg is not a substitute for influenza vaccination. Oseltamivir Capsules 75 mg will not change the effectiveness of the influenza vaccine. Even if a vaccination against influenza has been given to you Oseltamivir Capsules 75 mg may be prescribed by your doctor.

Taking Oseltamivir Capsules 75 mg with food and drink

Swallow Oseltamivir Capsules 75 mg with water. Oseltamivir Capsules 75 mg can be taken with or without food, although it is recommended to take oseltamivir with food to reduce the risk of feeling or being sick (nausea or vomiting).

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

The possible effects of oseltamivir on unborn children are unknown. You must tell your doctor if you are pregnant, if you think you are pregnant or if you are trying to get pregnant so that your doctor can decide if Oseltamivir Capsules 75 mg is right for you.

The effects on nursing infants are unknown. You must tell your doctor if you are breast-feeding so that your doctor can decide if Oseltamivir Capsules 75 mg is right for you.

Driving and using machines

Oseltamivir has no effect on your ability to drive or use machines.

3. HOW TO TAKE OSELTAMIVIR CAPSULES 75 MG

Always take Oseltamivir Capsules 75 mg exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Take Oseltamivir Capsules 75 mg as soon as you get the prescription, as this will help to slow the spread of the influenza virus in the body.

Swallow Oseltamivir Capsules 75 mg whole with water. Do not break or chew Oseltamivir Capsules 75 mg.

The usual dose is as follows:

Treatment

Adolescents (13 to 17 years of age) and adults: For treatment of influenza take one capsule as soon as you get the prescription and then take one capsule twice a day (usually it is convenient to take one in the morning and one in the evening for five days). It is important to complete the whole 5-day course, even if you start to feel better quickly.

Children weighing more than 40 kg, who are able to swallow capsules, may take Oseltamivir Capsules 75 mg twice daily for 5 days.

Children 1 year of age and older weighing up to 40 kg: If available, other formulations such as oral suspension or capsules containing less oseltamivir should be used (see paragraph “When oseltamivir oral suspension or tablets containing less oseltamivir are not available”).

Prevention

Oseltamivir Capsules 75 mg can also be used for prevention of influenza following exposure to an infected individual, such as a family member.

Adolescents (13 to 17 years of age) and adults: When used to prevent influenza following contact with an infected individual, such as a family member, Oseltamivir Capsules 75 mg should be taken once daily for 10 days. It is best to take this dose in the mornings with breakfast.

Children weighing more than 40 kg, who are able to swallow capsules, may take Oseltamivir Capsules 75 mg once daily for 10 days.

Children 1 year of age and older weighing up to 40 kg: If available, other formulations such as oral suspension or capsules containing less oseltamivir should be used (see paragraph “When oseltamivir oral suspension or tablets containing less oseltamivir are not available”).

In special situations the doctor may decide that one continues to take Oseltamivir Capsules 75 mg for longer than 10 days, if it is prescribed to prevent influenza.

Children 1 year of age or younger:

Use of Oseltamivir Capsules 75 mg is generally not recommended.

When oseltamivir oral suspension or tablets containing less oseltamivir are not available

In situations when commercially manufactured oral suspension or capsules containing less oseltamivir are not readily available, adults, adolescents or children who are unable to swallow capsules may receive appropriate doses of oseltamivir by following the instructions below.

For patients requiring a 75 mg single dose, follow these instructions:

What you need:

- a small bowl
- a teaspoon
- a sweetened product (such as regular or sugar-free chocolate syrup, honey (only for children two years or older), light brown or table sugar dissolved in water, dessert toppings, sweetened condensed milk, apple sauce **or** yogurt)
- water (room temperature).

1. Hold one Oseltamivir Capsule 75 mg over a small bowl. Then, carefully pull the capsule open by taking off the yellow colour cap of the capsule shell from the white part.
2. Pour the powder into the bowl. Make sure that the capsule shell is entirely emptied into the bowl.
3. Add 1 teaspoon of a sweetened food product (for details on the type of food see list above) to the bowl and mix well. This is for masking the bitter taste.
4. Give the entire contents of the bowl to the patient. The mixture must be swallowed immediately after its preparation. If there is some mixture left inside the bowl, rinse the bowl with a small amount of water and have the patient drink this remaining mixture.
5. Thoroughly rinse the teaspoon and the bowl for the next use.

Repeat this procedure every time you need to take the medicine.

For patients requiring a 30 – 60 mg single dose, follow these instructions to ensure proper dosing:

What you need:

- a 5 ml syringe with markings (called “graduated”)
- three small bowls (best if about 4 to 5 cm in diameter and about 3 to 4 cm in height)
- a teaspoon
- a sweetened product (such as regular or sugar-free chocolate syrup, honey (only for children two years or older), light brown or table sugar dissolved in water, dessert toppings, sweetened condensed milk, apple sauce **or** yogurt)
- water (room temperature).

Make sure to follow all the steps (1-11):

1. Fill one of the bowls (bowl 1) with water.
2. Hold one Oseltamivir Capsule 75 mg over another bowl (bowl 2). Then, carefully pull the capsule open by taking off the yellow colour cap of the capsule shell from the white part.
3. Pour the powder into this bowl. Make sure that the capsule shell is entirely emptied into the bowl.
4. Draw up 5 ml of water from bowl 1 into the syringe.
5. Add this water to the powder in bowl 2 by slowly pushing down the plunger of the syringe to empty its entire contents.

6. Stir for about two minutes. This can be done with the syringe or with a teaspoon. The teaspoon should be rinsed to remove remaining mixture from its surface before using it for step 9.
7. Draw up into the syringe the correct amount of mixture from the bowl. This amount is based upon the patient's weight. Details are given in the tables below.

Note: It is not necessary to draw up any undissolved white powder, as this is inert material.

Dose recommendation for treatment of influenza

Body Weight	Recommended dose for 5 days	Amount of Oseltamivir Capsules 75 mg mixture for one dose
Less than or equal to 15 kg	30 mg twice daily	2 ml
More than 15 kg and up to 23 kg	45 mg twice daily	3 ml
More than 23 kg and up to 40 kg	60 mg twice daily	4 ml

Dose recommendation for prevention of influenza

Body Weight	Recommended dose for 10 days	Amount of Oseltamivir Capsules 75 mg mixture for one dose
Less than or equal to 15 kg	30 mg once daily	2 ml
More than 15 kg and up to 23 kg	45 mg once daily	3 ml
More than 23 kg and up to 40 kg	60 mg once daily	4 ml

8. Push down the plunger of the syringe to empty its entire contents into a third bowl (bowl 3).
9. Add one teaspoon of a sweetened food product (for details on the type of food see list above) into bowl 3 and mix well. This is for masking the bitter taste.
10. Give the entire contents of the bowl 3 to the patient. This mixture must be swallowed immediately after its preparation. If there is some mixture left inside this bowl, rinse the bowl with a small amount of water and have the patient drink this remaining mixture.
11. Discard any unused mixture of bowl 2. Rinse the syringe by drawing up some of the remaining water. Empty all bowls, rinse the devices thoroughly and keep them for the next use.

Repeat this procedure every time you need to take the medicine.

If you take more Oseltamivir Capsules 75 mg than you should

Contact your doctor, health care provider or pharmacist immediately.

If you have forgotten to take Oseltamivir Capsules 75 mg

Do not take a double dose to make up for a forgotten capsule.

If you stop taking Oseltamivir Capsules 75mg

There are no side effects when Oseltamivir Capsules 75 mg is discontinued prior to advice from your doctor. If Oseltamivir Capsules 75 mg is stopped earlier than your doctor told you, the symptoms of influenza may reoccur.

If you have any further questions on the use of this product, ask your doctor, health care provider or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Oseltamivir Capsules 75 mg can cause side effects, although not everybody gets them.

- Common side effects of Oseltamivir Capsules 75 mg

The most common side effects of Oseltamivir Capsules 75 mg are nausea, vomiting, diarrhoea, stomach ache and headache. These side effects mostly occur only after the first dose of the medicine and will usually stop as treatment continues. The frequency of these effects is reduced if Oseltamivir Capsules 75 mg is taken with food.

- Less common side effects of Oseltamivir Capsules 75 mg

In adults and adolescents (children aged 13 years and older)

Other side effects, which may also be caused by influenza, are upper abdominal fullness, bleeding in the gastrointestinal tract, bronchitis, upper respiratory tract infections, dizziness, tiredness, sleeping difficulties, skin reactions, mild to severe liver function disorders, visual disturbances and heart rhythm abnormalities.

Influenza can be associated with a variety of neurologic and behavioural symptoms, which can include events such as hallucinations, delirium and abnormal behaviour, in some cases resulting in fatal outcomes. These events may occur in the setting of inflammation of the brain due to influenza, but can occur without obvious severe disease.

During oseltamivir treatment, events like convulsions and delirium (including symptoms such as altered level of consciousness, confusion, abnormal behaviour, delusions, hallucinations, agitation, anxiety, nightmares) have been reported, in a very few cases resulting in accidental injury, in some instances with a fatal outcome. These events were reported primarily among children and adolescents and often had an abrupt onset and rapid resolution. The contribution of oseltamivir to those events is unknown. Such neuropsychiatric events have also been reported in patients with influenza who were not taking oseltamivir.

In children (aged 1 to 12 years)

The following additional less common side effects, which may also be caused by influenza, were observed in children (aged 1 to 12 years): ear inflammation, inflammation of the lungs, sinusitis, bronchitis, aggravation of pre-existing asthma, nose bleeding, ear disorders, inflammation of the skin, swelling of the lymph nodes, conjunctivitis, visual disturbances and heart rhythm abnormalities.

If you or your child is often sick, you should inform your doctor. You should also tell your doctor, if the influenza symptoms get worse or the fever continues.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, tell your doctor, health care provider or pharmacist.

5. HOW TO STORE OSELTAMIVIR CAPSULES 75 MG

Keep out of the reach and sight of children.

Do not use Oseltamivir Capsules 75 mg after the expiry date which is stated on the carton, bottle label and blister . The expiry date refers to the last day of that month.

Store below 25°C.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Oseltamivir capsules 75 mg contains

- The active substance is oseltamivir (as phosphate).
- The other ingredients are:
capsule contents: Croscarmellose sodium, pregelatinised starch, sodium stearyl fumarate, talc.
capsule shell: Gelatin, iron oxide yellow, titanium dioxide.
printing ink: Shellac, black iron oxide and propylene glycol.

What Oseltamivir Capsules 75 mg looks like and contents of the pack

Oseltamivir Capsules 75 mg are white to off-white free flowing powder filled in size “2” hard capsules having white body spin printed with “75mg” and yellow colour cap. Imprints are black.

- White, induction-sealed, 50 ml HDPE bottles fitted with child-resistant closures and containing a silica gel bag desiccant. The HDPE bottles are kept in a carton box. Pack size: 30 capsules.
- Carton box containing 10 capsules in a blister pack (clear PVC/PE/PVDC film, sealed with aluminium foil).

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For any information about this medicinal product, please contact the supplier

This leaflet was last approved in June 2009

Detailed information on this medicine is available on the World Health Organization (WHO) web site:
<http://www.who.int/prequal/> .