

PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER
Oseltamivir (as phosphate) 75mg Capsules*
Oseltamivir

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

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

What is in this leaflet:

1. What Oseltamivir (as phosphate) 75mg Capsules is and what it is used for
2. What you need to know before you take Oseltamivir (as phosphate) 75mg Capsules
3. How to take Oseltamivir (as phosphate) 75mg Capsules
4. Possible side effects
5. How to store Oseltamivir (as phosphate) 75mg Capsules
6. Contents of the pack and other information

1. What Oseltamivir (as phosphate) 75mg Capsules is and what it is used for

- Oseltamivir (as phosphate) 75mg Capsules is used for adults, adolescents, infants and children 1 year old and older.
- Oseltamivir (as phosphate) 75mg Capsules is prescribed to you for **treating flu** (*influenza*). It can be used when you have flu symptoms, and the flu virus is known to be circulating in your community. Other times it may be used as listed below.
 - Oseltamivir (as phosphate) 75mg Capsules is prescribed for **preventing flu**. It can be used if you have been in contact with someone who has flu. This is generally decided on a case-by-case basis.
 - Oseltamivir (as phosphate) 75mg Capsules is prescribed as **preventive treatment** in exceptional cases. For example, it can be used when the seasonal flu vaccine may not provide sufficient protection and when there is a flu pandemic (global epidemic of flu).
- **During a flu pandemic, Oseltamivir (as phosphate) 75mg Capsules can also be used to treat or prevent flu in babies below 1 year of age.** Doctors should make decisions on whether to use {product name} in babies of this age, based on the severity of the disease caused by the flu virus and the baby's state of health, to ensure that the baby is likely to benefit from the medicine.
- Oseltamivir (as phosphate) Capsules contains oseltamivir, which belongs to a group of medicines named *neuraminidase inhibitors*. These medicines prevent the flu virus from spreading inside the body. They help to ease or prevent the symptoms of the flu virus infection.
- Influenza, usually called flu, is an infection caused by a virus. The signs of flu often include a sudden fever (more than 37.8 °C), cough, runny or stuffy nose, headaches, muscle aches and extreme tiredness. These symptoms can also be caused by other infections. True influenza infection only occurs during annual outbreaks (*epidemics*) when flu viruses are spreading in the local community. Outside epidemic periods, flu-like symptoms are usually caused by a different type of infection or illness.

* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

2. What you need to know before you take Oseltamivir (as phosphate) 75mg Capsules

Do not take Oseltamivir (as phosphate) 75mg Capsules

- if you are allergic (hypersensitive) to oseltamivir or any of the other ingredients of Oseltamivir (as phosphate) 75mg Capsules listed in section 6.

Warnings and precautions

Before you take Oseltamivir (as phosphate) 75mg Capsules, make sure your prescribing doctor knows

- if you are allergic to other medicines
- if you have problems with your kidneys. If so, your dose may need adjustment.
- if you have a severe medical condition, which may require immediate hospitalisation
- if your immune system is not working
- if you have chronic heart disease or respiratory disease.

During treatment with Oseltamivir (as phosphate) 75mg Capsules, tell your prescribing doctor

- if you notice changes in behaviour or mood (*neuropsychiatric events*), especially in children and adolescents).

Oseltamivir (as phosphate) 75mg Capsules is not a flu vaccine

Oseltamivir (as phosphate) 75mg Capsules is not a vaccine: it treats infection, or prevents the flu virus spreading. A vaccine gives you antibodies against the virus. Oseltamivir (as phosphate) 75mg Capsules will not change the effectiveness of a flu vaccine, and you might be prescribed both by your doctor.

Other medicines and Oseltamivir (as phosphate) 75mg Capsules

Tell your doctor or pharmacist if you are taking any other medicines, or have recently taken any. This includes medicines obtained without a prescription. The following medicines are particularly important:

- chlorpropamide (used to treat diabetes)
- methotrexate (used to treat e.g. rheumatoid arthritis)
- phenylbutazone (used to treat pain and inflammation)
- probenecid (used to treat gout)

Pregnancy and breast-feeding

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 (as phosphate) 75mg Capsules is right for you. The effects on breastfed infants are unknown. You must tell your doctor if you are breast-feeding so that your doctor can decide if Oseltamivir (as phosphate) 75mg Capsules is right for you. Ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Oseltamivir (as phosphate) 75mg Capsules has no effect on your ability to drive or use machines.

3. How to take Oseltamivir (as phosphate) 75mg Capsules

Take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Take Oseltamivir (as phosphate) 75mg Capsules as soon as possible, ideally within the first two days of the start of flu symptoms.

The recommended doses

For treating flu, take two doses daily. It is usually convenient to take one dose in the morning and one in the evening. **It is important to complete the whole 5-day course**, even if you start to feel better quickly.

For preventing flu or after being exposed to an infected person, take one dose daily for 10 days. It is best to take this in the mornings with breakfast.

In special situations, such as widespread flu and for patients with a weak immune system, treatment will continue for up to 6 weeks or 12 weeks.

Oseltamivir oral suspension can be used by people who find it hard to take capsules.

You must use the amount of oral suspension prescribed by the doctor.

The recommended dose is based on the patient's body weight.

Adults and adolescents 13 to 17 years old

Body weight	Treating flu: dose for 5 days	Preventing flu: dose for 10 days
40 kg or more	75 mg twice daily	75 mg once daily

75 mg can be made up of a 30 capsule plus a 45 mg capsule

Children 1 to 12 years old

Body weight	Treating flu: dose for 5 days	Preventing flu: dose for 10 days
10 to 15 kg	30 mg twice daily	30 mg once daily
More than 15 kg and up to 23 kg	45 mg twice daily	45 mg once daily
More than 23 kg and up to 40 kg	60 mg twice daily	60 mg once daily
More than 40 kg	75 mg twice daily	75 mg once daily

75 mg can be made up of a 30 mg capsule plus a 45 mg capsule

Infants less than 1 year old

Giving Oseltamivir (as phosphate) 75mg Capsules to infants less than 1 year old should be based upon the judgment of a doctor after considering the potential benefit versus any potential risk to the infant.

Only limited data is available for infants less than 2 years old, and no data for infants less than 1 month old. *See following table.*

Age	Treating flu: dose for 5 days	Preventing flu: dose for 10 days
3 to 12 months	3 mg/kg twice daily	3 mg/kg once daily
1 to 3 months	2.5 mg/kg twice daily	2.5 mg/kg once daily
0 to 1 month	2 mg/kg twice daily	2 mg/kg once daily

mg/kg = mg per kilogram of infant body weight

Method of administration

Swallow the capsules whole with water. Do not break or chew the capsules.

Oseltamivir (as phosphate) 75mg Capsules can be taken with or without food, although taking it with food can reduce the chance of feeling or being sick (nausea or vomiting).

If you need oseltamivir as a liquid (oral suspension) but it's not available, you can make an oseltamivir suspension from these capsules. **See *Making oseltamivir suspension at home for instructions.***

If you take more Oseltamivir (as phosphate) 75mg Capsules than you should

Stop taking Oseltamivir (as phosphate) 75mg Capsules and contact your doctor, pharmacist or healthcare provider immediately.

In most cases of overdose, people have not reported any side effects. When side effects were reported, they were similar to those from normal doses, as listed in section 4.

If you forget to take Oseltamivir (as phosphate) 75mg Capsules

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

If you stop taking Oseltamivir (as phosphate) 75mg Capsules

There are no side effects when you stop Oseltamivir (as phosphate) 75mg Capsules. But if Oseltamivir (as phosphate) 75mg Capsules is stopped earlier than your doctor told you, the symptoms of flu may come back.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or healthcare provider.

4. Possible side effects

Like all medicines, Oseltamivir (as phosphate) 75mg Capsules can cause side effects, although not everybody gets them. Many of the side effects listed below may also be caused by influenza.

The following serious side effects have been rarely reported since oseltamivir has been marketed:

- Anaphylactic and anaphylactoid reactions: severe allergic reactions, with face and skin swelling, itchy rashes, low blood pressure and breathing difficulties
- Hepatic disorders (fulminant hepatitis, hepatic function disorder and jaundice): yellowing of the skin and white of the eyes, change in stool color, changes in behaviour
- Angioneurotic oedema: sudden onset of severe swelling of the skin mainly around the head and neck area, including eyes and tongue, with difficulties breathing
- Stevens-Johnson syndrome and toxic epidermal necrolysis: complicated, possibly life-threatening allergic reaction, severe inflammation of the outer and possibly inner skin, initially with fever, sore throat, and fatigue, skin rashes, leading to blisters, peeling, shedding of larger areas of skin, possible breathing difficulties and low blood pressure
- Gastrointestinal bleeding: prolonged bleeding from the large bowel or spitting up blood
- Neuropsychiatric disorders, as described below.

If you notice any of these symptoms, get medical help immediately.

The most frequently (very common and common) reported side effects of oseltamivir are feeling or being sick (nausea, vomiting), stomach ache, stomach upset, headache and pain. These side effects mostly occur after the first dose of the medicine and will usually stop as treatment continues. The frequency of these effects is reduced if the medicinal product is taken with food.

Rare but serious effects: get medical help at once

(These may affect up to 1 in 1,000 people)

During oseltamivir treatment, rare events have been reported that include

- Convulsions and delirium, including altered level of consciousness
- Confusion, abnormal behaviour
- Delusions, hallucinations, agitation, anxiety, nightmares

These are reported primarily among children and adolescents and often started suddenly and resolved rapidly. A few cases resulted in self-injury, some with fatal outcome. Such neuropsychiatric events have also been reported in patients with influenza who were not taking oseltamivir.

- Patients, especially children and adolescents, should be closely monitored for the behavioural changes described above.
- **If you notice any of these symptoms, especially in younger people, get medical help immediately.**

Adults and adolescents 13 to 17 years old

Very common: may affect more than 1 in 10 people

- Headache
- Nausea.

Common: may affect up to 1 in 10 people

- Bronchitis
- Cold sore virus
- Cough
- Dizziness
- Fever
- Pain
- Pain in limb
- Runny nose
- Sleeping difficulties
- Sore throat
- Stomach ache
- Tiredness
- Upper abdominal fullness
- Upper respiratory tract infections (inflammation of the nose, throat and sinuses)
- Upset stomach
- Vomiting.

Uncommon: may affect up to 1 in 100 people

- Allergic reactions
- Altered level of consciousness
- Convulsion
- Heart rhythm abnormalities
- Mild to severe liver function disorders
- Skin reactions (inflammation of the skin, red and itchy rash, scaling skin).

Rare: may affect up to 1 in 1,000 people

- Thrombocytopenia (low platelet count)
- Visual disturbances.

Children 1 to 12 years old

Very common: may affect more than 1 in 10 people

- Cough
- Nasal congestion
- Vomiting.

Common: may affect up to 1 in 10 people

- Conjunctivitis (red eyes and discharge or pain in the eye)
- Ear inflammation and other ear disorders
- Headache
- Nausea
- Runny nose
- Stomach ache
- Upper abdominal fullness
- Upset stomach.

Uncommon: may affect up to 1 in 100 people

- Inflammation of the skin
- Tympanic membrane (eardrum) disorder.

Infants 1 to 12 months old

The reported side effects in infants 1 to 12 months old are similar to the side effects reported for older children (1 year old or older).

Infants 0 to 1 months old

There is no information available for the use of oseltamivir in infants less than 1 month old.

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

- **if you or your child are repeatedly sick, or**
- **if the influenza symptoms get worse or the fever continues**

Tell your doctor as soon as possible.

5. How to store Oseltamivir (as phosphate) 75mg Capsules

Keep out of the sight and reach of children.

Do not use Oseltamivir (as phosphate) 75mg Capsules after the expiry date which is stated on the carton and blister. The expiry date refers to the last day of that month.

Store below 30°C. Protect from light and moisture.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist or healthcare provider how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Oseltamivir (as phosphate) 75mg Capsules contains

- Each hard capsule contains oseltamivir equivalent to 75 mg of oseltamivir.
- The other ingredients are

Capsule content: Croscarmellose sodium
Povidone
pre-gelatinised starch
sodium stearyl fumarate
talc

Capsule shell: Gelatin
iron oxide (red and yellow)
titanium dioxide.

Printing ink: Iron oxide black
potassium hydroxide
shellac

What Oseltamivir (as phosphate) 75mg Capsules look like and contents of the pack

Oseltamivir (as phosphate) 75mg Capsules are white to off-white free flowing powder filled in size '2' hard gelatin capsules with cream cap and brown body, printed 'OP' on cap and '75' on body in black.

- Carton box containing 10 capsules in a blister pack (clear PVC/PE/PVDC film, sealed with aluminium foil).

Information for the user

Making oseltamivir suspension at home

When neither commercially manufactured nor pharmacy compounded oseltamivir suspension is available, an oseltamivir suspension can be made up at home.

To make oseltamivir suspension for patients who cannot swallow capsules:

If you have the right capsule strength for the dose needed (such as a 75 mg capsule for a 75 mg dose), you can make the suspension by opening the capsule and stirring its contents with no more than one teaspoon of a suitable sweetened food product. The first set of instructions shows you how.

When smaller doses are needed, making the suspension involves extra steps. This is suitable for patients weighing less than 40 kg. The second set of instructions shows you how.

Adults, adolescents (13 to 17 years old) and infants and children 1 year old or older who weigh 40 kg and over

To prepare a 75 mg dose using a 75 mg capsule

To make an exact dose of oseltamivir suspension, carry out three basic steps.

You will need:

- **One 75 mg oseltamivir capsule**
- **Sharp scissors**
- **Two small bowls**
(use separate pairs of bowls for each child)
- **One oral dose dispenser**
for the oseltamivir suspension showing measurements of 0.1 ml
- **Teaspoon (5 ml spoon)**
- **Sweet food** to hide the bitter taste of the oseltamivir powder.
Examples are: chocolate syrup; cherry syrup; or dessert toppings, like caramel or fudge sauce. Or you can make sugar water by mixing a teaspoon of water with three-quarters (3/4) of a teaspoon of sugar.

How to do it – the three steps:

1. Find the correct dose.

To find the correct amount to use, find the patient's weight on the left side of table.

Then, look at the right column to see the number of capsules you will need to give the patient for a single dose.

Weight	Dose of oseltamivir	Number of capsules
40 kg and over	75 mg	1 capsule

Children who weigh less than 40 kg

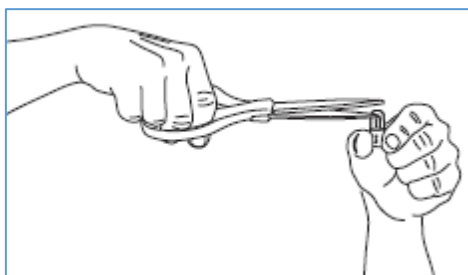
You will need to prepare a dose of less than 75 mg for children weighing less than 40 kg. *See below*

2. Open the 75 mg oseltamivir capsule and pour out the powder.

Hold a **75 mg capsule** upright over one of the bowls and carefully snip off the rounded tip with scissors.

Pour all of the powder into the bowl.

Be careful with the powder, because it may irritate your skin and eyes.



3. Sweeten the suspension and give it to the patient

Add a small amount of the sweet food (no more than one teaspoonful) to the powder in the bowl. This will hide the bitter taste of the oseltamivir powder. Stir the mixture well.



Give the whole contents of the bowl to the patient straight away.

If there is some mixture left in the bowl, rinse the bowl with a small amount of water and get the patient to drink this remaining mixture.

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

Infants and children 1 year old or older who weigh less than 40 kg

To prepare doses of less than 75 mg using a 75 mg capsule

This is for infants and children who weigh **less than 40 kg**, including all infants less than 1 year old.

Infants and children 1 year old or older who weigh less than 40 kg



+ 5 ml water

Infants less than 1 year old



+ 7.5 ml water

To make a **smaller dose** of oseltamivir suspension, carry out **five basic steps**.

You will need:

- **75 mg oseltamivir capsule**
- **Sharp scissors**
- **Two small bowls**
(use separate pairs of bowls for each child)
- **One oral dose dispenser for water – a 5 or 10 ml dispenser**
See below for how much water to use
- **One oral dose dispenser for the oseltamivir mixture showing measurements of 0.1 ml**
- **Teaspoon (5 ml spoon)**
- **Sweet food** to hide the bitter taste of the oseltamivir suspension.
Examples are: chocolate syrup; cherry syrup; or dessert toppings, like caramel or fudge sauce.
Or you can make sugar water by mixing a teaspoon of water with three-quarters (3/4) of a teaspoon of sugar.

How much water to use for mixing

Children more than 12 months who weigh less than 40 kg:	use 5 ml water
Children less than 12 months old	use 7.5 ml water

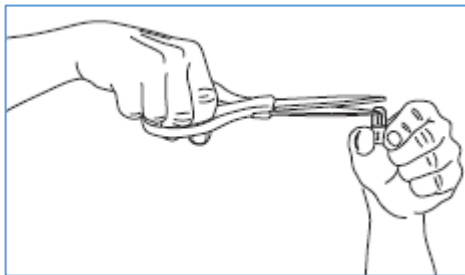
How to do it – the five steps:

1. Open a 75 mg oseltamivir capsule

Hold a 75 mg capsule upright over one of the bowls and carefully snip off the rounded tip with scissors.

Pour all of the powder into the bowl.

Be careful with the powder: it may irritate your skin and eyes.



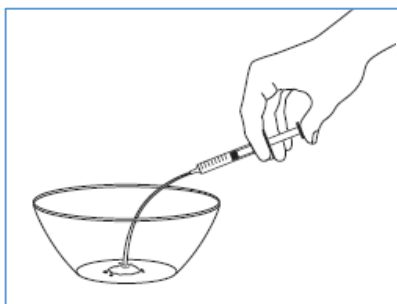
2. Prepare a suspension of powder and water

Use the first dispenser to draw up either **5 ml or 7.5 ml of water**. See 'You will need'.

Then add it to the powder in the bowl.

Stir the suspension with the teaspoon for about 2 minutes.

Don't worry if not all of the powder dissolves. The undissolved powder is just inactive ingredients.



3. Find the correct dose

Now that you have a oseltamivir suspension, look at the tables.

First find the right table for your child's age.

Next find the child's weight on the left side of the table.

Then look at the column on the right side of the table to see the amount of the oseltamivir suspension you will need.

Infants and children 1 year old or older who weigh less than 40 kg

Weight (nearest)	Dose of oseltamivir	How much suspension to draw up	Dispenser size to use (grading 0.1 ml)
Up to 15 kg	30.0 mg	2.0 ml	3.0 ml
15 to 23 kg	45.0 mg	3.0 ml	3.0 ml (or 5.0 ml)
23 to 40 kg	60.0 mg	4.0 ml	5.0 ml

Infants between 1 month and 12 months old:

Infants between 1 month and 12 months old: Weight (nearest)	Dose of oseltamivir	How much suspension to draw up	Dispenser size to use (grading 0.1 ml)
4 kg	10.0 mg	1.0 ml	2.0 ml (or 3.0 ml)
4.5 kg	11.25 mg	1.1 ml	2.0 ml (or 3.0 ml)
5 kg	12.5 mg	1.3 ml	2.0 ml (or 3.0 ml)
5.5 kg	13.75 mg	1.4 ml	2.0 ml (or 3.0 ml)
6 kg	15.0 mg	1.5 ml	2.0 ml (or 3.0 ml)
7 kg	21.0 mg	2.1 ml	3.0 ml
8 kg	24.0 mg	2.4 ml	3.0 ml
9 kg	27.0 mg	2.7 ml	3.0 ml
more than 10 kg	30.0 mg	3.0 ml	3.0 ml (or 5.0 ml)

Infants less than 1 month old:

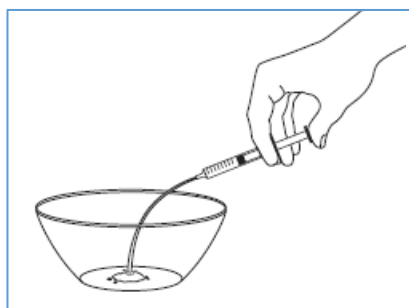
Weight (nearest)	Dose of oseltamivir	How much suspension to draw up	Dispenser size to use (grading 0.1 ml)
3 kg	6.0 mg	0.6 ml	1.0 ml (or 2.0 ml)
3.5 kg	7.0 mg	0.7 ml	1.0 ml (or 2.0 ml)
4 kg	8.0 mg	0.8 ml	1.0 ml (or 2.0 ml)
4.5 kg	9.0 mg	0.9 ml	1.0 ml (or 2.0 ml)

4. Draw up the suspension in a dispenser.

Make sure you have the right size of dispenser.

Draw up the correct amount of suspension from the first bowl.

Gently squirt it from the dispenser into the second bowl.



5. Sweeten the suspension and give it to the child

Add a small amount of the sweet food (no more than one teaspoon) to the second bowl.
This will hide the bitter taste of the oseltamivir suspension.
Mix the sweet food and oseltamivir suspension well.



Give the whole contents of the second bowl (oseltamivir suspension with sweet food added) to the child straight away.

If there is anything left in the second bowl, rinse the bowl with a small amount of water and feed the child this remaining mixture. For children unable to drink from a bowl, spoonfeed or use a bottle to feed the child the remaining mixture.

Give the child something to drink.

Throw away any unused oseltamivir suspension left in the first bowl.

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