

Oseltamivir 12mg/ml powder for oral suspension

Package Leaflet: Information for the user

Oseltamivir 12mg/ml powder for oral suspension

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 or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any of the side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Oseltamivir is and what it is used for

- Oseltamivir is used for adults, adolescents, children and infants (including full-term newborn babies) for **treating flu** (*influenza*). It can be used when you have flu symptoms, and the flu virus is known to be going round in your community.
- Oseltamivir can also be prescribed for adults, adolescents, children and infants above 1 year of age for **preventing flu**, on a case-by-case

basis – for instance, if you have been in contact with someone who has flu.

- Oseltamivir may be prescribed for adults, adolescents, children and infants (including full-term newborn babies) as **preventive treatment** in exceptional circumstances – for example, if there is a global epidemic of flu (a flu *pandemic*) and the seasonal flu vaccine may not provide sufficient protection.

Oseltamivir 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 illness.

2. What you need to know before you take Oseltamivir

Do not take Oseltamivir:

- **if you are allergic** (*hypersensitive*) to oseltamivir or any of the other ingredients of Oseltamivir listed in section 6.

Talk to your doctor if this applies to you. **Do not take Oseltamivir.**

Warnings and precautions:

Before you take Oseltamivir, make sure the 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, **tell a doctor immediately:**

- if you notice changes in behaviour or mood (*neuropsychiatric events*), especially in children and adolescents). These may be signs of rare but serious side effects.

Oseltamivir is not a flu vaccine

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

Other medicines and Oseltamivir

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 is right for you.

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

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

Driving and using machines

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

Oseltamivir contains fructose

Before you take Oseltamivir, make sure your prescribing doctor knows if you have hereditary fructose intolerance. This medicine contains sorbitol, which is a form of fructose.

Sorbitol can have a mild laxative effect.

3. How to take Oseltamivir

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

Always use the oral dispenser that is provided in the box and has markings indicating the dose in millilitres (ml).

Take Oseltamivir as soon as possible, ideally within two days of the flu symptoms starting.

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 adult patients with a weak immune system, treatment will continue for 10 days.

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, or for patients with a weak immune system, treatment will continue for up to 6 or 12 weeks.

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

amount of Oseltamivir prescribed by the doctor. The oral suspension can be used by people who find it hard to take capsules. See the instructions overleaf to make up and give a dose.

Adults, and adolescents 13 years and over

For adults and adolescents 13 years and over and weighing 40 kg or more, the recommended dose for treating flu is 12.5 ml twice daily for 5 days.

For adults and adolescents 13 years and over and weighing 40 kg or more, the recommended dose for preventing flu is 12.5 ml once daily for 10 days.

A 12.5 ml dose can be made up of a 5 ml dose plus a 7.5 ml dose.

Children 1 to 12 years

For children aged 1 to 12 years and weighing 10 kg to 15 kg, the recommended dose for treating flu is 5.0 ml twice daily for 5 days.

For children aged 1 to 12 years and weighing 10 kg to 15 kg, the recommended dose for preventing flu is 5.0 ml once daily for 10 days.

For children aged 1 to 12 years and weighing more than 15 kg and up to 23 kg, the recommended dose for treating flu is 7.5 ml twice daily for 5 days.

For children aged 1 to 12 years and weighing more than 15 kg and up to 23 kg, the recommended dose for preventing flu is 7.5 ml once daily for 10 days.

For children aged 1 to 12 years and weighing more than 23 kg and up to 40 kg, the recommended dose for treating flu is 10.0 ml twice daily for 5 days.

For children aged 1 to 12 years and weighing more than 23 kg and up to 40 kg, the recommended dose for preventing flu is 10.0 ml once daily for 10 days.

For children aged 1 to 12 years and weighing more than 40 kg, the recommended dose for treating flu is 12.5 ml twice daily for 5 days.

For children aged 1 to 12 years and weighing more than 40 kg, the recommended dose for treating flu is 12.5 ml once daily for 10 days.

Infants less than 1 year (0 to 12 months)

Giving Oseltamivir to infants less than 1 year old for preventing flu during flu pandemic should be based upon the judgment of a doctor after considering the potential benefit versus any potential risk to the infant.

A 3 ml oral dispenser (graduated in 0.1 ml steps) should be used for dosing infants less than 1 year old requiring 1 to 3 ml of Oseltamivir oral suspension.

For infants aged between 0 and 12 months, weighing around 3 kg, the recommended dose for treating flu is 1.5 ml twice daily for 5 days using a dispenser size of 3 ml.

For infants aged between 0 and 12 months, weighing around 3 kg, the recommended dose for preventing flu is 1.5 ml once daily for 10 days using a dispenser size of 3 ml.

For infants aged between 0 and 12 months, weighing around 3.5 kg, the recommended dose for treating flu is 1.8 ml twice daily for 5 days using a dispenser size of 3 ml.

For infants aged between 0 and 12 months, weighing around 3.5 kg, the recommended dose for preventing flu is 1.8 ml once daily for 10 days using a dispenser size of 3 ml.

For infants aged between 0 and 12 months, weighing around 4 kg, the recommended dose for treating flu is 2.0 ml twice daily for 5 days using a dispenser size of 3 ml.

For infants aged between 0 and 12 months, weighing around 4 kg, the recommended dose for preventing flu is 2.0 ml once daily for 10 days using a dispenser size of 3 ml.

For infants aged between 0 and 12 months, weighing around 4.5 kg, the recommended dose for treating flu is 2.3 ml twice daily for 5 days using a dispenser size of 3 ml.

For infants aged between 0 and 12 months, weighing around 4.5 kg, the recommended

dose for preventing flu is 2.3 ml once daily for 10 days using a dispenser size of 3 ml.

For infants aged between 0 and 12 months, weighing around 5 kg, the recommended dose for treating flu is 2.5 ml twice daily for 5 days using a dispenser size of 3 ml.

For infants aged between 0 and 12 months, weighing around 5 kg, the recommended dose for preventing flu is 2.5 ml once daily for 10 days using a dispenser size of 3 ml.

For infants aged between 0 and 12 months, weighing around 5.5 kg, the recommended dose for treating flu is 2.8 ml twice daily for 5 days using a dispenser size of 3 ml.

For infants aged between 0 and 12 months, weighing around 5.5 kg, the recommended dose for preventing flu is 2.8 ml once daily for 10 days using a dispenser size of 3 ml.

For infants aged between 0 and 12 months, weighing around 6 kg, the recommended dose for treating flu is 3.0 ml twice daily for 5 days using a dispenser size of 3 ml.

For infants aged between 0 and 12 months, weighing around 6 kg, the recommended dose for preventing flu is 3.0 ml once daily for 10 days using a dispenser size of 3 ml.

For infants aged between 0 and 12 months, weighing more than 6 kg and up to 7 kg, the recommended dose for treating flu is 3.5 ml twice daily for 5 days using a dispenser size of 10 ml.

For infants aged between 0 and 12 months, weighing more than 6 kg and up to 7 kg, the recommended dose for preventing flu is 3.5 ml once daily for 10 days using a dispenser size of 10 ml.

For infants aged between 0 and 12 months, weighing more than 7 kg and up to 8 kg, the recommended dose for treating flu is 4.0 ml twice daily for 5 days using a dispenser size of 10 ml.

For infants aged between 0 and 12 months, weighing more than 7 kg and up to 8 kg, the recommended dose for preventing flu is 4.0 ml

once daily for 10 days using a dispenser size of 10 ml.

For infants aged between 0 and 12 months, weighing more than 8 kg and up to 9 kg, the recommended dose for treating flu is 4.5 ml twice daily for 5 days using a dispenser size of 10 ml.

For infants aged between 0 and 12 months, weighing more than 8 kg and up to 9 kg, the recommended dose for preventing flu is 4.5 ml once daily for 10 days using a dispenser size of 10 ml.

For infants aged between 0 and 12 months, weighing more than 9 kg and up to 10 kg, the recommended dose for treating flu is 5.0 ml twice daily for 5 days using a dispenser size of 10 ml.

For infants aged between 0 and 12 months, weighing more than 9 kg and up to 10 kg, the recommended dose for preventing flu is 5.0 ml once daily for 10 days using a dispenser size of 10 ml.

If you take more Oseltamivir than you should

Stop taking Oseltamivir and contact a doctor or pharmacist 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.

Overdose has been reported to have occurred more frequently when Oseltamivir was given to children than to adults and adolescents. Caution should be exercised when preparing liquid Oseltamivir for children and when administering Oseltamivir capsules or liquid Oseltamivir to children.

If you forget to take Oseltamivir

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

If you stop taking Oseltamivir

There are no side effects when you stop Oseltamivir. But if Oseltamivir is stopped earlier

than your doctor told you, the symptoms of flu may come back. Always complete the course that your doctor prescribed.

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

4. Possible side effects

Like all medicines, this medicine 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 and over

Very common side effects

(may affect more than 1 in 10 people)

- Headache
- Nausea.

Common side effects

(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 side effects

(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 side effects

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

- Thrombocytopenia (low platelet count)
- Visual disturbances.

Children 1 to 12 years

Very common side effects

(may affect more than 1 in 10 people)

- Cough
- Nasal congestion
- Vomiting.

Common side effects

(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 side effects

(may affect up to 1 in 100 people)

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

Infants less than 1 year

The reported side effects in infants 0 to 12 months old are mostly similar to the side effects reported for older children (1 year old or older). Additionally, diarrhoea and diaper rash have been reported.

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.

Reporting of side effects

If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below).

5. How to store Oseltamivir

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and bottle after EXP. The expiry date refers to the last day of that month.

Powder: Do not store above 30°C.

After reconstitution, store below 25 °C for 10 days.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist 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 contains

- The active substance is oseltamivir (12mg/ml oseltamivir after reconstitution).
- The other ingredients are sorbitol, sodium dihydrogen citrate, xanthan gum, sodium benzoate, saccharin sodium, titanium dioxide and tuttifrutti flavour (including maltodextrins [maize], propylene glycol, arabic gum and natural identical flavouring substances [mainly consisting of banana, pineapple and peach flavour]).

What Oseltamivir looks like and contents of the pack

Powder for oral suspension

The powder is a granulate or clumped granulate with a white to light yellow colour.

Oseltamivir 12mg/ml powder for oral suspension is available in a bottle containing 13 g powder for mixing with 55 ml of water.

The box also contains 1 plastic measuring jug (55 ml), 1 plastic bottle adapter (to help get the drug into the dispenser), 1 plastic 3 ml oral dispenser and 1 plastic 10 ml oral dispenser (to give the correct amount of medicine via the mouth). Shown on the oral dispenser are

millilitre (ml) markings of the medicine (see figures in *Instructions for the user*).

For details on how to prepare the oral suspension and how to measure and take the medicine, read *Instructions for the user*, over the page.

Instructions for the user

There are two stages to taking Oseltamivir oral suspension.

Stage 1 Prepare a new bottle of the medicine

Your pharmacist may have prepared the medicine for you when you collected your prescription. If not, you can do it easily yourself. See the first set of instructions. **You only need to do this once**, at the beginning of your course.

Stage 2 Measure and give the correct dose

Shake the suspension well and draw the appropriate recommended dose into the dispenser. See the second set of instructions. You will need to do this every time you need a dose.

Stage 1: Prepare a new bottle of the medicine

You will need:

- The bottle, containing Oseltamivir powder (in the medicine pack)
- The bottle cap (in the medicine pack)
- A plastic measuring jug (in the medicine pack)
- The plastic bottle adapter (in the medicine pack)
- Water
- **Tap the bottle to loosen the powder**
Tap the closed bottle gently several times to loosen the powder.
- **Use the jug to measure 55 ml of water**
The measuring jug in the pack has a line marked to show you an exact amount.

Fill it with water to the indicated level.

- **Add all the water, close and shake**
Pour all of the water from the jug into the bottle, onto the powder.
Always use 55 ml of water, whatever the dose you need.
Put the cap back on the bottle. Shake the bottle well for 15 seconds.
- **Press in the adapter**
Open the bottle and press the bottle adapter hard into the neck of the bottle.
- **Close the bottle again**
Screw the cap tightly onto the top of the bottle, which now includes the adapter.
This will make sure that the bottle adapter fits in the bottle in the right position.

You now have a bottle of Oseltamivir oral suspension ready to measure out a dose. You will not need to prepare it again unless you start a new bottle.

Stage 2: Measure and give the correct dose

You will need:

- **A bottle of prepared Oseltamivir oral suspension**
- **Depending on the required dose you will need the 3 ml oral dispenser (yellow plunger, 0.1 ml graduation) or the 10 ml oral dispenser (white plunger 0.5 ml graduation) from the medicine pack.**
- For doses from 1.0 ml to 3.0 ml, the 3 ml oral dispenser should be used. For doses above 3.0 ml to 10 ml, 10 ml oral dispenser should be used.

Always use the oral dispenser provided with your medicine to measure a correct dose.

- **Shake the bottle**
Check the cap is secure, and then shake the bottle of Oseltamivir oral suspension.
Always shake well before use.
- **Prepare the oral dispenser**
Depending on the required dose, use the 3 ml dispenser (yellow plunger) or the 10 ml oral dispenser (white plunger) provided in the pack.
Push the plunger completely down toward the tip of the dispenser.
- **Fill the dispenser with the correct dose**
Unscrew the cap from the bottle.
Push the tip of the dispenser into the bottle adapter.
Then **turn the whole unit upside down** (bottle and dispenser together). Slowly pull out the plunger to draw medicine into the dispenser.
Stop at the mark that shows the dose you need.
Turn the whole unit upright.
Remove the dispenser from the bottle.
- **Give the medicine into the mouth**
Deliver the suspension directly into the mouth by pushing down the plunger of the dispenser.
Make sure the medicine is swallowed.
You may drink and eat something after taking the medicine.
- **Close the bottle, keep it safe**
Put the cap back on the bottle. Keep it out of sight and reach of children.
Store the medicine below 25 ° C for up to 10 days. See 5 *How to store Oseltamivir*, overleaf.

7. Manufactured By:

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