

OSELTAMIVIR VIATRIS

Oseltamivir capsule 75 mg



What is in this leaflet

Please read this leaflet carefully before you start taking Oseltamivir Viatriis.

This leaflet answers some common questions about Oseltamivir Viatriis.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Oseltamivir Viatriis against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Oseltamivir Viatriis is used for

Oseltamivir Viatriis is used to treat

- Influenza (flu) in adults and children from 2 weeks of age or older
- Prevention of the flu in adults and children 1 year or older

The flu is an infection caused by influenza virus. Typical symptoms include fever, headache, muscle aches, sore throat, cough and extreme tiredness. Oseltamivir is not effective against the common cold or throat or chest infections caused by other viruses.

Oseltamivir Viatriis contains the active ingredient oseltamivir. It belongs to a group of medicines called neuraminidase inhibitors.

It works by attacking the influenza virus and prevent it from spreading inside your body.

Taking oseltamivir can prevent you from catching the flu, or if you have already caught the flu, it can make the symptoms less severe and help you recover fast. Oseltamivir will help reduce the chances of you passing the flu onto someone else. You will also be less likely to develop complications of the flu, such as bronchitis, pneumonia, sinusitis (infected sinuses) and earache.

Your doctor may have prescribed this medicine for another reason.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Ask your pharmacist or doctor about having the flu vaccination. Vaccination every year is the best way to prevent the flu.

This medicine is available only with a doctor's prescription.

Before you take Oseltamivir Viatriis

When you must not take it

Do not take Oseltamivir Viatriis if you have an allergy to:

- any medicine containing oseltamivir.
- any of the ingredients listed at the end of this leaflet.
- Some of the symptoms of an allergic reaction may include: shortness of breath; wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not give Oseltamivir Viatriis to children under 2 weeks of age for the prevention of influenza.

Safety and effectiveness of Oseltamivir Viatriis in children under 2 weeks of age have not been established when used for the prevention of influenza. Please consult with your doctor if you would like to use Oseltamivir Viatriis in children.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- any other health problem, especially kidney disease
- suppressed immune system.

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.

Your doctor can discuss with you the risks and benefits involved.

It is not known whether oseltamivir is harmful to an unborn baby when taken by a pregnant woman. If there is a need to take oseltamivir when you are pregnant your doctor will discuss risks and benefits to you and the unborn baby.

Oseltamivir may pass into breast milk. Your doctor will discuss the risks and benefits of using

oseltamivir if you are breast-feeding.

If you have not told your doctor about any of the above, tell them before you start taking Oseltamivir Viatriis.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop.

You should also tell any health professional who is prescribing a new medication for you that you are taking Oseltamivir Viatriis.

Some medicines may interfere with Oseltamivir Viatriis, or may affect how well it works. You may need to use different amounts of your medicine, or you may need to take different medicines. Your pharmacist or doctor will advise you.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take Oseltamivir Viatriis

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to take

Take Oseltamivir Viatriis exactly as your pharmacist or doctor has advised.

Your pharmacist or doctor will tell you how much Oseltamivir Viatriis to take each day.

If you have kidney disease your pharmacist or doctor may advise

you to take a lower dose of Oseltamivir Viatriis.

If you are unable to swallow capsules your pharmacist can advise you on what to do.

Treatment of the flu

Start taking Oseltamivir as soon as possible after you have been diagnosed with the flu.

The earlier you start treatment with Oseltamivir Viatriis, the shorter the duration of your flu.

Adults and children 13 years or older

The usual dose is one Oseltamivir Viatriis 75 mg capsule twice a day for five days.

Children 1 year or older

Please consult with your doctor if you would like to use Oseltamivir Viatriis in children.

Children 2 weeks to less than 1 year of age

Please consult with your doctor or pharmacist for instruction of preparing oral solution of Oseltamivir Viatriis.

Prevention of the flu

Adults and children 13 years or older

The usual dose is one Oseltamivir Viatriis 75 mg capsule once a day for 10 days following close contact with someone who has the flu. You should start taking Oseltamivir Viatriis within 2 days of the close contact.

When there is an outbreak of the flu in the community, one Oseltamivir Viatriis 75 mg capsule can be taken once a day while protection is required. Oseltamivir Viatriis has been shown to be well tolerated and effective when taken for up to six weeks.

Children 1 year or older

Please consult with your doctor if you would like to use Oseltamivir Viatriis in children.

Do not give Oseltamivir Viatriis to children under 1 year of age,

for prevention of the flu. Safety and effectiveness in children under one year of age have not been established.

How to take it

Swallow the capsules whole with a full glass of water.

Do not break or chew the capsules before swallowing.

If you cannot swallow the capsule

Adults and children 13 years or older

Adults and children who are unable to swallow capsules may receive a 75 mg dose of Oseltamivir Viatriis by following the instruction below.

1. Hold one Oseltamivir Viatriis mg capsule over a small bowl, carefully pull the capsule open and pour the powder into the bowl.
2. Add a suitable, small amount (1 teaspoon maximum) of sweetened food product such as regular or sugar-free chocolate syrup, honey, light brown or table sugar dissolved in water, dessert toppings, sweetened condensed milk, apple sauce or yogurt to mask the bitter taste of the medicine.
3. Stir the mixture well and give the entire contents to the patients. 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. It is not necessary to administer any undissolved white powder.

Children (1 year or older)

Please consult with your doctor if you would like to use Oseltamivir Viatriis in children.

Children who are unable to swallow and require a dose different to that available in capsule form may receive appropriate dose of

Oseltamivir Viatris by following the instruction below.

1. Hold one Oseltamivir Viatris 75 mg capsule over a small bowl, carefully pull the capsule open and pour the powder into the bowl.
2. Add 5 ml water to the powder using a syringe with markings (called a “graduated syringe”) to show how much fluid has been drawn up. Stir for about two minutes.
3. Draw up into the syringe the correct amount of mixture from the bowl based on the recommended dose required, which is body weight dependent. It is not necessary to draw up any undissolved white powder.
4. Push down on the plunger of the syringe, to empty its entire contents into a second bowl. Discard any unused mixture.
5. In the second bowl, add a suitable, small amount (1 teaspoon maximum) of sweetened food 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 to the mixture to mask the bitter taste of the medicine.
6. Stir this mixture well and give the entire contents of the second bowl to the patients. This 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.

When to take it

Oseltamivir Viatris should be started as soon as possible; within the first two days of the onset of the first symptoms of the flu or exposure to someone with the flu.

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

Oseltamivir Viatris can be taken with or without food. However, you may find Oseltamivir Viatris is easier on your stomach when taken with food.

How long to take it

Continue taking Oseltamivir Viatris until your pharmacist or doctor tells you to stop or your course of treatment is complete.

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

While you are taking Oseltamivir Viatris

Things you must do

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Oseltamivir Viatris.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery.

If you become pregnant while taking this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are taking this medicine. It may interfere with the results of some tests.

Tell your doctor or pharmacist if, for any reason, you have not taken your medicine exactly as advised. Otherwise, your doctor or pharmacist may think it was not effective and change your treatment unnecessarily.

Things you must not do

Do not take Oseltamivir Viatris to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

If you stop taking it suddenly, your condition may worsen or you may have unwanted side effects. If possible, your doctor will gradually reduce the amount you take each day before stopping the medicine completely.

Do not let yourself run out of medicine over the weekend or on holidays.

Do not take any other medicines, whether they require a prescription or not, without first telling your pharmacist or doctor that you are taking Oseltamivir Viatris.

Things to be careful of

Be careful driving or operating machinery until you know how Oseltamivir Viatris affects you. However, Oseltamivir Viatris is not

expected to affect your ability to drive a car or operate machinery.

Be careful when drinking alcohol while you are taking this medicine.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much Oseltamivir Viatrix. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Symptoms of an overdose may include nausea and vomiting.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Oseltamivir Viatrix.

This medicine helps most people with flu, but it may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- nausea (feeling like vomiting)
- vomiting
- dizziness/spinning sensation (vertigo)
- headache
- stomach pain, indigestion
- diarrhoea
- cough
- bronchitis
- asthma (breathlessness, wheezing, a cough sometimes brought on by exercising and a feeling of tightness in the chest)
- sinusitis (stuffy nose and/or feeling of tension or fullness in the nose, cheeks and behind the eyes, sometimes with a throbbing ache)
- runny nose or nose bleeds
- ear problems or ear infection
- conjunctivitis (discharge from the eyes with itching and crusty eyelids)
- insomnia (difficulty sleeping)
- fatigue
- aches and pains
- mild skin rash

These are the more common side effects of Oseltamivir Viatrix. Mostly these are mild. If nausea and vomiting do occur, they will usually do so with the first dose and their effects will generally decrease as you get used to your medicine.

Taking Oseltamivir Viatrix with food may reduce the chance of feeling or being sick (nausea or vomiting).

Tell your doctor as soon as possible if you notice any of the following:

- sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing.
- yellowing of the skin and/or eyes, itching and dark coloured urine.
- chest infection with fever, chills, shortness of breath, cough, phlegm and occasional blood.

- convulsions, confusion, drowsiness, abnormal behaviour, delusions, hallucinations, agitation, anxiety and nightmares. These symptoms may also occur in flu patients not treated with Oseltamivir Viatrix.

Patients (especially children) and their caregivers should look out for signs of abnormal behaviour and contact a doctor immediately.

- diarrhoea with blood, along with fever and severe stomach pain.

These are serious side effect. You may need urgent medical attention. Serious side effects are rare.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

Ask your pharmacist or doctor if you don't understand anything in this list.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people. Tell your doctor if you notice any other effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After taking Oseltamivir Viatrix

Storage

Keep your capsules in the pack until it is time to take it.

If you take the capsules out of the pack they may not keep well.

Keep your capsules in a cool dry place where the temperature stays below 25°C.

Do not store Oseltamivir Viatris or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

White to off-white powder filled in hard shell gelatin capsule with yellow opaque cap and white opaque body imprinted axially with 'MYLAN' over 'OS3' in black ink on cap and body.

Ingredients

Active ingredient(s):

Oseltamivir Viatris contains 75 mg of oseltamivir as the active ingredient.

Inactive ingredient(s):

Oseltamivir Viatris also contains:

- pregelatinized starch
- povidone
- croscarmellose sodium
- talc
- sodium stearyl fumarate
- gelatin
- titanium dioxide
- D&C Yellow 10
- FD&C Yellow 6
- water

The capsule printing ink contains:

- shellac
- dehydrated alcohol
- isopropyl alcohol
- butyl alcohol
- propylene glycol

- ammonia solution, concentrated
- black iron oxide
- potassium hydroxide
- purified water

Contains benzoates and phenylalanine.

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine

Oseltamivir Viatris is supplied in New Zealand by:

Viatris Ltd
PO Box 11-183
Eilerslie
AUCKLAND
www.viatris.co.nz
Telephone 0800 168 169

Date of Preparation

07 November 2024.
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