

# Oseltamivir Lupin

## Consumer Medicine Information (CMI) Summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### 1. Why am I using Oseltamivir Lupin?

Oseltamivir Lupin contains the active ingredient oseltamivir phosphate. Oseltamivir Lupin is used to treat and prevent influenza (an infection caused by influenza virus).

For more information, see Section [1. Why am I using Oseltamivir Lupin?](#) in the full CMI.

### 2. What should I know before I use Oseltamivir Lupin?

Do not use if you have ever had an allergic reaction to oseltamivir phosphate or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use Oseltamivir Lupin?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with Oseltamivir Lupin and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use Oseltamivir Lupin?

- Your doctor will tell you how much Oseltamivir Lupin to take.
- Taking Oseltamivir Lupin with food may reduce the potential for some or all of side effects.
- Do not break or chew the capsules before swallowing.
- If you are unable to swallow capsules, your doctor may prescribe Oseltamivir Lupin 6 mg/mL oral suspension.

More instructions can be found in Section [4. How do I use Oseltamivir Lupin?](#) in the full CMI.

### 5. What should I know while using Oseltamivir Lupin?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using Oseltamivir Lupin.</li><li>• If symptoms do not improve and you still feel unwell after taking Oseltamivir Lupin, talk to your doctor.</li><li>• Tell your doctor if you have kidney failure, impairment, or any other problems with your kidneys.</li><li>• Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed.</li><li>• Be sure to keep all of your appointments with your doctor so that your progress can be checked.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not stop using this medicine suddenly.</li><li>• Do not give Oseltamivir Lupin capsules to anyone else even if they have the same condition as you.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Be careful driving or operating machinery until you know how Oseltamivir Lupin affects you.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Keep your capsules in the blister pack until it is time to take them.</li><li>• Keep Oseltamivir Lupin capsules in a cool dry place where the temperature stays below 25°C.</li></ul>

For more information, see Section [5. What should I know while using Oseltamivir Lupin?](#) in the full CMI.

### 6. Are there any side effects?

Tell your doctor as soon as possible if you do not feel well while you are taking Oseltamivir Lupin capsules. Common side effects include nausea, vomiting, headache and pain. Tell your doctor immediately or go to your nearest Emergency Department if you notice signs or symptoms of a serious allergic reaction 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

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# Oseltamivir Lupin

Active ingredient(s): *oseltamivir phosphate*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using Oseltamivir Lupin. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Oseltamivir Lupin.**

**Where to find information in this leaflet:**

- [1. Why am I using Oseltamivir Lupin?](#)
- [2. What should I know before I use Oseltamivir Lupin?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Oseltamivir Lupin?](#)
- [5. What should I know while using Oseltamivir Lupin?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using Oseltamivir Lupin?

**Oseltamivir Lupin contains the active ingredient oseltamivir phosphate.** Oseltamivir Lupin is an antiviral medicine.

**Oseltamivir Lupin is used for treatment and prevention of influenza (an infection caused by influenza virus). It has no effect on the common cold or other respiratory virus infections .**

Oseltamivir Lupin attacks the influenza virus and prevents it from spreading inside your body. Take Oseltamivir Lupin capsules as directed by your doctor or pharmacist.

Oseltamivir Lupin is absorbed to the key sites of influenza infection and treats the cause. Oseltamivir Lupin will help reduce the chances of you passing the flu onto someone else. Taking Oseltamivir Lupin can prevent you from catching the flu, or if you have already caught the flu, taking Oseltamivir Lupin may help you feel better faster.

You will also be less likely to develop complications of influenza, such as bronchitis, pneumonia and sinusitis. Typical symptoms of influenza include fever, headache, muscle aches, sore throat, cough and generally feeling unwell.

**Ask your doctor or pharmacist if you have any questions about why Oseltamivir Lupin has been prescribed for you.**

Oseltamivir Lupin is not addictive.

**Ask your doctor about having the influenza vaccination.**

Vaccination every year is the best way to prevent influenza.

## 2. What should I know before I use Oseltamivir Lupin?

### Warnings

**Do not use Oseltamivir Lupin if:**

- you are allergic to oseltamivir, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine. 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.
- the expiry date printed on the pack has passed or if the packaging is torn or shows signs of tampering .

**If you are not sure if you should be taking Oseltamivir Lupin, talk to your doctor.**

**Check with your doctor if you:**

- have any other medical conditions especially kidney failure, kidney impairment or kidney disease.
- have a weakened immune system, caused by medical condition or medication you are taking.
- take any medicines for any other condition.
- are allergic to any other medicines, foods, dyes or preservatives.
- have a suppressed immune system.

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

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

### Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

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

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Oseltamivir Lupin may pass into breast milk. Your doctor will discuss the risks and benefits of using Oseltamivir Lupin if you are breastfeeding.

## Use in the elderly

Although there is limited experience with use of Oseltamivir Lupin in patients 65 years and older, the dose recommended for use in elderly patients is the same as that recommended for adults.

## Use in children

**Do not give Oseltamivir Lupin to children under 1 year of age for the prevention of influenza.**

Safety and effectiveness of Oseltamivir Lupin in children under 1 year of age have not been established when used for the prevention of influenza.

## 3. What if I am taking other medicines?

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

**Some medicines may interfere with Oseltamivir Lupin and affect how it works.**

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Oseltamivir Lupin including:

- immunosuppressants, medicines used to suppress the immune system;
- probenecid, a medicine used to treat gout.

It is safe to take aspirin, paracetamol and cough medicines with Oseltamivir Lupin capsules. However, medical advice should be sought before giving aspirin to children with viral illnesses.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Oseltamivir Lupin.**

## 4. How do I use Oseltamivir Lupin?

### How much to use

- Take Oseltamivir Lupin as exactly as your doctor has prescribed.
- If you have kidney disease, your doctor may prescribe you a lower dose of Oseltamivir Lupin.
- Follow the instructions provided and use Oseltamivir until your doctor tells you to stop.

### Treatment of influenza

#### **Adults and adolescents 13 years of age and older**

The recommended oral dose of Oseltamivir Lupin for adults and adolescents 13 years of age and older is 75 mg twice a day for 5 days.

#### **Children 1 year of age and older and less than 13 years of age**

Give Oseltamivir Lupin as directed by your child's doctor or pharmacist.

The usual dose of Oseltamivir Lupin is one dose taken TWICE a day for 5 days. The dose depends on your child's weight.

### Prevention of influenza

For prevention of influenza, Oseltamivir Lupin capsules are taken once a day at the recommended dose while protection is required. Safety and effectiveness have been shown in patients taking Oseltamivir Lupin for up to 6 weeks.

#### **Adults and adolescents 13 years of age and older**

The recommended prevention dose of Oseltamivir Lupin for adults and adolescents 13 years and older is 75 mg once a day for 10 days.

#### **Children 1 year of age and older and less than 13 years of age**

Give Oseltamivir Lupin as directed by your child's doctor or pharmacist.

The usual dose of Oseltamivir Lupin is one dose taken ONCE a day for 10 days. The dose may vary depending on your child's weight.

**Do not give Oseltamivir Lupin to children under 1 year of age for the prevention of influenza.**

Safety and effectiveness in children under 1 year of age have not been established.

### **How to take Oseltamivir Lupin**

- Swallow capsules whole with a glass of water with or without food.
- It does not matter whether you take Oseltamivir Lupin with food or not. However, if Oseltamivir Lupin upsets your stomach, it is better to take Oseltamivir Lupin with food.
- **Do not break or chew the capsules before swallowing.**
- If you cannot swallow the capsule whole note the following:

**For adults, adolescents or children 1 year of age or older who are unable to swallow capsules please follow these instructions to ensure proper dosing:**

1. Hold the required dosage capsule over a small bowl, carefully pull the capsule open and pour the powder into the bowl.
2. Add a suitable, small amount (one 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 white sugar dissolved in water, dessert toppings, sweetened condensed milk, apple sauce or yoghurt to mask the bitter taste of the medicine.
3. Stir the mixture well and 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. It is not

necessary to take an undissolved white powder, as this is inactive.

**For children 1 year of age or older requiring doses different to that available in capsule form, please follow these instructions to ensure proper dosing:**

1. Hold one Oseltamivir Lupin 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 added. Stir for about two minutes.
3. Draw up the correct amount of mixture from the bowl into the syringe based on the recommended dose required which is body weight dependent (see table below). It is not necessary to draw up any undissolved white powder:

Recommended Dose	Amount of Oseltamivir Lupin Mixture for One Dose
30 mg	2 mL
45 mg	3 mL
60 mg	4 mL

4. In the second bowl, add a suitable, small amount (one teaspoon maximum) of sweetened food product (see below) to the mixture to mask the bitter taste of the medicine.  
The appropriate dose must be mixed by the caregiver with an equal quantity of sweetened food product such as regular or sugar-free chocolate syrup, light brown or white sugar dissolved in water, dessert toppings, sweetened condensed milk, apple sauce or yoghurt to mask the bitter taste of the medicine.
5. Stir this mixture well and give the entire contents of the second bowl to the patient. 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.

Patients who are unable to swallow capsules may receive an oseltamivir 6 mg/mL oral suspension.

### When to take it

- **Treatment with Oseltamivir Lupin capsules should be started as soon as possible, but no later than 48 hours after the first symptoms of influenza.**
- **For influenza treatment, Oseltamivir Lupin capsules should be taken in the morning and in the evening.**
- **For influenza prevention, Oseltamivir Lupin capsules should be taken once a day.**
- If you have kidney problems, your doctor may tell you to take Oseltamivir Lupin less often.
- Taking your medicine at the same time each day will help you remember when to take your Oseltamivir Lupin capsules.

### How long to take it

- **Continue taking Oseltamivir Lupin capsules until your doctor tells you to stop or your course of treatment is complete.**
- If you have a weakened immune system, your doctor may tell you to take a longer course.

### If you forget to use Oseltamivir Lupin

Oseltamivir Lupin should be used regularly at the same time each day.

**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 it as you would normally.

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

### If you use too much Oseltamivir Lupin

If you think that you have used too much Oseltamivir Lupin, you may need urgent medical attention.

The following are some symptoms of overdose which may or may not occur:

- nausea (feeling like vomiting);
- vomiting.

#### You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**); or
- contact your doctor; or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## 5. What should I know while using Oseltamivir Lupin?

### Things you should do

- **Tell your doctor if:**
  - you have kidney failure or impairment or any other problems with your kidneys;
  - you become pregnant while taking Oseltamivir Lupin;
  - for any reason, you have not taken your medicine exactly as prescribed.

Otherwise, your doctor may think that it was not effective and may change your treatment unnecessarily.

- Be sure to keep all of your appointments with your doctor so that your progress can be checked.

### Call your doctor straight away if you:

- feel your symptoms have worsened after starting Oseltamivir Lupin.

Remind any doctor, dentist or pharmacist you visit that you are using Oseltamivir Lupin.

## Things you should not do

- Do not stop using this medicine suddenly or change the dose without first checking with your doctor.
- Do not let yourself run out of medicine over the weekend or on holidays.
- Do not give Oseltamivir Lupin to anyone else even if they have the same condition as you.
- Do not use Oseltamivir Lupin to treat other complaints unless your doctor says so.
- Do not take any other medicines whether they require a prescription or not without first telling your doctor or consulting a pharmacist.

## Driving or using machines

**Be careful before you drive or use any machines or tools until you know how Oseltamivir Lupin affects you.**

However, Oseltamivir Lupin is not expected to affect your ability to drive a car or operate machinery.

## Looking after your medicine

- Keep Oseltamivir Lupin capsules in a cool dry place where the temperature stays below 25°C.
- Keep your capsules in the blister pack until it is time to take them. If you take the capsules out of the blister pack they may not keep well.

Follow the instructions on the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink; or
- in the car or on window sills.

**Keep it where young children cannot reach it.**

## Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
<b>Stomach:</b> <ul style="list-style-type: none"> <li>• Nausea (feeling like vomiting).</li> <li>• Vomiting.</li> <li>• Stomach ache, indigestion.</li> <li>• Diarrhoea.</li> </ul>	<b>Speak to your doctor if you have any of these less serious side</b>

	effects and they worry you.
<b>Nervous system:</b> <ul style="list-style-type: none"> <li>• Dizziness/spinning sensations (vertigo).</li> <li>• Headache.</li> <li>• Insomnia (difficulty sleeping).</li> </ul> <b>Nose:</b> <ul style="list-style-type: none"> <li>• Sinusitis (stuffy nose and/or feeling of tension or fullness in the nose, cheeks and behind the eyes, sometimes with a throbbing ache).</li> <li>• Runny nose or nose bleeds.</li> </ul> <b>Throat:</b> <ul style="list-style-type: none"> <li>• Cough.</li> <li>• Bronchitis.</li> <li>• Asthma (breathlessness, wheezing, a cough sometimes brought on by exercise and a feeling of tightness in the chest).</li> </ul> <b>Ear:</b> <ul style="list-style-type: none"> <li>• Ear problems or ear infection.</li> </ul> <b>Eyes:</b> <ul style="list-style-type: none"> <li>• Conjunctivitis (discharge from the eyes with itching and crusty eyelids).</li> <li>• Visual disturbances.</li> </ul> <b>Body:</b> <ul style="list-style-type: none"> <li>• Fatigue.</li> <li>• Aches and pains.</li> </ul> <b>Skin:</b> <ul style="list-style-type: none"> <li>• Mild skin rash.</li> </ul>	

### Serious side effects

Serious side effects	What to do
<b>Stomach:</b> <ul style="list-style-type: none"> <li>• Diarrhoea with blood, along with fever and severe stomach pain.</li> </ul> <b>Skin and other allergies:</b> <ul style="list-style-type: none"> <li>• 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.</li> <li>• Yellowing of the skin and/or eyes, itching and dark coloured urine infection.</li> <li>• Chest infection with fever, chills, shortness of breath, cough, phlegm and occasional blood.</li> </ul>	<b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b>

<p><b>Psychological:</b></p> <ul style="list-style-type: none"> <li>• Convulsions, confusion, drowsiness, abnormal behaviour, delusions, hallucinations, agitation, anxiety and nightmares.</li> </ul> <p>These symptoms may also occur in influenza patients not treated with Oseltamivir Lupin.</p> <p>Patients (especially children and adolescents) should be closely monitored and their healthcare professional should be contacted immediately if the patient shows any signs of unusual behaviour.</p>	
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**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

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

### What Oseltamivir Lupin contains

<b>Active ingredient (main ingredient)</b>	Oseltamivir phosphate
<b>Other ingredients (inactive ingredients)</b>	<p><b>Capsule contents:</b></p> <p>Pregelatinised maize starch Povidone Croscarmellose sodium Purified talc Sodium stearyl fumarate Ethanol absolute</p> <p><b>Capsule shell:</b></p> <p>Gelatin Titanium dioxide Iron oxide black Iron oxide yellow TekPrint SB-6003 Blue Ink (PI 12154)</p>
<b>Potential allergens</b>	Contains sulfites (as gelatin)

**Do not take this medicine if you are allergic to any of these ingredients.**

Oseltamivir Lupin capsules are gluten free and lactose free.

### What Oseltamivir Lupin looks like

Oseltamivir Lupin 30 mg is a size "4" hard gelatin capsule with light yellow cap imprinted with "30 mg" in blue ink and light yellow body imprinted with "LU" in blue ink containing white to off-white granular powder (AUST R 328422).

Oseltamivir Lupin 45 mg is a size "4" hard gelatin capsule with grey opaque cap imprinted with "45 mg" in blue ink and grey opaque body imprinted with "LU" in blue ink containing white to off-white granular powder (AUST R 328424).

Oseltamivir Lupin 75 mg is a size "2" hard gelatin capsule with light yellow cap imprinted with "75 mg" in blue ink and grey opaque body imprinted with "LU" in blue ink containing white to off white granular powder (AUST R 328428).

### Who distributes Oseltamivir Lupin

Generic Health Pty Ltd

Suite 2, Level 2

19-23 Prospect Street

Box Hill, VIC, 3128

Australia

✉ [ghinfo@generichealth.com.au](mailto:ghinfo@generichealth.com.au)

☎ +61 3 9809 7900

🌐 [www.generichealth.com.au](http://www.generichealth.com.au)

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