

Tamiflu Oral Suspension®

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 Tamiflu?

Tamiflu contains the active ingredient oseltamivir. Tamiflu is used to treat and prevent influenza (an infection caused by influenza virus). For more information, see Section [1. Why am I using Tamiflu?](#) in the full CMI.

2. What should I know before I use Tamiflu?

Do not use if you have ever had an allergic reaction to Tamiflu 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 Tamiflu?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Tamiflu 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 Tamiflu?

- Take Tamiflu oral suspension exactly as your doctor has prescribed.
- Use the measuring dispenser provided to take Tamiflu.
- Taking Tamiflu with food may reduce the potential for some or all of side effects.

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

5. What should I know while using Tamiflu?

Things you should do

- Remind any doctor, dentist or pharmacist you visit that you are using Tamiflu.
- If symptoms do not improve and you still feel unwell after taking Tamiflu, talk to your doctor.

	<ul style="list-style-type: none"> • Tell your doctor if you have kidney failure, impairment, or any other problems with your kidneys. • Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed. • Be sure to keep all of your appointments with your doctor so that your progress can be checked.
Things you should not do	<ul style="list-style-type: none"> • Do not stop using this medicine suddenly. • Do not give Tamiflu Oral Suspension to anyone else even if they have the same condition as you.
Driving or using machines	<ul style="list-style-type: none"> • Be careful driving or operating machinery until you know how Tamiflu affects you.
Looking after your medicine	<ul style="list-style-type: none"> • After water has been added to the Tamiflu powder, the suspension only lasts for a limited

time. After this time, it may not work as well.

- If the Tamiflu oral suspension is stored at room temperature (where the temperature stays below 25°C), the suspension must be discarded after 10 days.
- The Tamiflu suspension may however be kept in the fridge (between 2 - 8°C) for up to 17 days. Do not freeze the suspension.

For more information, see Section [5. What should I know while using Tamiflu?](#) 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 Tamiflu oral suspension. 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.

Tamiflu Oral Suspension®

Active ingredient: oseltamivir

Consumer Medicine Information (CMI)

This leaflet provides important information about using Tamiflu.

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 Tamiflu.

Where to find information in this leaflet:

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

1. Why am I using Tamiflu?

Tamiflu contains the active ingredient oseltamivir. Tamiflu is an antiviral medicine.

Tamiflu 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.

Tamiflu attacks the influenza virus and prevents it from spreading inside your body. Give Tamiflu suspension as directed by your child's doctor or pharmacist.

The usual dose of Tamiflu is one dose taken TWICE a day. The dose may vary depending on your child's weight.

Tamiflu is absorbed to the key sites of influenza infection and treats the cause. Taking Tamiflu can prevent you from catching the flu, or if you have already caught the flu, taking Tamiflu means you feel better faster.

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

Tamiflu will help reduce the chances of you passing the flu onto someone else.

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

Tamiflu 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 Tamiflu?

Warnings

Do not use Tamiflu 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 package is torn or shows signs of tampering
- the expiry date (EXP) printed on the pack has passed. If you take this medicine after the expiry date has passed, it may not work as well.

If you are not sure if you should be taking Tamiflu, talk to your doctor.

Check with your doctor if you:

- have any other medical conditions, especially kidney failure, kidney impairment or kidney disease
- weakened immune system, caused by medical condition or medication you are taking
- take any medicines for any other condition

- you have a hereditary intolerance to fructose
One 75mg dose of Tamiflu 6mg/mL oral suspension contains 2.1g of sorbitol. If you have hereditary fructose intolerance, Tamiflu 6mg/mL oral suspension is not recommended. Sorbitol may have a laxative effect and cause diarrhoea.
- you are allergic to any other medicines, foods, dyes or preservatives
- if you have a suppressed immune system

If you have not told your doctor about any of the above, tell them before you start taking Tamiflu oral suspension.

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 Tamiflu is harmful to an unborn baby when taken by a pregnant woman. If there is a need to take Tamiflu 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.

Tamiflu may pass into breast milk. Your doctor will discuss the risks and benefits of using Tamiflu if you are breast-feeding.

Use in the elderly

Although there is limited experience with use of Tamiflu 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 Tamiflu oral suspension to children under 1 year of age for the prevention of influenza.

Safety and effectiveness of Tamiflu oral suspension in children under 1 year of age has 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 Tamiflu and affect how it works.

You may need to use different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Tamiflu 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 Tamiflu oral suspension. However, medical advice should be sought before giving aspirin to children with viral illness.

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

4. How do I use Tamiflu?

How much to use

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

When to use Tamiflu

- Tamiflu should be used to treat and prevent influenza.

Treatment of Influenza

Adults and adolescents

Adults and adolescents who are unable to swallow capsules may receive Tamiflu 6mg/mL oral suspension. The usual treatment dose is 75mg twice daily for 5 days. This should be taken as a 30mg dose plus a 45mg dose in the morning and a 30mg dose plus a 45mg dose at night, using the oral dispenser provided. A 30mg dose is equivalent to 5.0mL of suspension. A 45mg dose is equivalent to 7.5mL of suspension.

Children

Give Tamiflu suspension as directed by your child's doctor or pharmacist.

The usual dose of Tamiflu for treatment of influenza is one dose taken TWICE a day for 5 days. The dose may vary depending on your child's weight.

Prevention of Influenza

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

Adults and adolescents

Adults and adolescents who are unable to swallow capsules may receive Tamiflu 6mg/mL oral suspension. The usual prevention dose is 75mg once daily for 10 days. This should be taken as a 30mg dose plus a 45mg

dose, using the oral dispenser provided. A 30 mg dose is equivalent to 5.0mL of suspension. A 45mg dose is equivalent to 7.5mL of suspension.

Children 1 year of age and older

Give Tamiflu suspension as directed by your child's doctor or pharmacist.

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

For dosing 3 mL and 10 mL oral dispensers (dosing syringes) have been provided in the carton.

Do not give Tamiflu 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 it

Shake the suspension well every time you use it to ensure you get the right dose. The powder in the suspension may settle during storage.

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

Your pharmacist may have prepared the oral suspension for you when you collected your prescription. However, if they have not done this then you can do it easily yourself. You only need to prepare the suspension once, at the beginning of your course.

After that, all you need to do is shake the suspension well and draw up the appropriate recommended dose.

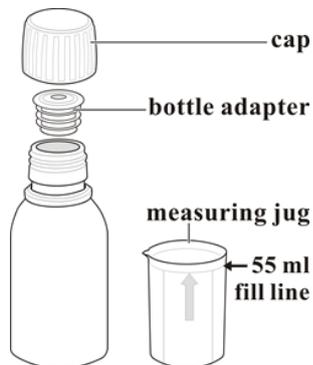


Figure 1

Tap the closed bottle gently several times to loosen the powder.

1. Measure 55mL of water by filling the measuring cup to the indicated level (measuring cup included in the box). You should always use 55mL of water, irrespective of the recommended dose you are taking. It is best to use bottled water or boiled water that has been cooled.
2. Add all 55mL of water into the bottle, recap the bottle and shake the closed bottle well for 15 seconds. The powder plus 55mL of water will make a total volume of 65mL.
3. Remove the cap and push the bottle adapter into the neck of the bottle.
4. Place the cap tightly over the top of the bottle, which now includes the bottle adapter. This will make sure that the bottle adapter fits in the bottle in the right position.

How to measure and give a dose of oral suspension

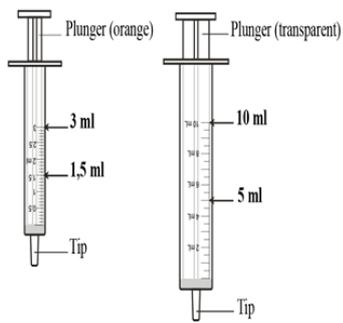


Figure 2

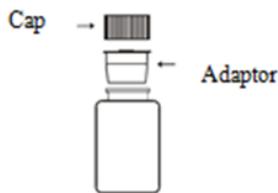


Figure 3

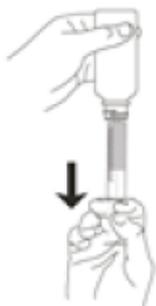


Figure 4

1. Shake the closed bottle of Tamiflu oral suspension well before use.
2. Take the dispenser (see Figure 2) and push the plunger completely down toward the tip of the dispenser.
3. Remove the cap from the bottle of oral suspension.

4. Insert the bottle adaptor into the neck of the bottle (see Figure 3).
5. Insert the tip of the dispenser into the bottle adapter.
6. Turn the entire unit (bottle and dispenser) upside down (see Figure 4).
7. Slowly pull out the plunger to the graduation marks in mL which your doctor or pharmacist has instructed you to take.
8. Turn the entire unit upright.
9. Slowly remove the dispenser from the bottle.
10. Push the suspension directly into the mouth by pushing down the plunger of the dispenser. Swallow the medicine. You may drink and eat something after taking the medicine.
11. Immediately after administration, take the dispenser apart and rinse both parts of the dispenser under running tap water. Allow dispenser to air dry before next use.
12. Do not boil the oral dispenser to avoid damage of the dispenser.
13. Contact your doctor or pharmacist if the dispenser is lost. If the dispenser is damaged, do not use it, contact your doctor or pharmacist and they will advise you on how to continue to take your medication.

Each bottle of Tamiflu 6mg/mL oral suspension contains 390mg of oseltamivir in a final volume of 65mL suspension. Depending on the dose your doctor has prescribed for you or your child, you may have suspension left over. Discard any unused suspension once you have completed your treatment course.

When to take it

Treatment with Tamiflu oral suspension should be started as soon as possible, but no later than 48 hours after the first symptoms of influenza.

For influenza treatment, Tamiflu oral suspension should be taken in the morning and in the evening.

For influenza prevention, Tamiflu oral suspension should be taken once a day.

If you have kidney problems, your doctor may tell you to take Tamiflu less often.

Taking your medicine at the same time each day will help you remember when to take your Tamiflu oral suspension.

How long to take it

Continue taking Tamiflu oral suspension 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 Tamiflu

Tamiflu 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.
- If you are not sure what to do, ask your doctor or pharmacist. If you have trouble remembering your dose, ask your pharmacist for some hints.
- Do not take a double dose to make up for the dose you missed.

If you use too much Tamiflu

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

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

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

- nausea (feeling like vomiting)
- vomiting

5. What should I know while using Tamiflu?

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 Tamiflu.**
- if 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 straightaway if you:

- feel your symptoms have worsened after starting Tamiflu.

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

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 Tamiflu oral suspension to anyone else even if they have the same condition as you.
- Do not use Tamiflu oral suspension to treat other complaints unless your doctor says to.
- 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 Tamiflu affects you.

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

Looking after your medicine

- After water has been added to the Tamiflu powder, the suspension only lasts for a limited time. After this time, it may not work as well.
- The Tamiflu suspension may however be kept in the fridge (between 2 - 8°C) for up to 17 days. Do not freeze the suspension.

Follow the instructions in 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 windowsills.

Keep it where young children cannot reach it.

When to discard your medicine (as relevant)

If the Tamiflu oral suspension is stored at room temperature (where the temperature stays below 25°C), the suspension must be discarded after 10 days.

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.

This is not a complete list of all possible side effects.

Less serious side effects

Less serious side effects	What to do
<p>Stomach</p> <ul style="list-style-type: none"> ● nausea (feeling like vomiting) ● vomiting ● stomach ache, indigestion ● diarrhoea <p>Nervous system</p> <ul style="list-style-type: none"> ● dizziness/spinning sensation (vertigo) ● headache ● insomnia (difficulty sleeping) <p>Nose</p> <ul style="list-style-type: none"> ● 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 <p>Throat</p> <ul style="list-style-type: none"> ● cough 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p> <p>Taking Tamiflu with food may reduce the potential for some or all of these side effects.</p>

Less serious side effects	What to do
<ul style="list-style-type: none"> ● bronchitis ● asthma (breathlessness, wheezing, a cough sometimes brought on by exercise and a feeling of tightness in the chest) <p>Ear</p> <ul style="list-style-type: none"> ● ear problems or ear infection <p>Eyes</p> <ul style="list-style-type: none"> ● conjunctivitis (discharge from the eyes with itching and crusty eyelids) ● visual disturbances <p>Body</p> <ul style="list-style-type: none"> ● fatigue ● aches and pains <p>Skin</p> <ul style="list-style-type: none"> ● mild skin rash 	

Serious side effects

Serious side effects	What to do
<p>Stomach</p> <ul style="list-style-type: none"> • diarrhoea with blood, along with fever and severe stomach pain <p>Skin and other allergies</p> <ul style="list-style-type: none"> • 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. <p>Infection</p> <ul style="list-style-type: none"> • chest infection with fever, chills, shortness of breath, cough, phlegm and occasional blood. <p>Psychological</p> <ul style="list-style-type: none"> • convulsions, confusion, drowsiness, abnormal behaviour, delusions, 	<p>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.</p>

Serious side effects	What to do
<p>hallucinations, agitation, anxiety and nightmares.</p> <p>These symptoms may also occur in influenza patients not treated with Tamiflu.</p> <p>Patients (especially children and adolescents) and their caregivers should look out for signs of abnormal behaviour and contact a doctor immediately.</p>	

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.

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

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. 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 Tamiflu contains

Active ingredient (main ingredient)	Osetamivir
Other ingredients (inactive ingredients)	sorbitol sodium dihydrogen citrate xanthan gum sodium benzoate saccharin sodium titanium dioxide Tutti Frutti flavour Tamiflu powder for oral suspension is gluten free and lactose free.
Potential allergens	Tamiflu oral suspension contains benzoates, saccharin and sorbitol.

	Maximum recommended daily dose of Tamiflu (150mg) exceeds 2g of sorbitol. Products containing sorbitol may have a laxative effect or cause diarrhoea..
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Do not take this medicine if you are allergic to any of these ingredients.

What Tamiflu looks like

Tamiflu oral suspension is a white to light yellow liquid.

Tamiflu 6mg/mL oral suspension comes in a bottle with an adapter, oral dispensers and a measuring cup. Tamiflu is also available as 30mg, 45mg and 75mg capsules.

Tamiflu 6mg/mL oral suspension is registered with the TGA as AUST R 188016.

Who distributes Tamiflu

Tamiflu is distributed by:

Roche Products Pty Limited

ABN 70 000 132 865

Level 8, 30-34 Hickson Road

Sydney NSW 2000

AUSTRALIA

Medical enquiries: 1800 233 950

This leaflet was prepared in August 2023.