

Tamiflu® Capsules

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?

- Taking Tamiflu 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 Tamiflu 6 mg/mL oral suspension.

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	<ul style="list-style-type: none">• 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.• 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 capsules 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">• Keep your capsules in the blister pack until it is time to take them.• Keep Tamiflu capsules in a cool dry place where the temperature stays below 25°C.

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 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.

Tamiflu® Capsules

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 capsules as directed by your doctor or pharmacist.

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

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 to children under 1 year of age for the prevention of influenza.

Safety and effectiveness of Tamiflu 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 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 capsules. 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 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 13 years of age and older

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

Children under 1 year of age

Tamiflu 6mg/mL oral suspension is the preferred product (see separate [Tamiflu 6mg/mL oral suspension Consumer Medicine Information](#)).

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

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

The usual dose of Tamiflu 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, Tamiflu capsules are 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 13 years of age and older

The recommended prevention dose of Tamiflu 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 Tamiflu as directed by your child's doctor or pharmacist.

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

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

Swallow capsules whole with a glass of water with or without food.

It does not matter whether you take Tamiflu with food or not. However, if Tamiflu upsets your stomach, it is better to take Tamiflu with food.

Do not break or chew the capsules before swallowing.

If you cannot swallow the capsule whole:

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 (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 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 Tamiflu 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 (see table below), which is body weight dependent (below).

It is not necessary to draw up any undissolved white powder.

- Recommended dose 30mg: Amount of Tamiflu mixture for one dose - 2mL
- Recommended dose 45mg: Amount of Tamiflu mixture for one dose - 3mL

- Recommended dose 60mg: Amount of Tamiflu mixture for one dose - 4mL

Push down on the plunger of the syringe, to empty its entire contents into a second bowl.

Discard any unused mixture.

- in the second bowl, add a suitable, small amount (1 teaspoon maximum) of sweetened food product 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 table sugar dissolved in water, dessert toppings, sweetened condensed milk, apple sauce or yoghurt to mask the bitter taste of the medicine.

- 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 Tamiflu 6 mg/mL oral suspension.

When to take it

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

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

For influenza prevention, Tamiflu capsules 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 capsules.

How long to take it

Continue taking Tamiflu 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 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 to anyone else even if they have the same condition as you.
- Do not use Tamiflu 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

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

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.

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 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 	<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>

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, hallucinations, agitation, anxiety and nightmares. <p>These symptoms may also occur in influenza patients not treated with Tamiflu.</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>	<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>

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)	<p>Oseltamivir</p> <ul style="list-style-type: none"> 30 mg capsules contain 30 mg oseltamivir (present as 39.4 mg oseltamivir phosphate)
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	<ul style="list-style-type: none">• 45 mg capsules contain 45 mg oseltamivir (present as 59.1 mg oseltamivir phosphate)• 75 mg capsules contain 75 mg oseltamivir (present as 98.5 mg oseltamivir phosphate)
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• Capsule contents: pregelatinised maize starch povidone croscarmellose sodium purified talc sodium stearyl fumarate• Capsule shell: gelatin titanium dioxide iron oxide black iron oxide red iron oxide yellow shellac indigo carmine <p>Tamiflu capsules are gluten free and lactose free.</p>

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

What Tamiflu looks like

Tamiflu capsules are available in the following strengths: 30 mg, 45 mg and 75 mg.

Tamiflu 30 mg hard gelatin capsules have a light yellow/opaque cap and a light yellow/opaque body. "ROCHE" is printed in blue ink on the light yellow body and "30 mg" is printed in blue ink on the light yellow cap (AUST R 145953).

Tamiflu 45 mg hard gelatin capsules have a grey/opaque cap and a grey/opaque body. "ROCHE" is printed in blue ink on the grey body and "45 mg" is printed in blue ink on the grey cap (AUST R 145957).

Tamiflu 75 mg hard gelatin capsules have a light yellow/opaque cap and a grey/opaque body. "ROCHE" is printed in blue ink on the grey body and "75 mg" is printed in blue ink on the light yellow cap (AUST R 76017).

Tamiflu comes in blister packs containing 10 capsules.

Tamiflu is also available as 6mg/mL oral suspension.

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