

Tamiflu®

6mg/mL Oral Suspension

contains the active ingredient oseltamivir

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Tamiflu oral suspension.

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 Tamiflu 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 Tamiflu is used for

Tamiflu is an antiviral medicine containing the active ingredient oseltamivir.

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

Tamiflu belongs to a group of medicines called neuraminidase inhibitors. These medicines attack the influenza virus and prevent 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.

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

Ask your doctor about having the influenza vaccination.

Vaccination every year is the best way to prevent influenza.

Before you take Tamiflu

When you must not take it

Do not take Tamiflu if:

- 1. you have had an allergic reaction to oseltamivir or any**

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

2. the package is torn or shows signs of tampering

3. 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.

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.

Before you start to take it

Tell your doctor if:

1. you are pregnant or plan 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.

2. you are breast-feeding or plan to breast-feed

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

3. you have any other health problems, especially the following:

kidney failure, kidney impairment or kidney disease.

4. 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.

5. you are allergic to any other medicines, foods, dyes or preservatives.

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

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you have bought from a pharmacy, supermarket or health food shop.

These medicines may be affected by Tamiflu, 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 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.

How to take Tamiflu oral suspension

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

They may differ from the information contained in this leaflet.

Start taking Tamiflu as soon as possible within the first two days of the onset of the first symptoms of influenza or exposure to someone with influenza.

The earlier you start treatment with Tamiflu, the shorter the duration of your influenza.

How much to take

Take Tamiflu oral suspension exactly as your doctor has prescribed.

If you have kidney disease your doctor may prescribe you a lower dose of Tamiflu.

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 75 mg twice daily for 5 days. This should be taken as a 30 mg dose plus a 45 mg dose in the morning and a 30 mg dose plus a 45 mg dose at night,

using the oral dispenser provided. A 30 mg dose is equivalent to 5.0 mL of suspension. A 45 mg dose is equivalent to 7.5 mL 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 75 mg once daily for 10 days. This should be taken as a 30 mg dose plus a 45 mg dose, using the oral dispenser provided. A 30 mg dose is equivalent to 5.0 mL of suspension. A 45 mg dose is equivalent to 7.5 mL of suspension.

Children 1 year of age or 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.

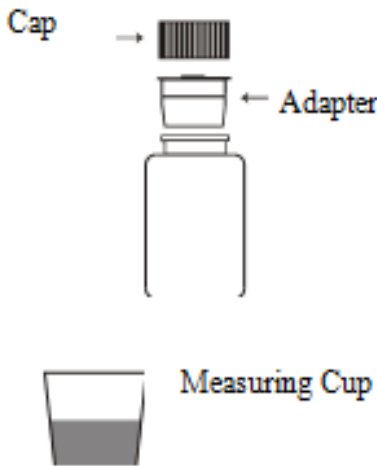


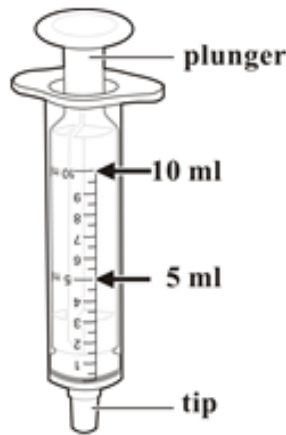
Figure 1

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

1. Measure 55 mL of water by filling the measuring cup to the indicated level (measuring cup included in the box). You should always use 55 mL 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 55 mL of water into the bottle, recap the bottle and shake the closed bottle well for 15 seconds. The powder plus 55 mL of water will make a total volume of 65 mL.

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



OR



Figure 2

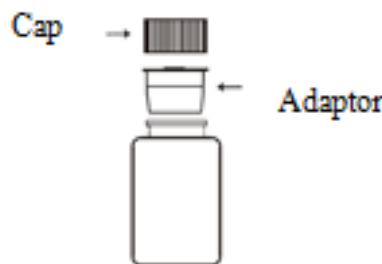


Figure 3



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 adaptor.
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. Air dry prior to next use.

Each bottle of Tamiflu 6mg/mL oral suspension contains 390 mg of oseltamivir in a final volume of 65 mL 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.

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 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 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.

In case of an overdose

If you think you or anyone else may have taken too much Tamiflu immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26 in Australia or 0800 764 766 [0800 POISON] in New Zealand), or go to Accident and Emergency at your nearest hospital. Do this even if there are no signs of discomfort or poisoning.

Keep telephone numbers for these places handy.

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

While you are taking Tamiflu oral suspension

Things you must do

Tell your doctor if you have kidney failure or impairment or any other problems with your kidneys.

Tell all doctors, dentists and pharmacists who are treating you that you are taking Tamiflu.

Tell your doctor if you become pregnant while taking Tamiflu.

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed.

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

Tell your doctor if you feel your symptoms have worsened after starting Tamiflu.

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

Things you must not do

Do not stop taking Tamiflu oral suspension 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.

Things to be careful of

Be careful driving or operating machinery until you know how Tamiflu affects you.

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

Tamiflu oral suspension contains sorbitol. Sorbitol may have a laxative effect or cause diarrhoea.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Tamiflu oral suspension.

Tamiflu helps most people with influenza 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 if you notice any of the following and they worry you:

- nausea (feeling like vomiting)
- vomiting
- dizziness/spinning sensation (vertigo)
- headache
- stomach ache, indigestion
- diarrhoea
- cough
- bronchitis

- asthma (breathlessness, wheezing, a cough sometimes brought on by exercise 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)
- visual disturbances
- insomnia (difficulty sleeping)
- fatigue
- aches and pains
- mild skin rash

These are the more common side effects of Tamiflu. Mostly these are mild.

Taking Tamiflu with food may reduce the potential for some or all of these side effects.

Tell your doctor immediately or go to your nearest Accident and Emergency, 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 influenza patients not treated with Tamiflu.

Patients (especially children and adolescents) 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

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.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

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

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

After taking Tamiflu oral suspension

Storage

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.

Keep Tamiflu oral suspension in a cool dry place.

Do not store it, or any other medicine, in a bathroom or near a sink.

Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep Tamiflu oral suspension where young children cannot reach it.

A locked cupboard at least 1.5 metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking Tamiflu oral suspension, or the suspension has passed its expiry date, ask your pharmacist what to do with the rest of the suspension that is left over.

Product description

Availability

Tamiflu 6mg/mL oral suspension comes in a bottle with an adapter, oral dispensers and a measuring cup.

Tamiflu is also available as 30 mg, 45 mg and 75 mg capsules.

What Tamiflu oral suspension looks like

Tamiflu oral suspension is a white to light yellow liquid.

Ingredients

Active ingredient

- oseltamivir

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.

Distributor

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

Roche Products (New Zealand)

Limited

P O Box 109113 Newmarket

AUCKLAND 1149

Medical enquiries: 0800 276 243

Please check with your pharmacist
for the latest Consumer Medicine
Information.

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