

Consumer Medicine Information

TAMIFLU®

Oseltamivir

Capsules 75 mg

Powder for oral suspension 12 mg in 1 mL

What is in this leaflet

This leaflet answers some common questions about TAMIFLU capsules and 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 expected 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 of influenza (flu) in adults and children 1 year or older.

TAMIFLU is also used for the prevention of the flu in adults and children 1 year or older.

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

TAMIFLU belongs to a group of medicines called neuraminidase inhibitors. These medicines attack the influenza virus and prevent it from spreading inside your body.

Taking TAMIFLU 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 faster. TAMIFLU will help reduce the chances of you passing the flu on to someone else. You will also be less likely to develop complications of the flu, such as bronchitis, pneumonia, sinusitis (infected sinuses) and earache.

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

TAMIFLU is a prescription medicine and is also subject to classification conditions, which allow it to be sold by a pharmacist under certain conditions. Ask your pharmacist or doctor for current information regarding these conditions.

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

Before you take TAMIFLU

When you must not take it

Do not take TAMIFLU if:

- 1. you have had an allergic reaction to TAMIFLU or any ingredients listed at the end of this leaflet**
- 2. the package is torn or shows signs of tampering**
- 3. the expiry date 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 children

Do not give TAMIFLU to children under 1 year of age.

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

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 kidney disease**
- 4. you have a hereditary intolerance to fructose**
A bottle of 30 g TAMIFLU powder for oral suspension contains 25.713 g of sorbitol. One dose of 45 mg of TAMIFLU oral suspension administered twice daily contains 2.6 g of sorbitol. If you have a hereditary fructose intolerance this is above the recommended daily maximum limit of sorbitol.
- 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.

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.

Some 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.

How to take TAMIFLU

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

They may differ from the information contained in this leaflet.

How much to take

Take TAMIFLU exactly as your doctor has prescribed.

Your doctor will tell you how many TAMIFLU capsules or how much TAMIFLU oral suspension to take each day.

Adults and adolescents who are unable to swallow capsules can take TAMIFLU oral suspension as an alternative.

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

Treatment of the flu

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

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

Adults and adolescents (13 years or older)

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

Children 1 year or older

The usual dose of TAMIFLU oral suspension for children 1 year or older is:

Body weight	Recommended dose for 5 days	Equivalent dose as a volume of suspension (12 mg/mL)
≤ 15 kg	30 mg twice daily	2.50 mL twice daily
> 15 to 23 kg	45 mg twice daily	3.75 mL twice daily
> 23 kg to 40 kg	60 mg twice daily	5.00 mL twice daily
> 40 kg	75 mg twice daily	6.25 mL twice daily

A dosing dispenser marked with 30 mg, 45 mg and 60 mg dosing levels is provided in the pack to administer TAMIFLU oral suspension. Each 75 mg dose 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.

Children weighing more than 40 kg who are able to swallow capsules can take one TAMIFLU 75 mg capsule twice daily as an alternative to TAMIFLU oral suspension.

Prevention of the flu

Adults and adolescents (13 years or older)

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

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

Children 1 year or older

The usual dose of TAMIFLU oral suspension for children 1 year or older is:

Body weight	Recommended dose for 10 days	Equivalent dose as a volume of suspension (12 mg/mL)
≤ 15 kg	30 mg once daily	2.50 mL once daily
> 15 to 23 kg	45 mg once daily	3.75 mL once daily
> 23 kg to 40kg	60 mg once daily	5.00 mL once daily
> 40 kg	75 mg once daily	6.25 mL once daily

A dosing dispenser marked with 30 mg, 45 mg and 60 mg dosing levels is provided in the pack to administer TAMIFLU oral suspension. Each 75 mg dose should be taken as a 30 mg dose plus a 45 mg dose, using the oral dispenser provided.

Do not give TAMIFLU to children under 1 year of age. Safety and effectiveness in children under one year of age have not been established.

How to take it

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

Capsules

Swallow capsules whole with a glass of water.

Do not break or chew the capsules before swallowing.

If you cannot swallow the capsule

Adults and adolescents (13 years or older)

Adults and adolescents who are unable to swallow capsules may receive a 75 mg dose of TAMIFLU by following the instructions below.

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 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 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 administer any undissolved white powder.

Children (1 year or older)

Children who are unable to swallow capsules and require a dose different to that available in capsule form may receive appropriate doses of TAMIFLU by following the instructions below.

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 (see table below) based on the recommended dose required, which is body weight dependent (see tables above).

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

Body weight	Recommended dose	Amount of TAMIFLU mixture for one dose (15 mg/mL)
≤ 15 kg	30 mg	2 mL
> 15 to 23 kg	45 mg	3 mL
> 23 kg to 40kg	60 mg	4 mL
> 40 kg	75 mg	5 mL

Note: This procedure results in a 15 mg/mL mixture, which is different from the commercially supplied Tamiflu Oral Suspension, which has a concentration of 12 mg/mL.

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 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.

Oral suspension

HOW TO PREPARE THE ORAL SUSPENSION:

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.

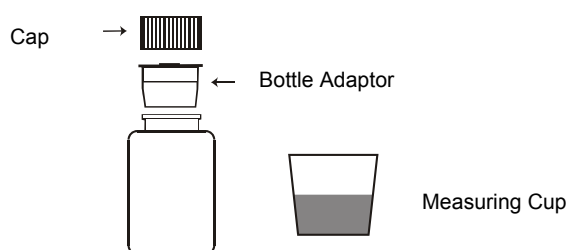


Figure 1

1. Tap the closed bottle gently several times to loosen the powder.
2. Measure 52 mL of water by filling the measuring cup to the indicated level (measuring cup included in the box). **You should always use 52 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.
3. Add all 52 mL of water into the bottle, recap the bottle and shake the closed bottle well for 15 seconds. The powder plus 52 mL of water will make a total volume of 75 mL.
4. Remove the cap and push the bottle adaptor into the neck of the bottle.
5. 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

Always shake TAMIFLU oral suspension well before use

Oral Dispenser

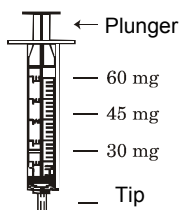


Figure 2

Figure 3

How to measure the correct amount of suspension:

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. The dispenser provided with your medicine must always be used to measure the correct dose.
3. Remove the cap from the bottle of oral suspension.
4. Insert the tip of the dispenser into the bottle adapter.
5. Turn the entire unit (bottle and dispenser) upside down (see Figure 3).
6. Slowly pull out the plunger to the graduation which marks the mg dose which your doctor or pharmacist has instructed you to take.
7. Turn the entire unit upright.
8. Slowly remove the dispenser from the bottle.
9. 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.
10. Immediately after administration, take the dispenser apart and rinse both parts of the dispenser under running tap water.

When to take it

TAMIFLU 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.

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

How long to take it

Continue taking TAMIFLU 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.

If you take too much (overdose)

Immediately telephone your doctor or National Poisons Information Centre (telephone 0800 POISON or 0800 764 766), or go to an Accident and Emergency Centre if you or anyone else may have taken too much TAMIFLU. Do this even if there are no signs of discomfort or poisoning.

Keep telephone numbers for these places handy.

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

- nausea (feeling like vomiting)
- vomiting

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

While you are taking TAMIFLU

Things you must do

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

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 or change the dose without first checking with your doctor or pharmacist.

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 a pharmacist that you are taking TAMIFLU.

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.

Side effects

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

TAMIFLU helps most people with the flu but it may have unwanted side effects in some 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 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)
- insomnia (difficulty sleeping)
- fatigue
- aches and pains
- mild skin rash

These are the more common side effects of TAMIFLU. 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 TAMIFLU with food may reduce the chance of feeling or being sick (nausea or vomiting).

Tell your doctor immediately or go to your nearest Accident and Emergency Centre, 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 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.

These are serious side effects. 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.

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 in this list.

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

After taking TAMIFLU

Storage

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

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

Heat and dampness can destroy some medicines.

Keep TAMIFLU where young children cannot reach it.

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

Capsules

Keep your TAMIFLU 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 75 mg capsules in a cool dry place where the temperature stays at or below 25 °C.

Oral suspension

After water has been added to the TAMIFLU powder, the suspension only lasts for a limited time.

If the TAMIFLU 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 (2 – 8 °C) for up to 17 days.

Do not freeze the suspension.

Disposal

If your doctor tells you to stop taking TAMIFLU, or it has passed its expiry date, ask your pharmacist what to do with any left over medicine.

Product description

Availability

TAMIFLU 75 mg capsules come in blister packs containing 10 capsules.

TAMIFLU 12 mg in 1 mL oral suspension comes in a bottle pack containing 30 g of powder with an oral dispenser. (Your pharmacist will have usually made up the TAMIFLU oral suspension so that it is ready to use).

What TAMIFLU looks like

Capsules

TAMIFLU 75 mg capsules have a grey opaque body with "ROCHE" printed on it in blue ink and a light yellow opaque cap with "75 mg" printed on it in blue ink.



Oral suspension

TAMIFLU powder for oral suspension is provided in granulate form which is white to light yellow in colour.

Ingredients

Active ingredient – oseltamivir

TAMIFLU 75 mg capsules contain 75 mg oseltamivir.

TAMIFLU powder for oral suspension contains 12 mg in 1 mL oseltamivir when made up into the suspension (total volume of 75 mL).

Inactive ingredients

Capsules

TAMIFLU capsules contain: pre-gelatinised starch, polyvidone K30, croscarmellose sodium, talc, sodium stearyl fumarate.

The capsule shell also contains: gelatin, black iron oxide, red iron oxide, yellow iron oxide, titanium dioxide.

The printing ink on the capsule shell also contains: dehydrated alcohol, shellac, n-butyl alcohol, titanium dioxide, FDC Blue 2, SDA-3A alcohol.

TAMIFLU capsules are gluten free and lactose free.

Oral Suspension

TAMIFLU powder for oral suspension contains: sorbitol, titanium dioxide, sodium benzoate, xanthan gum, sodium dihydrogen citrate (monosodium citrate), saccharin sodium, flavour – PERMASEAL 11900-31 tutti frutti.

Distributor

TAMIFLU is distributed by:

Roche Products (New Zealand) Limited
P O Box 12492
Penrose
AUCKLAND 1642

Customer enquiries: 0800 656 464

This leaflet was prepared on 8 April 2011.