

TAMIFLU[®] Capsules



contains the active ingredient oseltamivir

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about TAMIFLU capsules.

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 contains 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.

TAMIFLU is absorbed to the key sites of influenza infection and treats

the cause. Taking TAMIFLU means 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 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.

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 (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 same dose is recommended in elderly patients.

Use in children

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.

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**

It is not known whether TAMIFLU passes 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 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.

These medicines may be affected by TAMIFLU, or may effect 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.

It is safe to take aspirin, paracetamol and cough medicines with TAMIFLU. However, medical advice should be sought before giving aspirin to children with viral illness.

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.

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

The earlier you start treatment with TAMIFLU, the shorter will be the duration of your influenza.

How much to take

Take TAMIFLU exactly as your doctor has prescribed.

Treatment of influenza

Adults

The recommended oral dose of TAMIFLU for adults and adolescents is 75 mg twice a day for 5 days.

Children

The recommended oral dose of TAMIFLU for children >1 year of age is:

| Body weight (kg) | Recommended dose for 5 days |
|------------------|-----------------------------|
| ≤15 | 30 mg twice daily |
| >15 - 23 | 45 mg twice daily |
| >23 - 40 | 60 mg twice daily |
| >40 | 75 mg twice daily |

Prevention of influenza

For prevention of influenza TAMIFLU 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

The recommended oral prevention dose of TAMIFLU for adults and adolescents is 75 mg once a day for 10 days.

Children

The recommended oral prevention dose of TAMIFLU for children >1 year of age is:

| Body weight (kg) | Recommended dose for 10 days |
|------------------|------------------------------|
| ≤15 | 30 mg once daily |
| >15 - 23 | 45 mg once daily |
| >23 - 40 | 60 mg once daily |
| >40 | 75 mg once daily |

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

For adults, adolescents or children 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.

For children 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 (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.

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

| Recommended dose | Amount of TAMIFLU mixture for one dose |
|------------------|--|
| 30 mg | 2 mL |
| 45 mg | 3 mL |
| 60 mg | 4 mL |

- 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
- 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.

When to take it

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

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

For influenza prevention, TAMIFLU should be taken once a day.

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

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.

In case of an overdose

Immediately telephone your doctor, or Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at your nearest hospital, if you think you or anyone else may have taken too much TAMIFLU. Do this even if there are no signs of discomfort or poisoning.

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

- nausea (feeling like vomiting)
- vomiting

Keep telephone numbers for these places handy.

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

While you are taking TAMIFLU

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 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 so.

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.

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 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
- stomach ache

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.

People with influenza, including those taking TAMIFLU may be at an increased risk of seizures, confusion, hallucinations, and/or abnormal behaviour during their illness. These events may occur shortly after beginning TAMIFLU or may occur when influenza is not treated. These events are uncommon but may result in accidental injury to the patient.

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.

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

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 in a cool dry place where the temperature stays below 25°C.

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 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.

Disposal

If your doctor tells you to stop taking TAMIFLU, or the capsules have passed their expiry date, ask your pharmacist what to do with any tablets that are left over.

Product description

Availability

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

TAMIFLU comes in blister packs containing 10 capsules.

TAMIFLU is also available as a powder for oral suspension.

What TAMIFLU looks like

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.

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.

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.

Ingredients

Active ingredient – oseltamivir

- 30 mg capsules contain 30 mg oseltamivir (present as 39.4 mg oseltamivir phosphate).
- 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)

Inactive ingredients –

- Capsule contents:
 - maize starch
 - povidone K 30
 - croscarmellose sodium
 - talc
 - sodium stearyl fumarate
- Capsule shell:

- gelatin
- titanium dioxide (171)
- black iron oxide (172)
- red iron oxide (172)
- yellow iron oxide (172)
- shellac (904)
- indigo carmine (132)

TAMIFLU capsules are gluten free and lactose free.

Distributor

TAMIFLU is distributed by:

Roche Products Pty Limited
ABN 70 000 132 865
4-10 Inman Road
Dee Why NSW 2099

Customer enquiries: 1800 233 950

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

Australian Registration Number

- 30 mg: AUST R 145953
- 45 mg: AUST R 145957
- 75 mg: AUST R 76017

This leaflet was prepared on 4 June 2009.