

# TAMIFLU(R) Suspension

contains the active ingredient oseltamivir

## Consumer Medicine Information

### What is in this leaflet

This leaflet answers some common questions about TAMIFLU 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 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 has 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 have a hereditary intolerance to fructose**

One 45 mg dose of TAMIFLU oral suspension contains 1.3 g of sorbitol. Two 45 mg doses in one day is equivalent to 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.**

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.

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.

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**How to take TAMIFLU**

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**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**

Adults and adolescents who are unable to swallow capsules may receive TAMIFLU 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 75 mg dose is 6.25 mL of suspension.

**Children**

Children who are unable to swallow capsules may receive TAMIFLU suspension. The recommended oral treatment dose of TAMIFLU suspension for children greater than 1 year of age is:

- \* Body weight less than or equal 15 kg  
Recommended dose twice daily for 5 days 30mg (equivalent 2.50 ml of suspension)
- \* Body weight from 15kg to 23kg  
Recommended dose twice daily for 5 days 45mg (equivalent 3.75 ml of suspension)
- \* Body weight from 23kg to 40kg  
Recommended dose twice daily for 5 days 60mg (equivalent 5.00 ml of suspension)
- \* Body weight greater than 40kg  
Recommended dose twice daily for 5 days 75mg (equivalent 6.25 ml of suspension)

**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**

Adults and adolescents who are unable to swallow capsules may receive TAMIFLU 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 75 mg dose is 6.25 mL of suspension.

**Children**

Children who are unable to swallow capsules may receive TAMIFLU suspension. The recommended oral prevention dose of TAMIFLU suspension for children greater than 1 year of age is:

- \* Body weight less than or equal 15 kg  
Recommended dose once daily for 10 days 30mg (equivalent 2.50 ml of suspension)
- \* Body weight from 15kg to 23kg  
Recommended dose once daily for 10 days 45mg (equivalent 3.75 ml of suspension)
- \* Body weight from 23kg to 40kg  
Recommended dose once daily for 10 days 60mg (equivalent 5.00 ml of suspension)
- \* Body weight greater than 40kg  
Recommended dose once daily for 10 days 75mg (equivalent 6.25 ml of suspension)

A dosing syringe marked with 30 mg, 45 mg and 60 mg dosing levels has been provided.

**How to take it**

**Shake the suspension well every time you use it to ensure you get the right dose.**

Water has been added to the powder by your pharmacist to make the suspension.

The powder in the suspension may settle during storage.

**How to measure and give a dose of oral suspension**

1. Shake the closed bottle of TAMIFLU oral suspension well before use.

2. Take the dispenser 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 mg dose.
3. Remove the cap from the bottle of oral suspension.
4. Insert the bottle adaptor into the neck of the bottle.
5. Insert the tip of the dispenser into the bottle adapter.
6. Turn the entire unit (bottle and dispenser) upside down
7. Slowly pull out the plunger to the graduation which marks the mg dose, 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.

Each bottle contains 900 mg of oseltamivir in 75 mL of suspension. Depending on the dose your doctor has prescribed for you or your child, you may have suspension left over.

### ***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 suspension should be taken in the morning and in the evening.**

**For influenza prevention, TAMIFLU 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.

### ***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.**

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## **While you are taking TAMIFLU**

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### ***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 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.

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## Side effects

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**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.

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## After taking TAMIFLU

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### 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 suspension is stored at room temperature (where the temperature stays below 25 degrees C) the suspension must be discarded after 10 days.

The TAMIFLU suspension may however be kept in the fridge (2 to 8 degrees C) for up to 17 days.

Do not freeze the suspension.

**Keep TAMIFLU 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 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 suspension has passed its expiry date, ask your pharmacist what to do with the rest of the suspension that is left over.**

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## Product description

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### Availability

TAMIFLU suspension comes in a bottle with an adapter, an oral dispenser and a measuring cup.

**The oral dispenser provided with TAMIFLU suspension should not be used for measuring doses of any other products.**

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

### What TAMIFLU looks like

TAMIFLU suspension is a white to light yellow liquid.

### Ingredients

#### Active ingredient

oseltamivir

#### Inactive ingredients

- \* sorbitol E420
- \* sodium dihydrogen citrate (E331(a))
- \* xanthan gum (E415)
- \* sodium benzoate (E211)
- \* saccharin sodium (E954)
- \* titanium dioxide (E171)
- \* Tutti Frutti flavour

TAMIFLU powder for oral suspension is gluten free and lactose free.

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## Distributor

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TAMIFLU is distributed by:  
Roche Products Pty Limited  
ABN 70 000 132 865  
4-10 Inman Road  
Dee Why NSW 2099  
AUSTRALIA

Customer enquiries: 1 800 233 950

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

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