

## Package Leaflet: Information for the user

### Tamiflu 6 mg/ml powder for oral suspension oseltamivir

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any of the side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

#### What is in this leaflet

1. What Tamiflu is and what it is used for
2. What you need to know before you take Tamiflu
3. How to take Tamiflu
4. Possible side effects
5. How to store Tamiflu
6. Contents of the pack and other information

#### **1. What Tamiflu is and what it is used for**

- Tamiflu is used for adults, adolescents, infants and children 1 year old and older.
- Tamiflu is prescribed to you for **treating flu** (*influenza*). It can be used when you have flu symptoms, and the flu virus is known to be circulating in your community. Other times it may be used as listed below.
  - Tamiflu is prescribed for **preventing flu**. It can be used if you have been in contact with someone who has flu. This is generally decided on a case-by-case basis.
  - Tamiflu is prescribed as **preventive treatment** in exceptional cases. For example, it can be used when the seasonal flu vaccine may not provide sufficient protection and when there is a flu pandemic (global epidemic of flu).
- **During a flu pandemic, Tamiflu can also be used to treat or prevent flu in babies below 1 year of age.** Doctors should make decisions on whether to use Tamiflu in babies of this age, based on the severity of the disease caused by the flu virus and the baby's state of health, to ensure that the baby is likely to benefit from the medicine.
- Tamiflu contains oseltamivir, which belongs to a group of medicines named *neuraminidase inhibitors*. These medicines prevent the flu virus from spreading inside the body. They help to ease or prevent the symptoms of the flu virus infection.
- Influenza, usually called flu, is an infection caused by a virus. The signs of flu often include a sudden fever (more than 37.8 °C), cough, runny or stuffy nose, headaches, muscle aches and extreme tiredness. These symptoms can also be caused by other infections. True influenza infection only occurs during annual outbreaks (*epidemics*) when flu viruses are spreading in the local community. Outside epidemic periods, flu-like symptoms are usually caused by a different type of infection or illness.

## 2. What you need to know before you take Tamiflu

### Do not take Tamiflu

- if you are allergic (*hypersensitive*) to oseltamivir or any of the other ingredients of Tamiflu listed in section 6.

### Warnings and precautions

Before you take Tamiflu, make sure your prescribing doctor knows

- if you are allergic to other medicines
- if you have problems with your kidneys. If so, your dose may need adjustment.
- if you have a severe medical condition, which may require immediate hospitalisation
- if your immune system is not working
- if you have chronic heart disease or respiratory disease.

During treatment with Tamiflu, tell your prescribing doctor

- if you notice changes in behaviour or mood (*neuropsychiatric events*), especially in children and adolescents.

### Tamiflu is not a flu vaccine

Tamiflu is not a vaccine: it treats infection, or prevents the flu virus spreading. A vaccine gives you antibodies against the virus. Tamiflu will not change the effectiveness of a flu vaccine, and you might be prescribed both by your doctor.

### Other medicines and Tamiflu

Tell your doctor or pharmacist if you are taking any other medicines, or have recently taken any. This includes medicines obtained without a prescription. The following medicines are particularly important:

- chlorpropamide (used to treat diabetes)
- methotrexate (used to treat e.g. rheumatoid arthritis)
- phenylbutazone (used to treat pain and inflammation)
- probenecid (used to treat gout)

### Pregnancy and breast-feeding

You must tell your doctor if you are pregnant, if you think you are pregnant or if you are trying to get pregnant so that your doctor can decide if Tamiflu is right for you.

The effects on breastfed infants are unknown. You must tell your doctor if you are breast-feeding so that your doctor can decide if Tamiflu is right for you.

Ask your doctor or pharmacist for advice before taking this medicine.

### Driving and using machines

Tamiflu has no effect on your ability to drive or use machines.

### Tamiflu contains fructose

Before you take Tamiflu, make sure your prescribing doctor knows if you have hereditary fructose intolerance. This medicine contains sorbitol, which is a form of fructose. Sorbitol can have a mild laxative effect.

## 3. How to take Tamiflu

Take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Always use the oral dispenser that is provided in the box and has markings indicating the dose in millilitre (ml).

Take Tamiflu as soon as possible, ideally within the first two days of the start of flu symptoms.

### The recommended doses

**For treating flu**, take two doses daily. It is usually convenient to take one dose in the morning and one in the evening. **It is important to complete the whole 5-day course**, even if you start to feel better quickly.

**For preventing flu or after being exposed to an infected person**, take one dose daily for 10 days. It is best to take this in the mornings with breakfast.

In special situations, such as widespread flu and for patients with a weak immune system, treatment will continue for up to 6 weeks or 12 weeks.

The oral suspension can be used by people who find it hard to take capsules. You must use the amount of oral suspension prescribed by the doctor. **The recommended dose is based on the patient's body weight.**

#### Adults and adolescents 13 to 17 years old

Body weight	Treating flu: dose for 5 days	Preventing flu: dose for 10 days
40 kg or more	12.5 ml twice daily	12.5 ml once daily

*12.5 ml is made up of a 5 ml dose plus a 7.5 ml dose*

#### Children 1 to 12 years old

Body weight	Treating flu: dose for 5 days	Preventing flu: dose for 10 days
10 kg to 15 kg	5.0 ml twice daily	5.0 ml once daily
More than 15 kg, up to 23 kg	7.5 ml twice daily	7.5 ml once daily
More than 23 kg, up to 40 kg	10.0 ml twice daily	10.0 ml once daily
More than 40 kg	12.5 ml twice daily	12.5 ml once daily

**For infants less than 1 year old** the treatment dose may change during a pandemic: your doctor will explain further.

In case of a pandemic, a 3 ml oral dispenser (graduated in 0.1 ml steps) should be used for dosing infants less than 1 year old. Your doctor will tell you where you can obtain the 3 ml oral dispenser.

#### Infants 0 to 1 month old

Body weight	Treating flu: dose for 5 days	Preventing flu: dose <b>once daily</b> for 10 days
3 kg	1.0 ml twice daily	1.0 ml once daily
3.5 kg	1.2 ml twice daily	1.2 ml once daily
4 kg	1.3 ml twice daily	1.3 ml once daily
4.5 kg	1.5 ml twice daily	1.5 ml once daily

**Infants 1 to 3 months old**

<b>Body weight</b>	<b>Treating flu:</b> dose <b>twice daily</b> for <i>5 days</i>	<b>Preventing flu:</b> dose <b>once daily</b> for <i>10 days</i>
4 kg	1.7 ml twice daily	1.7 ml once daily
4.5 kg	1.9 ml twice daily	1.9 ml once daily
5 kg	2.1 ml twice daily	2.1 ml once daily
5.5 kg	2.3 ml twice daily	2.3 ml once daily
6 kg	2.5 ml twice daily	2.5 ml once daily
6.5 kg	2.7 ml twice daily	2.7 ml once daily

**Infants 3 to 12 months old**

<b>Body weight</b>	<b>Treating flu:</b> dose <b>twice daily</b> for <i>5 days</i>	<b>Preventing flu:</b> dose <b>once daily</b> for <i>10 days</i>
6 kg	3.0 ml twice daily	3.0 ml once daily
7 kg	3.5 ml twice daily	3.5 ml once daily
8 kg	4.0 ml twice daily	4.0 ml once daily
9 kg	4.5 ml twice daily	4.5 ml once daily
10 kg	5.0 ml twice daily	5.0 ml once daily

**If you take more Tamiflu than you should, stop taking Tamiflu and contact your doctor or pharmacist immediately.**

You might experience nausea, vomiting and/or dizziness.

**If you forget to take Tamiflu**

Do not take a double dose to make up for a forgotten dose.

**If you stop taking Tamiflu**

There are no side effects when you stop Tamiflu. But if Tamiflu is stopped earlier than your doctor told you, the symptoms of flu may come back.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

**4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them. Many of the side effects listed below may also be caused by influenza.

The following serious side effects have been rarely reported since oseltamivir has been marketed:

- Anaphylactic and anaphylactoid reactions: severe allergic reactions, with face and skin swelling, itchy rashes, low blood pressure and breathing difficulties
- Hepatic disorders (fulminant hepatitis, hepatic function disorder and jaundice): yellowing of the skin and white of the eyes, change in stool colour, changes in behaviour
- Angioneurotic oedema: sudden onset of severe swelling of the skin mainly around the head and neck area, including eyes and tongue, with difficulties breathing
- Stevens-Johnson syndrome and toxic epidermal necrolysis: complicated, possibly life-threatening allergic reaction, severe inflammation of the outer and possibly inner skin, initially with fever, sore throat, and fatigue, skin rashes, leading to blisters, peeling, shedding of larger areas of skin, possible breathing difficulties and low blood pressure
- Gastrointestinal bleeding: prolonged bleeding from the large bowel or spitting up blood
- Neuropsychiatric disorders, as described below.

**If you notice any of these symptoms, get medical help immediately.**

The most frequently (very common and common) reported side effects of Tamiflu are feeling or being sick (nausea, vomiting), stomach ache, stomach upset, headache and pain. These side effects mostly occur after the first dose of the medicine and will usually stop as treatment continues. The frequency of these effects is reduced if the medicinal product is taken with food.

**Rare but serious effects: get medical help at once**

*(These may affect up to 1 in 1,000 people)*

During Tamiflu treatment, rare events have been reported that include

- Convulsions and delirium, including altered level of consciousness
- Confusion, abnormal behaviour
- Delusions, hallucinations, agitation, anxiety, nightmares

These are reported primarily among children and adolescents and often started suddenly and resolved rapidly. A few cases resulted in self-injury, some with fatal outcome. Such neuropsychiatric events have also been reported in patients with influenza who were not taking Tamiflu.

- Patients, especially children and adolescents, should be closely monitored for the behavioural changes described above.
- **If you notice any of these symptoms, especially in younger people, get medical help immediately.**

**Adults and adolescents 13 to 17 years old**

**Very common: may affect more than 1 in 10 people**

- Headache
- Nausea.

**Common: may affect up to 1 in 10 people**

- Bronchitis
- Cold sore virus
- Cough
- Dizziness
- Fever
- Pain
- Pain in limb
- Runny nose
- Sleeping difficulties
- Sore throat
- Stomach ache
- Tiredness
- Upper abdominal fullness
- Upper respiratory tract infections (inflammation of the nose, throat and sinuses)
- Upset stomach
- Vomiting.

**Uncommon: may affect up to 1 in 100 people**

- Allergic reactions
- Altered level of consciousness
- Convulsion
- Heart rhythm abnormalities
- Mild to severe liver function disorders
- Skin reactions (inflammation of the skin, red and itchy rash, scaling skin).

**Rare: may affect up to 1 in 1,000 people**

- Thrombocytopenia (low platelet count)

- Visual disturbances.

### **Children 1 to 12 years old**

#### **Very common: may affect more than 1 in 10 people**

- Cough
- Nasal congestion
- Vomiting.

#### **Common: may affect up to 1 in 10 people**

- Conjunctivitis (red eyes and discharge or pain in the eye)
- Ear inflammation and other ear disorders
- Headache
- Nausea
- Runny nose
- Stomach ache
- Upper abdominal fullness
- Upset stomach.

#### **Uncommon: may affect up to 1 in 100 people**

- Inflammation of the skin
- Tympanic membrane (eardrum) disorder.

### **Infants 1 to 12 months old**

The reported side effects in infants 1 to 12 months old are similar to the side effects reported for older children (1 year old or older).

### **Infants 0 to 1 month old**

There is no information available for the use of Tamiflu in infants less than 1 month old.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, tell your doctor or pharmacist. However,

- **if you or your child are repeatedly sick, or**
- **if the influenza symptoms get worse or the fever continues**

**Tell your doctor as soon as possible.**

## **5. How to store Tamiflu**

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and bottle after EXP. The expiry date refers to the last day of that month.

Powder: Do not store above 30°C.

After reconstitution, store below 25 °C for 10 days.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## 6. Contents of the pack and other information

### What Tamiflu contains

- The active substance is oseltamivir (6 mg/ml oseltamivir after reconstitution).
- The other ingredients are sorbitol (E420), sodium dihydrogen citrate (E331[a]), xanthan gum (E415), sodium benzoate (E211), saccharin sodium (E954), titanium dioxide (E171) and tutti frutti flavour (including maltodextrins [maize], propylene glycol, arabic gum E414 and natural identical flavouring substances [mainly consisting of banana, pineapple and peach flavour]).

### What Tamiflu looks like and contents of the pack

#### Powder for oral suspension

The powder is a granulate or clumped granulate with a white to light yellow colour.

Tamiflu 6 mg/ml powder for oral suspension is available in a bottle containing 13 g powder for mixing with 55 ml of water.

The box also contains 1 plastic measuring cup (55 ml), 1 plastic bottle adapter (to help get the drug into the dispenser) and 1 plastic 10 ml oral dispenser (to give the correct amount of medicine via the mouth). Shown on the oral dispenser are millilitre (ml) markings of the medicine (see figures in *Instructions for the user*).

For details on how to prepare the oral suspension and how to measure and take the medicine, read *Instructions for the user*.

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**This leaflet was last revised in September 2012.**

Detailed information on this medicine is available on the European Medicines Agency web site:  
<http://www.ema.europa.eu>.

## Instructions for the user

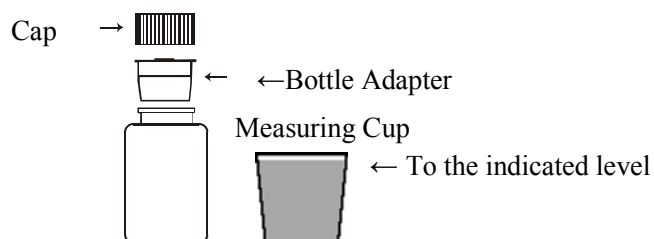
**How to prepare the oral suspension:** Your pharmacist may have prepared the oral suspension for you when you collected your prescription. However, if they have not done this, then you can do it easily yourself.

**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.

To prepare the suspension, you will need:

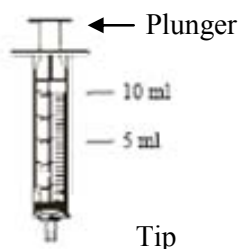
- The bottle, containing Tamiflu powder
- The bottle cap
- A measuring cup
- The bottle adapter

All of these should be in the medicine pack.



To measure and give a dose, you will need:

- The 10 ml oral dispenser (in the medicine pack).



Always use the oral dispenser provided with your medicine to measure a correct dose. Most of the time you will use the 10 ml oral dispenser provided in the pack. It is marked from 0 to 10 ml.

### How to prepare the suspension – four steps:

1. **Loosen the powder in the bottle:**  
Tap the closed bottle gently several times to loosen the powder.
2. **Measure 55 ml of water:**  
Use the measuring cup provided in the pack and fill it with water to the indicated level.  
**Always use 55 ml of water**, irrespective of the recommended dose you are taking.

3. **Mix the water with the powder:**

Add all 55 ml of water into the bottle. Recap the bottle and shake the closed bottle well for 15 seconds.

4. **Insert the bottle adapter and reclose the bottle:**

Remove the cap and push the bottle adapter into the neck of the bottle.

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.

You now have the prepared bottle of Tamiflu oral suspension ready to measure out and give a dose.

**How to measure and give a dose – four steps:**

1. **Shake the bottle:**

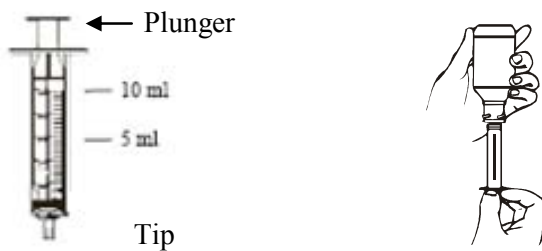
Thoroughly shake the closed bottle of Tamiflu oral suspension before use.

**Always shake well before use**

2. **Prepare the oral dispenser:**

Use the 10 ml oral dispenser provided in the pack.

**Push** the plunger completely down toward the tip of the dispenser.



3. **Fill the dispenser with the correct dose:**

Remove the cap from the bottle of oral suspension.

**Insert the tip of the dispenser** into the bottle adapter.

Then turn the entire unit **upside down** (bottle and dispenser together).

**Slowly pull out the plunger** to the mark that shows the dose you need. Then turn the entire unit **upright**.

Slowly remove the dispenser from the bottle.

4. **Give the medicine:**

Deliver the suspension directly into the mouth by pushing down the plunger of the dispenser.

Make sure the medicine is swallowed. You may drink and eat something after taking the medicine.

Take the dispenser apart straight after dosing, and rinse both parts of the dispenser under running tap water.

**Infants less than 1 year old:**

If flu levels have reached a pandemic, a **smaller, 3 ml oral dispenser** (marked in 0.1 ml steps) should be used for dosing infants less than 1 year old.

This 3 ml oral dispenser is not provided in the pack. Your doctor will tell you from where you can obtain a 3 ml dispenser.