

**PACKAGE LEAFLET: INFORMATION FOR THE USER**

**Tamiflu 75 mg hard capsules**  
oseltamivir

**Read all of this leaflet carefully before you start taking this medicine.**

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

**In this leaflet:**

1. What Tamiflu is and what it is used for
2. Before you take Tamiflu
3. How to take Tamiflu
4. Possible side effects
5. How to store Tamiflu
6. Further information

**1. WHAT TAMIFLU IS AND WHAT IT IS USED FOR**

- Tamiflu is prescribed to you for treating or preventing influenza.
- Tamiflu belongs to a group of medicines named “neuraminidase inhibitors”. These medicines prevent the influenza virus from spreading inside the body and so help to ease or prevent the symptoms arising from the influenza virus infection.
- Influenza is an infection caused by the influenza virus. The signs (symptoms) of influenza include the sudden onset of fever (more than 37.8 °C), cough, runny or stuffy nose, headaches, muscle aches and often extreme fatigue. These symptoms may also be caused by infections other than influenza. True influenza infection only occurs during annual outbreaks (epidemics) at times when influenza viruses are spreading in the local community. Outside of the epidemic period, these symptoms will mainly be caused by a different type of infection or illness.

**2. BEFORE YOU TAKE TAMIFLU**

**Do not take Tamiflu**

- if you are allergic (hypersensitive) to oseltamivir or any of the other ingredients of Tamiflu.

**Take special care with Tamiflu**

Before you take Tamiflu, make sure your prescribing doctor knows if you

- are allergic to other medicines
- have problems with your kidneys.

### **Taking other medicines**

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Tamiflu can be taken with appropriate medicines to treat fever (high temperature). Tamiflu is not expected to alter the effect of any other medicines.

### **Are there any interactions with an influenza vaccination?**

**Tamiflu is not a substitute for influenza vaccination.** Tamiflu will not change the effectiveness of the influenza vaccine. Even if a vaccination against influenza has been given to you Tamiflu may be prescribed by your doctor.

### **Taking Tamiflu with food and drink**

Swallow Tamiflu with water. Tamiflu can be taken with or without food, although it is recommended to take Tamiflu with food to reduce the chance of feeling or being sick (nausea or vomiting).

### **Pregnancy and breast-feeding**

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

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 nursing 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.

### **Driving and using machines**

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

## **3. HOW TO TAKE TAMIFLU**

Always take Tamiflu exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Take Tamiflu as soon as you get the prescription as this will help to slow the spread of the influenza virus in the body.

Swallow Tamiflu capsules whole with water. Do not break or chew Tamiflu capsules.

The usual dose is as follows:

<b><i>Treatment</i></b>
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➤ Adolescents (13 to 17 years of age) and adults: For treatment of influenza take one capsule as soon as you get the prescription and then take one capsule twice a day (usually it is convenient to take one in the morning and one in the evening for five days). It is important to complete the whole 5 day course, even if you start to feel better quickly.

30 mg and 45 mg capsules can be used by adults and adolescents as an alternative to 75 mg capsules.

➤ Infants 1 year of age and older, and children 2 to 12 years of age: Tamiflu oral suspension or 30 mg and 45 mg capsules can be used instead.

Children weighing more than 40 kg and who can swallow capsules may take Tamiflu 75 mg capsules twice daily for 5 days.

➤ Infants below 12 months of age: Limited pharmacokinetic and safety data are available for children less than 2 years of age. Pharmacokinetic modeling was undertaken using these data in addition to data from studies in adults and children older than 1 year of age. The results demonstrate that doses of 3 mg/kg twice daily for infants aged 3 to 12 months and 2.5 mg/kg twice daily for infants aged between 1 and 3 months provide exposures similar to those shown to be clinically efficacious in adults and children older than 1 year of age (see table below for weight-based dosing recommendations). There are currently no data available in infants less than 1 month of age using Tamiflu.

Age	Recommended dose for 5 days (Treatment)
> 3 months to 12 months	3 mg/kg twice daily
> 1 month to 3 months	2.5 mg/kg twice daily
0 to 1 month	2 mg/kg twice daily

Administration of Tamiflu to infants less than one year of age should be based upon the judgment of the physician after considering the potential benefit of treatment versus any potential risk to the infant.

#### **Prevention**

Tamiflu can also be used for prevention of influenza following exposure to an infected individual, such as family members.

➤ Adolescents (13 to 17 years of age) and adults: When used to prevent influenza following exposure to an infected individual, such as family members, Tamiflu should be taken once daily for 10 days. It is best to take this dose in the mornings with breakfast.

➤ Infants 1 year of age and older and children 2 to 12 years of age: Tamiflu oral suspension or 30 mg and 45 mg capsules can be used instead.

Children weighing more than 40 kg and can swallow capsules may take Tamiflu 75 mg capsules once daily for 10 days.

Your doctor will recommend the length of time to continue taking Tamiflu, if it is prescribed to prevent influenza.

➤ Infants below 12 months of age: The recommended prophylaxis dose for infants less than 12 months of age during a pandemic influenza outbreak is half of the daily treatment dose. This is based upon clinical data in children older than 1 year of age and adults showing that a prophylaxis dose equivalent to half the daily treatment dose is clinically efficacious for the prevention of influenza. The following weight-adjusted dosing prophylaxis regimens are recommended for infants below 1 year of age:

Age	Recommended dose for 10 days (Prevention)
> 3 months to 12 months	3 mg/kg once daily
> 1 month to 3 months	2.5 mg/kg once daily
0 to 1 month	2 mg/kg once daily

Administration of Tamiflu to infants less than one year of age should be based upon the judgment of the physician after considering the potential benefit of prophylaxis versus any potential risk to the infant.

#### **When Tamiflu oral suspension is not available**

During situations when commercially manufactured Tamiflu oral suspension is not readily available, adults, adolescents or children who are unable to swallow capsules may receive appropriate doses of Tamiflu by opening capsules and pouring the contents of capsules into a suitable, small amount (1 teaspoon maximum) of sweetened food product such as sugar water, chocolate syrup, cherry syrup, dessert toppings (like caramel or fudge sauce) to mask the bitter taste. The mixture should be stirred and the entire contents given to the patient. The mixture must be swallowed immediately after its preparation.

#### **Preparing Tamiflu doses for infants younger than 1 year — 75 mg capsules**

Infants who weigh 10 kg or less need a Tamiflu dose of 30 mg or less. To make doses of Tamiflu for these infants, you will need to open a Tamiflu capsule and mix the powder inside the capsule with food.

You will need:

1. One 75 mg Tamiflu capsule
2. Dosing chart to determine the correct dosage amount (see Tamiflu dosing chart under step 3 in the next section below)
3. A pair of scissors
4. Two small bowls per child (use separate pairs of bowls for each child)
5. One 5 ml (five millilitre) oral syringe that shows measurements of 0.2 ml (two-tenths of one millilitre)
6. One suitable oral dosing syringe that shows measurements of 0.1 ml (one-tenth of one millilitre). Ask the pharmacist for the correct syringe (1 ml, 2 ml, or 3 ml).
7. One teaspoon
8. One of these foods to hide the bitter taste of the Tamiflu powder:
  - Sugar water (If you plan to use sugar water, make this mixture now in a separate bowl or cup. Mix a teaspoon of water with three-fourths [3/4] of a teaspoon of sugar.)
  - Chocolate syrup
  - Cherry syrup
  - Dessert toppings, like caramel or fudge sauce

#### **Making the Tamiflu 10 mg/ml mixture for infants younger than 1 year — 75 mg capsules**

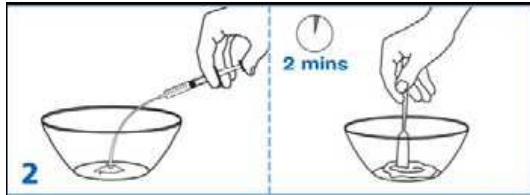
These instructions show you how to make one dose of Tamiflu, to be used immediately.

1. Carefully open ONE 75 mg Tamiflu capsule over the first small bowl. To open a capsule, hold the capsule upright and snip off the rounded tip with scissors (see accompanying picture). Pour all of the powder into the bowl. Handle the powder carefully, because it may be irritating to the skin and eyes.



2. Follow the chart below. Use the 5 ml dosing syringe to measure first 5.0 ml of water, and add it to the powder in the bowl. Then measure 2.5 ml of water, and add it to the powder in the bowl. *Stir for about 2 minutes.*

Tamiflu capsule	Amount of water to add
ONE 75 mg capsule 	7.5 ml (seven and a half millilitres)



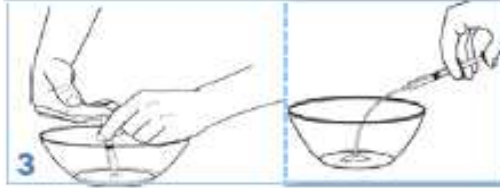
3. Follow the chart below. Find the child's weight on the left side of the chart, and then look at the column on the right side of chart to see the amount of the Tamiflu powder-water mixture to draw up into the dosing syringe. Draw up the correct amount of powder-water mixture from the first small bowl into the dosing syringe, and then gently expel it from the dosing syringe into the second bowl.

Tamiflu dosing chart for infants 1 to 12 months of age:

Weight (rounded to the nearest 0.5 kg)	Required dose of Tamiflu	Amount of Tamiflu powder-water mixture to be drawn up into the dosing syringe
4 kg	10 mg	1.00 ml
4.5 kg	11.25 mg	1.10 ml
5 kg	12.5 mg	1.30 ml
5.5 kg	13.75 mg	1.40 ml
6 kg	15 mg	1.50 ml
7 kg	21 mg	2.10 ml
8 kg	24 mg	2.40 ml
9 kg	27 mg	2.70 ml
≥ 10 kg	30 mg	3.00 ml

Tamiflu dosing chart for infants below 1 month of age:

Weight (rounded to the nearest 0.5 kg)	Required dose of Tamiflu	Amount of Tamiflu powder-water mixture to be drawn up into the dosing syringe
3 kg	6 mg	0.60 ml
3.5 kg	7 mg	0.70 ml
4 kg	8 mg	0.80 ml
4.5 kg	9 mg	0.90 ml



4. Add a small amount of one of the sweet foods (use no more than 1 teaspoon) into the second bowl. This will hide the bitter taste of the powder-water mixture.



5. Mix the sweet food and powder-water mixture well.



6. Give the entire contents of the second bowl (sweet food with powder-water mixture) to the child.
7. Give the child something suitable to drink.
8. Throw out any unused powder-water mixture left in the first bowl.

(Note: Not all capsule contents may dissolve. Do not worry, as the undissolved materials are inactive ingredients.)

### **Preparing Tamiflu doses for children 1 year of age or older — if you have only 75 mg capsules available**

Children who weigh less than 40 kg need a Tamiflu dose of less than 75 mg. To make doses of Tamiflu for these children, you will need to open a 75 mg capsule, prepare a powder-water mixture and mix the correct volume of the mixture with food.

You will need

1. One 75 mg Tamiflu capsule
2. Dosing chart to determine the correct dosage amount (see charts under step 3 in the next section below)
3. A pair of scissors
4. Two small bowls per child (use separate pairs of bowls for each child)
5. One 5 ml (five millilitre) oral syringe that shows measurements of 0.2 ml (two-tenths of one millilitre)
6. One suitable oral dosing syringe that shows measurements of 0.1 ml (one-tenth of one millilitre). Ask the pharmacist for the correct syringe (1 ml, 2 ml, or 3 ml).
7. One teaspoon
8. One of these foods to hide the bitter taste of the Tamiflu powder:

- Sugar water (If you plan to use sugar water, make this mixture now in a separate bowl or cup. Mix a teaspoon of water with three-fourths [3/4] of a teaspoon of sugar.)
- Chocolate syrup
- Cherry syrup
- Dessert toppings, like caramel or fudge sauce

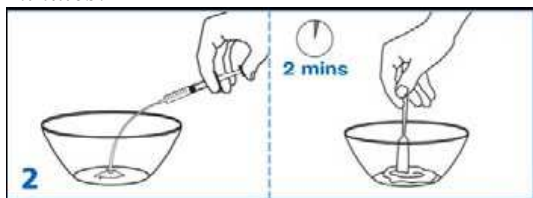
**Making the Tamiflu mixture for children 1 year of age or older — if you have only 75 mg capsules available**

These instructions show you how to make one dose of Tamiflu, to be used immediately.

1. Carefully open ONE 75 mg Tamiflu capsule over the first small bowl. To open a capsule, hold the capsule upright and snip off the rounded tip with scissors (see accompanying picture). Pour all of the powder into the bowl. Handle the powder carefully, because it may be irritating to the skin and eyes.



2. Use the 5 ml syringe to add 5 ml of water to the powder in the bowl. *Stir for about 2 minutes.*



(Note: Not all capsule contents may dissolve. Do not worry, as the undissolved materials are inactive ingredients.)

3. The next step will be to draw up the correct amount of powder-water mixture from the first small bowl, and to gently expel it into the second small bowl.

You must find what the correct amount of powder-water mixture to draw up into the dosing syringe is. If you know the child's weight, you can do this by finding the child's weight on the left side of the first table below. Then, look at the middle column of the table to see the correct amount of the powder-water mixture to draw up into the dosing syringe.

If you do not know the child's weight, find the child's age on the left side of the second table below. Then, look at the middle column of the table to see the correct amount of the powder-water mixture to draw up into the dosing syringe.

Weight	Amount of Tamiflu Mixture	Dose in mg
Up to 15 kg	2 ml = 1 dose	30 mg
15 kg up to 23 kg	3 ml = 1 dose	45 mg
23 kg up to 40 kg	4 ml = 1 dose	60 mg

Age	Amount of Tamiflu Mixture	Dose in mg
1 to 2 years	2 ml = 1 dose	30 mg
3 to 5 years	3 ml = 1 dose	45 mg
6 to 9 years	4 ml = 1 dose	60 mg

Once you have drawn up the correct amount of powder-water mixture into the dosing syringe, gently expel it from the dosing syringe into the second bowl.



4. Add a small amount of one of the sweet foods into the second bowl to hide the bitter taste of the powder-water mixture.



5. Mix the sweet food and powder-water mixture well.



6. Give the entire contents of the second bowl (sweet food with powder-water mixture) to the child.
7. Throw out any unused powder-water mixture left in the first bowl.

**Repeat this procedure every time you need to take the medicine.**

**If you take more Tamiflu, than you should**

Contact your doctor or pharmacist immediately.

**If you have forgotten to take Tamiflu**

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

**If you stop taking Tamiflu**

There are no side effects when Tamiflu is discontinued prior to advice from your doctor. If Tamiflu is stopped earlier than your doctor told you, the symptoms of influenza may reoccur.

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

#### **4. POSSIBLE SIDE EFFECTS**

Like all medicines, Tamiflu can cause side effects, although not everybody gets them.

##### **- Common side effects of Tamiflu**

The most common side effects of Tamiflu are nausea, vomiting, diarrhoea, stomach ache and headache. These side effects mostly occur only 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.

##### **- Less common side effects of Tamiflu**

###### **Adults and adolescents (children aged 13 years and older)**

Other less common side effects, which may also be caused by influenza, are upper abdominal fullness, bleeding in the gastrointestinal tract, bronchitis, upper respiratory tract infections, dizziness, tiredness, sleeping difficulties, skin reactions, mild to severe liver function disorders, visual disturbances and heart rhythm abnormalities.

Influenza can be associated with a variety of neurologic and behavioural symptoms which can include events such as hallucinations, delirium, and abnormal behaviour, in some cases resulting in fatal outcomes. These events may occur in the setting of encephalitis or encephalopathy but can occur without obvious severe disease.

During Tamiflu treatment, events like convulsions and delirium (including symptoms such as altered level of consciousness, confusion, abnormal behaviour, delusions, hallucinations, agitation, anxiety, nightmares) have been reported, in a very few cases resulting in accidental injury, in some instances with fatal outcome. These events were reported primarily among children and adolescents and often had an abrupt onset and rapid resolution. The contribution of Tamiflu to those events is unknown. Such neuropsychiatric events have also been reported in patients with influenza who were not taking Tamiflu.

###### **Children (aged 1 to 12 years)**

Other less common side effects, which may also be caused by influenza, are cough, nasal congestion, ear inflammation, inflammation of the lungs, sinusitis, bronchitis, aggravation of pre-existing asthma, nose bleeding, ear disorders, inflammation of the skin, swelling of the lymph nodes, conjunctivitis, visual disturbances and heart rhythm abnormalities.

###### **Infants (aged 6 to 12 months)**

The reported side effects of Tamiflu when used for treatment of influenza in infants 6 to 12 months of age are similar to the side effects reported for older children (1 year and older). Please read the section above for your information.

###### **Infants (aged 0 to 6 months)**

The reported side effects of Tamiflu when used for treatment of influenza in infants 1 to 6 months of age are similar to the side effects reported for infants 6 to 12 months of age and older children (1 year and older). There are no data available for the use of Tamiflu in infants less than 1 month of age. Please read the section above for your information.

***If you or your child are often sick, you should inform your doctor. You should also tell your doctor if the influenza symptoms get worse or the fever continues.***

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.

## **5. HOW TO STORE TAMIFLU**

Keep out of the reach and sight of children.

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

Do not store above 25 °C.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## **6. FURTHER INFORMATION**

### **What Tamiflu contains**

- The active substance is oseltamivir phosphate (75 mg oseltamivir in each hard capsule).
- The other ingredients are:
  - capsule contents: pregelatinised starch, talc, povidone, croscarmellose sodium and sodium stearyl fumarate
  - capsule shell: gelatin, yellow iron oxide (E172), red iron oxide (E172), black iron oxide (E172) and titanium dioxide (E171)
  - printing ink: shellac (E904), titanium dioxide (E171) and indigocarmine (E132).

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

The hard capsule consists of a grey opaque body bearing the imprint “ROCHE” and a light yellow opaque cap bearing the imprint “75 mg”. Imprints are blue.

Tamiflu 75 mg hard capsules are available in blister packs of 10.

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**This leaflet was last approved in March 2010**

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