

PACKAGE LEAFLET: INFORMATION FOR THE USER

Tamiflu 45 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:

<i>Treatment</i>

➤ Adolescents (13 to 17 years of age) and adults:

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

For treatment of influenza take one 30 mg and one 45 mg capsule as soon as you get the prescription and then take one 30 mg and one 45 mg capsule twice a day (usually it is convenient to take one 30 mg and one 45 mg in the morning and one 30 mg and one 45 mg in the evening for five days). It is important to complete the whole 5 day course, even if you start to feel better quickly.

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

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

You must give the amount of capsules to your child as prescribed by your doctor.

The usual dose for treatment of influenza in children depends on the body weight of the child (see table below).

Children 1 year of age and older:

Body Weight	Recommended dose for 5 days (Treatment)
Less than or equal to 15 kg	30 mg twice daily
More than 15 kg and up to 23 kg	45 mg twice daily
More than 23 kg and up to 40 kg	60 mg twice daily
More than 40 kg	75 mg twice daily (75 mg is made up of a 30 mg dose plus a 45 mg dose)

➤ Infants below 12 months of age: Limited pharmacokinetic and safety data are available for infants 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:

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

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 can be used instead of capsules.

The usual dose for prevention of influenza in children depends on the body weight of the child (see table below).

Children 1 year of age and older:

Body Weight	Recommended dose for 10 days (Prevention)
Less than or equal to 15 kg	30 mg once daily
More than 15 kg and up to 23 kg	45 mg once daily
More than 23 kg and up to 40 kg	60 mg once daily
More than 40 kg	75 mg once daily (75 mg is made up of a 30 mg dose plus a 45 mg dose)

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

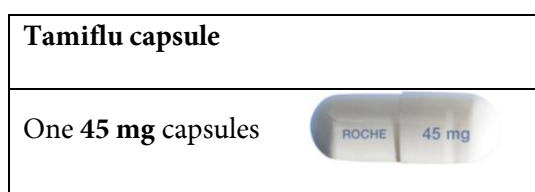
When commercially manufactured Tamiflu oral suspension is not available, a pharmacy preparation from Tamiflu capsules can be used (see end of package leaflet, information for medical or healthcare personnel). If the pharmacy preparation is not available either, Tamiflu doses may be prepared at home. The pharmacy preparation is the preferred option in infants below 12 months of age.

When appropriate capsule strengths are available, the dose is given by opening the capsule and mixing its contents with no more than one teaspoon of a suitable sweetened food product. The bitter taste can be masked by products such as sugar water, chocolate syrup, cherry syrup, dessert toppings (like caramel or fudge sauce). The mixture should be stirred and given entirely to the patient. The mixture must be swallowed immediately after its preparation.

When only 75 mg capsules are available, and doses of 30 mg or 45 mg are needed, the preparation involves additional steps.

➤ **Children one year old and above: Preparing 45 mg Tamiflu doses from 45 mg capsules**

To make doses of Tamiflu for patients who cannot swallow capsules, you will need to follow all the steps below to mix the powder from Tamiflu capsules with food.



You will need:

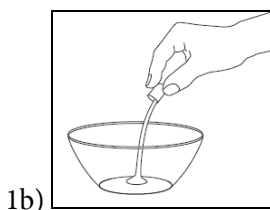
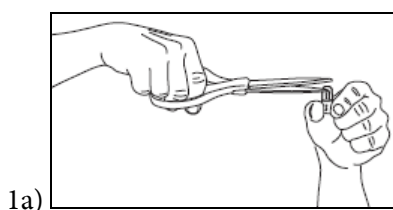
1. **One** 45 mg Tamiflu capsule
2. A pair of scissors
3. One small bowl for each patient (use a separate bowl for each patient)
4. One teaspoon
5. One of these foods to hide the bitter taste of the Tamiflu powder:
 - Sugar water (if you will be using this, make the mixture now in a separate bowl or cup by mixing a teaspoon of water with three-quarters $[3/4]$ of a teaspoon of sugar);
 - Chocolate syrup;
 - Cherry syrup; or
 - Dessert toppings, like caramel or fudge sauce

(Note: You should use only 45 mg capsules for 45 mg doses. Do not try to make a 30 mg or 75 mg dose by using the contents of 45 mg capsules.)

How to make the 45 mg dose from 45 mg capsules

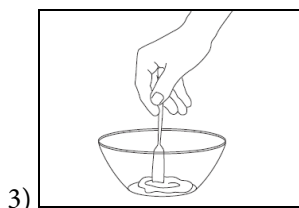
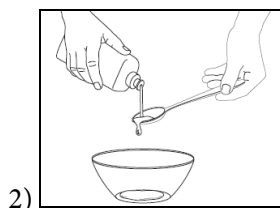
These instructions show you how to make **one** dose of Tamiflu, which you should use immediately.

1. Carefully open **one** 45 mg Tamiflu capsule over the bowl. To open a capsule, hold it upright and snip off the rounded tip with scissors (see picture 1a, below). Pour all of the powder into the bowl (picture 1b). Be careful with the powder, because it may irritate your skin and eyes.



2. Add a small amount of the sweet food (no more than one teaspoon) to the bowl to hide the bitter taste of the Tamiflu powder (picture 2).

3. Stir the mixture well (picture 3).



4. Give all the contents of the bowl to the patient.
5. If there is some mixture left in the bowl, rinse the bowl with a small amount of water and have the patient drink this remaining mixture.
6. Repeat this procedure every time you need to give the medicine.

➤ **Children less than one year old: Preparing Tamiflu doses from 45 mg capsules**

Children who weigh 10 kg or less need a Tamiflu dose of 30 mg or less. To make doses of Tamiflu for these children, you will need to open a Tamiflu capsule and first prepare a powder-water mixture. From this mixture you need to take the correct volume and to improve the taste you can mix it with sweet food for dosing. Follow the detailed instructions for these steps as described below.

You will need:

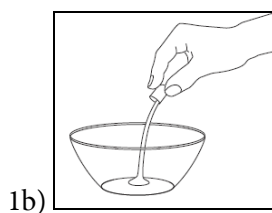
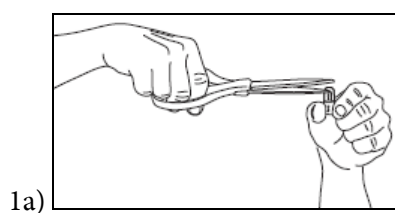
1. **One** 45 mg Tamiflu capsule
2. A pair of scissors
3. Two small bowls for each child (use separate pairs of bowls for each child)
4. Two oral-dosing syringes
 - one syringe that is suitable to draw up to a least 4.5 ml of water (5 ml syringe)
 - one syringe of the recommended size for the Tamiflu mixture that shows measurements of 0.1 ml (one-tenth of one millilitre) (see table in step 3 below)
5. One teaspoon
6. One of these foods to hide the bitter taste of the Tamiflu powder:

- Sugar water (if you will be using this, make the mixture now in a separate bowl or cup by mixing a teaspoon of water with three-quarters $[3/4]$ of a teaspoon of sugar);
- Chocolate syrup;
- Cherry syrup; or
- Dessert toppings, like caramel or fudge sauce


How to make Tamiflu doses for children less than one year old from 45 mg capsules

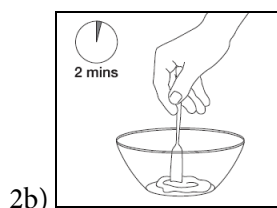
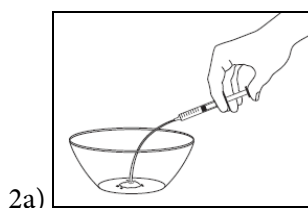
These instructions show you how to make **one** dose of Tamiflu, which you should use immediately.

1. Carefully open **ONE** 45 mg Tamiflu capsule over the first bowl. To open a capsule, hold it upright and snip off the rounded tip with scissors (see picture 1a, below). Pour all of the powder into the bowl (picture 1b). Be careful with the powder, because it may irritate your skin and eyes.



2. Follow the diagram below. Use the 5 ml syringe to measure 4.5 ml of water and add it to the powder in the bowl (picture 2a). Stir the mixture for about 2 minutes (picture 2b).

Tamiflu capsule	Amount of water to add
ONE 45 mg capsule 	4.5 ml (four and a half millilitres)



(Note: Some of the powder from the capsule might not dissolve. Do not worry, as the undissolved powder is just inactive ingredients.)

- Follow the tables below to find the correct dose of Tamiflu mixture. Use Table 3a for dosing children between one month and 12 months old. Use Table 3b for dosing children less than one month old.

Find the child's weight on the left side of the table, and then look at the column on the right side of the table to see the amount of the Tamiflu mixture you need to draw up into the appropriate sized syringe.

Draw up the correct amount of Tamiflu mixture from the first bowl into the appropriate sized syringe (picture 3a) and then gently squirt it from the syringe into the second bowl (picture 3b).

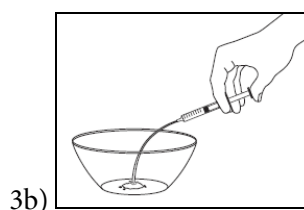
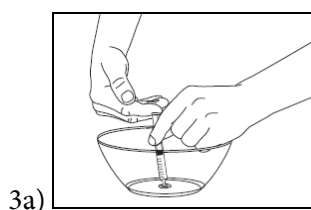
Table 3a Tamiflu dosing chart for children between one month and 12 months old

Weight	Dose of Tamiflu	Amount of Tamiflu mixture you need to draw up into the syringe	Syringe Size to Use
4 kg	10 mg	1.00 ml	2 ml (or 3 ml)
4.5 kg	11.25 mg	1.10 ml	2 ml (or 3 ml)
5 kg	12.5 mg	1.30 ml	2 ml (or 3 ml)
5.5 kg	13.75 mg	1.40 ml	2 ml (or 3 ml)
6 kg	15 mg	1.50 ml	2 ml (or 3 ml)
7 kg	21 mg	2.10 ml	3 ml
8 kg	24 mg	2.40 ml	3 ml
9 kg	27 mg	2.70 ml	3 ml

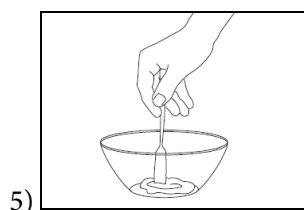
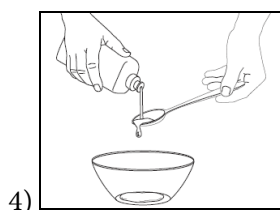
Weight	Dose of Tamiflu	Amount of Tamiflu mixture you need to draw up into the syringe	Syringe Size to Use
more than 10 kg	30 mg	3.00 ml	3 ml (or 5 ml)

Table 3b Tamiflu dosing chart for children less than one month old

Weight	Dose of Tamiflu	Amount of Tamiflu mixture you need to draw up into the syringe	Syringe Size to Use
3 kg	6 mg	0.60 ml	1 ml (or 2 ml)
3.5 kg	7 mg	0.70 ml	1 ml (or 2 ml)
4 kg	8 mg	0.80 ml	1 ml (or 2 ml)
4.5 kg	9 mg	0.90 ml	1 ml (or 2 ml)



4. Add a small amount of the sweet food (no more than one teaspoon) into the second bowl. This will hide the bitter taste of the Tamiflu mixture (picture 4).
5. Mix the sweet food and Tamiflu mixture well (picture 5).



- 6 Give all the contents of the second bowl (sweet food with Tamiflu mixture) to the child.

7. If there is some mixture left in the second bowl, rinse the bowl with a small amount of water and have the patient drink this remaining mixture.
8. Give the child something to drink.
9. Throw out any unused Tamiflu mixture left in the first bowl.
10. Repeat this procedure every time you need to give the medicine.

If you take more Tamiflu, than you should

Contact your doctor or pharmacist immediately.

If you forget 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.

The most frequently reported side effects of Tamiflu are nausea, vomiting, stomach ache, stomach upset, headache and pain. 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.

During Tamiflu treatment, rare (*likely to occur in 1 to 10 patients in 10,000*) 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 self-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. Such neuropsychiatric events have also been reported in patients with influenza who were not taking Tamiflu.

Adults and adolescents (children aged 13 years and older)

Very common side effects (likely to occur in more than 1 in 10 patients):

- Headache
- Nausea

Common side effects (likely to occur in 1 to 10 patients in 100):

- Bronchitis
- Cold sore virus
- Diarrhoea
- Dizziness
- Fever
- Inflammation of the liver
- Influenza-like illness
- Pain
- Sleeping difficulties
- Stomach ache
- Upper abdominal fullness
- Upper respiratory tract infections
- Tiredness
- Vomiting

Uncommon side effects (likely to occur in 1 to 10 patients in 1000):

- Heart rhythm abnormalities
- Mild to severe liver function disorders
- Skin reactions

Rare side effects (likely to occur in 1 to 10 patients in 10,000):

- Allergic reaction
- Bleeding in the gastrointestinal tract
- Thrombocytopenia (low platelet count)
- Visual disturbances

Children (aged 1 to 12 years)

Very common side effects (likely to occur in more than 1 in 10 patients):

- Cough
- Nasal congestion
- Vomiting

Common side effects (likely to occur in 1 to 10 patients in 100):

- Aggravation of pre-existing asthma
- Bronchitis
- Conjunctivitis
- Diarrhoea
- Ear inflammation and other ear disorders
- Fever
- Headache
- Inflammation of the lungs
- Inflammation of the skin
- Nausea
- Nose bleeding
- Skin reactions
- Stomach ache
- Upper abdominal fullness
- Upper respiratory tract infections

Uncommon side effects (likely to occur in 1 to 10 patients in 1000):

- Heart rhythm abnormalities
- Mild to severe liver function disorders
- Swelling of the lymph nodes

Rare side effects (likely to occur in 1 to 10 patients in 10,000):

- Allergic reaction
- Bleeding in the gastrointestinal tract
- Thrombocytopenia (low platelet count)
- Visual disturbances

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), except for thrombocytopenia (low platelet count). 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 (45 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, black iron oxide (E172) and titanium dioxide (E171)

printing ink: shellac (E904), titanium dioxide (E171) and FD and C Blue 2 (indigocarmine, E132).

What Tamiflu looks like and contents of the pack

45 mg hard capsule consists of a grey opaque body bearing the imprint “ROCHE” and a grey opaque cap bearing the imprint “45 mg”. Imprints are blue.

Tamiflu 45 mg hard capsules are available in blister packs of 10.

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This leaflet was last approved in November 2011.

Detailed information on this medicine is available on the European Medicines Agency web site:

<http://www.ema.europa.eu>

The following information is intended for medical or healthcare professionals only:

When commercially manufactured Tamiflu powder for oral suspension is not available, patients who are unable to swallow capsules may receive appropriate doses of Tamiflu prepared in a pharmacy or prepared at home.

For infants below 12 months, the pharmacy preparation should be preferred to home preparation.

Detailed information on the pharmacy preparation can be found in the SmPC of Tamiflu capsules section 4.2.

Syringes of appropriate volume and grading should be provided for administering the pharmacy compounded suspension as well as for the procedures involved in the home preparation. In both cases, the correct volumes should preferably be marked on the syringes. For home preparation, separate

syringes should be provided for taking the correct volume of water and for measuring the Tamiflu-water mixture. For measuring 4.5 ml of water a 5 ml syringe should be used.

Please see below the appropriate syringe size to be used for taking the correct volume of Tamiflu mixture.

For children between one month and 12 months old:

Dose of Tamiflu	Amount of Tamiflu Mixture	Syringe Size to Use (grading 0.1 ml)
10 mg	1.00 ml	2 ml (or 3 ml)
11.25 mg	1.10 ml	2 ml (or 3 ml)
12.5 mg	1.30 ml	2 ml (or 3 ml)
13.75 mg	1.40 ml	2 ml (or 3 ml)
15 mg	1.50 ml	2 ml (or 3 ml)
21 mg	2.10 ml	3 ml
24 mg	2.40 ml	3 ml
27 mg	2.70 ml	3 ml
30 mg	3.00 ml	3 ml (or 5 ml)

For children less than one month old:

Dose of Tamiflu	Amount of Tamiflu Mixture	Syringe Size to Use (grading 0.1 ml)
6 mg	0.60 ml	1 ml (or 2 ml)
7 mg	0.70 ml	1 ml (or 2 ml)
8 mg	0.80 ml	1 ml (or 2 ml)
9 mg	0.90 ml	1 ml (or 2 ml)

