

Package Leaflet: Information for the user

Tamiflu 75 mg hard capsules 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.

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.

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.

Tamiflu 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	75 mg twice daily	75 mg once daily

75 mg can be made up of a 30 mg capsule plus a 45 mg capsule

Children 1 to 12 years old

Body weight	Treating flu: dose for 5 days	Preventing flu: dose for 10 days
10 to 15 kg	30 mg twice daily	30 mg once daily
More than 15 kg and up to 23 kg	45 mg twice daily	45 mg once daily
More than 23 kg and up to 40 kg	60 mg twice daily	60 mg once daily
More than 40 kg	75 mg twice daily	75 mg once daily

75 mg can be made up of a 30 mg capsule plus a 45 mg capsule

Infants less than 1 year old

Giving Tamiflu to infants less than 1 year old should be based upon the judgment of a doctor after considering the potential benefit versus any potential risk to the infant. Only limited data is available for infants less than 2 years old, and no data for infants less than 1 month old. *See following table.*

Age	Treating flu: dose for 5 days	Preventing flu: dose for 10 days
3 to 12 months	3 mg/kg twice daily	3 mg/kg once daily
1 to 3 months	2.5 mg/kg twice daily	2.5 mg/kg once daily
0 to 1 month	2 mg/kg twice daily	2 mg/kg once daily

mg/kg = mg per kilogram of infant body weight

Method of administration

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

Tamiflu can be taken with or without food, although taking it with food can reduce the chance of feeling or being sick (nausea or vomiting).

If you need Tamiflu as a liquid (*oral suspension*) but it's not available, you can make a Tamiflu suspension from these capsules. **See *Making Tamiflu suspension at home for instructions.***

If you take more Tamiflu than you should

Stop taking Tamiflu and contact your doctor or pharmacist immediately.

In most cases of overdose, people have not reported any side effects. When side effects were reported, they were similar to those from normal doses, as listed in section 4.

Overdose has been reported to have occurred more frequently when Tamiflu was given to children than to adults and adolescents. Caution should be exercised when preparing liquid Tamiflu for children and when administering Tamiflu capsules or liquid Tamiflu to children.

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 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 months 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 blister after EXP. The expiry date refers to the last day of that month.

Do not store above 25 °C.

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

- Each hard capsule contains oseltamivir equivalent to 75 mg of oseltamivir
- 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) FD and C Blue 2 (indigo carmine 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 revised in November 2012.

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

Information for 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 less than 1 year old, 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 6.6.

Oral dose dispensers 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 dispensers. For home preparation, separate dispensers should be provided for taking the correct volume of water and for measuring the Tamiflu-water mixture. For measuring 5.0 ml or 7.5 ml of water a 5 ml or 10 ml dispenser should be used.

Please see below the appropriate dispenser size to be used for taking the correct volume of Tamiflu suspension (10 mg/ml).

Dispenser size to use for infants 1 year old or older weighing less than 40 kg:

Dose of Tamiflu	Amount of Tamiflu suspension	Dispenser size to use (grading 0.1 ml)
30 mg	2.0 ml	3.0 ml
45 mg	3.0 ml	3.0 ml (or 5.0 ml)
60 mg	4.0 ml	5.0 ml

Dispenser size to use for infants between 1 month and 12 months old:

Dose of Tamiflu	Amount of Tamiflu suspension	Dispenser size to use (grading 0.1 ml)
10 mg	1.0 ml	2.0 ml (or 3.0 ml)
11.25 mg	1.1 ml	2.0 ml (or 3.0 ml)
12.5 mg	1.3 ml	2.0 ml (or 3.0 ml)
13.75 mg	1.4 ml	2.0 ml (or 3.0 ml)
15 mg	1.5 ml	2.0 ml (or 3.0 ml)
21 mg	2.1 ml	3.0 ml
24 mg	2.4 ml	3.0 ml
27 mg	2.7 ml	3.0 ml
30 mg	3.0 ml	3.0 ml (or 5.0 ml)

Dispenser size to use for infants less than 1 month old:

Dose of Tamiflu	Amount of Tamiflu suspension	Dispenser size to use (grading 0.1 ml)
6 mg	0.6 ml	1.0 ml (or 2.0 ml)
7 mg	0.7 ml	1.0 ml (or 2.0 ml)
8 mg	0.80 ml	1.0 ml (or 2.0 ml)
9 mg	0.9 ml	1.0 ml (or 2.0 ml)

Information for the user

Making Tamiflu suspension at home

When commercially manufactured Tamiflu powder for oral suspension is not available, a suspension can be made up at the pharmacy from Tamiflu capsules (see *Information for healthcare professionals*). This pharmacy preparation is the best option for infants less than 1 year old.

If the pharmacy preparation is also not available, Tamiflu suspension may be made up at home. The instructions are shown below.

To make Tamiflu suspension for patients who cannot swallow capsules:

- **If you have the right capsule strength** for the dose needed (such as a 30 mg capsule for a 30 mg dose), you can make the suspension by opening the capsule and stirring its contents with no more than one teaspoon of a suitable sweetened food product.

This is usually suitable for infants and children 1 year old or older. The first set of instructions shows you how.

- **When smaller doses are needed**, making the suspension involves extra steps.

This is suitable for younger, lighter children and babies who need a Tamiflu dose of less than 30 mg. The second set of instructions shows you how to make smaller doses.

Adults, adolescents (13 to 17 years old) and infants and children 1 year old or older who weigh 40 kg and over

To prepare a 75 mg dose using a 75 mg capsule



This is for adults, adolescents (13 to 17 years old) and infants and children 1 year old or older who weigh **more than 40 kg**.

To make an **exact dose** of Tamiflu suspension, carry out **three** basic steps.

You will need:

- **One 75 mg Tamiflu capsule**
- **Sharp scissors**
- **Two small bowls**
(use separate pairs of bowls for each child)
- **One oral dose dispenser**
for the Tamiflu suspension showing measurements of 0.1 ml
- **Teaspoon (5 ml spoon)**
- **Sweet food** to hide the bitter taste of the Tamiflu powder.
Examples are: chocolate syrup; cherry syrup; or dessert toppings, like caramel or fudge sauce.
Or you can make sugar water by mixing a teaspoon of water with three-quarters (3/4) of a teaspoon of sugar.

How to do it – the three steps:

1. **Find the correct dose.**

To find the correct amount to use, find the patient's weight on the left side of table. Then, look at the right column to see the number of capsules you will need to give the patient for a single dose.

You should use only 75 mg capsules for 75 mg doses. Do not try to make a 75 mg dose by using the contents of 30 mg or 45 mg capsules. Use the appropriate size capsule instead.

Weight	Dose of Tamiflu	Number of capsules
40 kg and over	75 mg	1 capsule

Children who weigh less than 40 kg

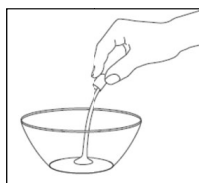
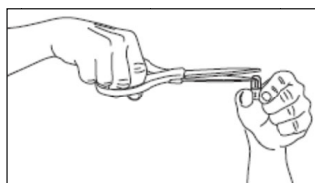
You will need to prepare a dose of less than 75 mg for children weighing less than 40 kg. *See below*

2. **Open the 75 mg Tamiflu capsule and pour out the powder.**

Hold a **75 mg capsule** upright over one of the bowls and carefully snip off the rounded tip with scissors.

Pour all of the powder into the bowl.

Be careful with the powder, because it may irritate your skin and eyes.

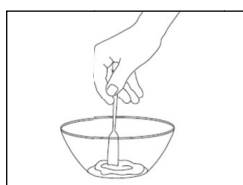


3. **Sweeten the suspension and give it to the patient**

Add a small amount of the sweet food (no more than one teaspoonful) to the powder in the bowl.

This will hide the bitter taste of the Tamiflu powder.

Stir the mixture well.




Give the whole contents of the bowl to the patient straight away.


If there is some mixture left in the bowl, rinse the bowl with a small amount of water and get the patient to drink this remaining mixture.

Repeat this procedure every time you need to give the medicine.

**Infants and children 1 year old or older who weigh less than 40 kg
To prepare doses of less than 75 mg using a 75 mg capsule**

This is for infants and children who weigh **less than 40 kg**, including all infants less than 1 year old.

Infants and children 1 year old or older who weigh less than 40 kg	 + 5 ml water
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Infants less than 1 year old	 + 7.5 ml water
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To make a **smaller dose** of Tamiflu suspension, carry out **five basic steps**.

You will need:

- **75 mg Tamiflu capsule**
- **Sharp scissors**
- **Two small bowls**
(use separate pairs of bowls for each child)
- **One oral dose dispenser for water – a 5 or 10 ml dispenser**
See below for how much water to use
- **One oral dose dispenser for the Tamiflu mixture showing measurements of 0.1 ml**
- **Teaspoon (5 ml spoon)**
- **Sweet food** to hide the bitter taste of the Tamiflu suspension.
Examples are: chocolate syrup; cherry syrup; or dessert toppings, like caramel or fudge sauce.
Or you can make sugar water by mixing a teaspoon of water with three-quarters (3/4) of a teaspoon of sugar.

How much water to use for mixing

Children more than 12 months who weigh less than 40 kg :	use 5 ml water
Children less than 12 months old	use 7.5 ml water

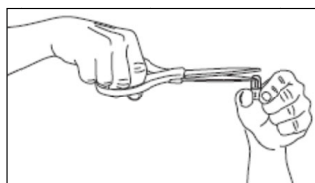
How to do it – the five steps:

1. **Open a 75 mg Tamiflu capsule**

Hold a 75 mg capsule upright over one of the bowls and carefully snip off the rounded tip with scissors.

Pour all of the powder into the bowl.

Be careful with the powder: it may irritate your skin and eyes.

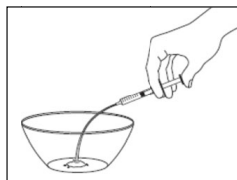


2. **Prepare a suspension of powder and water**

Use the first dispenser to draw up either **5 ml or 7.5 ml of water**. See 'You will need'. Then add it to the powder in the bowl.

Stir the suspension with the teaspoon for about 2 minutes.

Don't worry if not all of the powder dissolves. The undissolved powder is just inactive ingredients.



3. **Find the correct dose**

Now that you have a Tamiflu suspension, look at the tables.

First find the right table for your child's age.

Next find the child's weight on the left side of the table.

Then look at the column on the right side of the table to see the amount of the Tamiflu suspension you will need.

Infants and children 1 year old or older who weigh less than 40 kg

Weight (nearest)	Dose of Tamiflu	How much suspension to draw up	Dispenser size to use (grading 0.1 ml)
Up to 15 kg	30.0 mg	2.0 ml	3.0 ml
15 to 23 kg	45.0 mg	3.0 ml	3.0 ml (or 5.0 ml)
23 to 40 kg	60.0 mg	4.0 ml	5.0 ml

Infants between 1 month and 12 months old:

Weight (nearest)	Dose of Tamiflu	How much suspension to draw up	Dispenser size to use (grading 0.1 ml)
4 kg	10.0 mg	1.0 ml	2.0 ml (or 3.0 ml)
4.5 kg	11.25 mg	1.1 ml	2.0 ml (or 3.0 ml)
5 kg	12.5 mg	1.3 ml	2.0 ml (or 3.0 ml)
5.5 kg	13.75 mg	1.4 ml	2.0 ml (or 3.0 ml)
6 kg	15.0 mg	1.5 ml	2.0 ml (or 3.0 ml)
7 kg	21.0 mg	2.1 ml	3.0 ml
8 kg	24.0 mg	2.4 ml	3.0 ml
9 kg	27.0 mg	2.7 ml	3.0 ml
more than 10 kg	30.0 mg	3.0 ml	3.0 ml (or 5.0 ml)

Infants less than 1 month old:

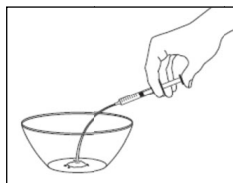
Weight (nearest)	Dose of Tamiflu	How much suspension to draw up	Dispenser size to use (grading 0.1 ml)
3 kg	6.0 mg	0.6 ml	1.0 ml (or 2.0 ml)
3.5 kg	7.0 mg	0.7 ml	1.0 ml (or 2.0 ml)
4 kg	8.0 mg	0.8 ml	1.0 ml (or 2.0 ml)
4.5 kg	9.0 mg	0.9 ml	1.0 ml (or 2.0 ml)

4. **Draw up the suspension in a dispenser.**

Make sure you have the right size of dispenser.

Draw up the correct amount of suspension from the first bowl.

Gently squirt it from the dispenser into the second bowl.

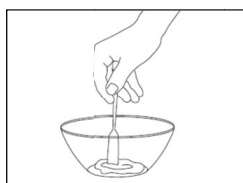


5. **Sweeten the suspension and give it to the child**

Add a small amount of the sweet food (no more than one teaspoon) to the second bowl.

This will hide the bitter taste of the Tamiflu suspension.

Mix the sweet food and Tamiflu suspension well.



Give the whole contents of the second bowl (Tamiflu suspension with sweet food added) to the child straight away.

If there is anything left in the second bowl, rinse the bowl with a small amount of water and feed the child this remaining mixture. For children unable to drink from a bowl, spoon-feed or use a bottle to feed the child the remaining mixture.

Give the child something to drink.

Throw away any unused Tamiflu suspension left in the first bowl.

Repeat this procedure every time you need to give the medicine.