

Package leaflet: information for the user

Tamiflu 75 mg hard capsules
oseltamivir

Read the entire 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.

Do you have any questions? Contact your doctor or pharmacist.

Do not pass this medicine on to others, as it has been prescribed only for you. It may harm others, even if their symptoms are the same as yours.

Do you experience any side effects listed in section 4? Or do you experience a side effect not listed in this leaflet? Contact your doctor or pharmacist.

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1. What is Tamiflu and what is it used for?

Tamiflu is used in adults, adolescents up to 18 years, children, and infants (including full-term newborns) to treat flu (influenza). It can be used when you have flu symptoms and it is known that the flu virus is circulating in the community.

Tamiflu can also be prescribed to adults, adolescents up to 18 years, children, and infants older than 1 year to prevent flu. This is considered on a case-by-case basis – for example, if you have been in contact with someone who has the flu.

Tamiflu can be prescribed to adults, adolescents up to 18 years, children, and infants (including full-term newborns) as a preventive treatment in exceptional circumstances – for example, if there is a global flu epidemic (flu pandemic) and the seasonal flu vaccination may not provide sufficient protection.

Tamiflu contains oseltamivir, which belongs to a group of medicines called neuraminidase inhibitors. These medicines prevent the spread of the influenza virus in your body. They help to relieve or prevent the symptoms of influenza virus infection.

Influenza, commonly called the flu, is an infection caused by a virus. The symptoms of the flu usually include a sudden fever (more than 37.8°C), cough, runny or stuffy nose, headache, muscle aches, and extreme fatigue. These symptoms can also be caused by Other infections. A true influenza infection only occurs during annual outbreaks (epidemics) when flu viruses spread among the local population. Outside epidemic periods, flu-like symptoms are usually caused by another type of illness.

2. When should you not take this medicine or be extra careful with it?

When should you not use this medicine?

You are allergic to any of the ingredients in this medicine. You can find these ingredients in section 6.

Contact your doctor if this applies to you. Do not take Tamiflu.

When should you be extra careful with this medicine?

Contact the treating physician before using this medicine:

if you are allergic to other medicines.

if you have kidney problems. If this is the case, your dose may need to be adjusted.

if you have a serious medical condition that may require immediate hospitalization.

if your immune system does not function properly.

if you have a chronic heart or respiratory condition.

During treatment with Tamiflu, tell a doctor immediately:

if you notice changes in behavior or mood (neuropsychiatric side effects), especially in children and adolescents up to 18 years old. These may be symptoms of rare but serious side effects.

Tamiflu is not a flu vaccine (flu shot)

Tamiflu is not a vaccine: it treats the infection or prevents the spread of the influenza virus. A vaccine gives you antibodies against the virus. Tamiflu does not alter the effectiveness of a flu shot, and both can be prescribed to you by your doctor.

Are you using any other medicines?

Are you using any other medicines besides Tamiflu, have you recently done so, or is there a possibility that you will use other medicines soon? Then tell your doctor or pharmacist. This also applies to medicines for which you do not need a prescription. The following medicines are especially important:

chlorpropamide (for the treatment of diabetes)

methotrexate (for the treatment of e.g. rheumatoid arthritis)

phenylbutazone (for the treatment of pain and inflammation)

probenecid (for the treatment of gout)

Pregnancy and breastfeeding

Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you breastfeeding? Then contact your doctor before using this medicine.

The effects on breastfed babies are not known. You must tell your doctor if you are breastfeeding so that your doctor can determine if Tamiflu is suitable 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 and use machines.

Tamiflu contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per capsule, which means it is essentially 'sodium-free'.

3. How to take this medicine?

Always take this medicine exactly as your doctor or pharmacist has told you. If you are unsure about the correct use, contact your doctor or pharmacist.

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

The recommended dosages

For the treatment of flu, take two doses per day. It is usually easiest to take one dose in the morning and one dose in the evening. It is important that you complete the entire five-day course, even if you start to feel better quickly.

Patients with a weakened immune system will be treated for 10 days.

For the prevention of flu or after exposure to an infected person, take one dose per day for 10 days. It is best to take this dose in the morning with breakfast.

In special situations, such as a widespread flu or in patients with a weak immune system, the treatment may last 6 to 12 weeks.

The recommended dosage depends on the patient's body weight. You must take the amount of oral capsules or suspension prescribed by your doctor.

Adults and adolescents aged 13 years and older

Body weight	Flu treatment: dose for 5 days	Flu treatment: (patients with a weak immune system) dose for 10 days*	Flu prevention: dose for 10 days
More than 40 kg	75 mg** twice daily	75 mg** twice daily	75 mg** once daily

* Patients with a weak immune system are treated for 10 days

** 75 mg can be made from a 30 mg capsule plus a 45 mg capsule

Children aged 1 to 12 years

Body weight	Flu treatment: dose for 5 days	Flu treatment: (patients with a weakened immune system) dose for 10 days*	Flu prevention: dose for 10 days
10 kg to 15 kg	30 mg twice daily	30 mg twice daily	30 mg once daily
More than 15 kg and up to 23 kg	45 mg twice daily	45 mg twice daily	45 mg once daily
More than 23 kg and up	60 mg twice daily	60 mg twice daily	60 mg once daily

to 40 kg			
More than 40 kg	75 mg** twice daily	75 mg** twice daily	75 mg** once daily

* Children with a weak immune system are treated for 10 days

** 75 mg can be made from a 30 mg capsule plus a 45 mg capsule

Infants younger than 1 year (0 to 12 months)

The decision to give Tamiflu to infants younger than 1 year to prevent flu during a flu pandemic should be made by a doctor after considering the possible benefits and risks for the child.

Body weight	Flu treatment: dose for 5 days	Flu treatment: (patients with a weak immune system) dose for 10 days*	Flu prevention: dose for 10 days
3 kg to 10+ kg	3 mg per kg body weight**, twice daily	3 mg per kg body weight**, twice daily	3 mg per kg**, once daily

* Infants with a weak immune system are treated for 10 days

** mg per kg = mg for each kilogram of the infant's body weight. For example:

If a 6-month-old infant weighs 8 kg, the dose is

8 kg x 3 mg per kg = 24 mg

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 may reduce the chance of nausea or vomiting.

People who find it difficult to swallow capsules can use a liquid medicine, Tamiflu oral suspension. If you need Tamiflu oral suspension but it is not available at your pharmacy, you can make a liquid form of Tamiflu from the capsules. See Home preparation of liquid Tamiflu at the bottom of the leaflet.

Have you taken too much of this medicine?

Stop using Tamiflu and contact a doctor or pharmacist immediately. In most cases of overdose, users have not reported side effects. When side effects were reported, they were similar to the side effects after taking normal doses, as mentioned in section 4.

Overdose was reported more often when Tamiflu was given to children than to adults and adolescents up to 18 years. Caution is advised when preparing a Tamiflu suspension for children and administering Tamiflu capsules or Tamiflu suspension to children.

Did you forget to take this medicine?

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

If you stop taking this medicine

There are no side effects when you stop Tamiflu. But if Tamiflu is stopped earlier than your doctor has told you, flu symptoms may return. Always complete the course prescribed by your doctor.

Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

4. Possible side effects

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

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

Anaphylactic and anaphylactoid reactions: severe allergic reactions, with swelling of the face and skin, itchy rash, low blood pressure, and breathing problems

Liver disorders (fulminant hepatitis, impaired liver function, and jaundice): yellowing of the skin and whites of the eyes, change in stool color, and changes in behavior

Angioneurotic edema: sudden onset of severe skin swelling mainly in the head and neck area, including the eyes and tongue, with breathing problems

Stevens-Johnson syndrome and toxic epidermal necrolysis: complicated, potentially life-threatening allergic reaction, severe inflammation of the epidermis and possibly also the dermis, starting with fever, sore throat, and fatigue, rash that may worsen to blisters, peeling, loss of larger areas of skin, possible breathing problems, and low blood pressure

Gastrointestinal bleeding: prolonged bleeding of the large intestine or vomiting of blood

Neuropsychiatric disorders, as described below.

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

The most frequently (very common and common) reported side effects of Tamiflu are nausea or vomiting, stomach pain, stomach upset, headache, and pain. These side effects usually occur after the first dose of the medicine and will generally stop if the treatment is continued. The frequency of these side effects decreases when the medicine is taken with food.

Rare but serious side effects: seek immediate medical attention

(These occur in less than 1 in 1000 users)

During treatment with Tamiflu, rare side effects have been reported including Seizures (convulsions) and delirium with altered consciousness

Confusion, abnormal behavior

Delusions, hallucinations, agitation, anxiety, and nightmares

These side effects have been reported mainly in children and adolescents up to 18 years old. They often started suddenly and disappeared quickly. In a small number of cases, this led to self-injury, sometimes with fatal outcomes. Such neuropsychiatric side effects have also been reported in patients with influenza who did not use Tamiflu.

Patients, especially children and adolescents up to 18 years old, should be closely monitored for behavioral changes as described above.

If you observe any of these symptoms, especially in younger individuals, seek immediate medical attention.

Adults and adolescents aged 13 years and older

Very common side effects

(occur in more than 1 in 10 users)

Headache
Nausea.

Common side effects

(occur in less than 1 in 10 users)

Bronchitis
Cold sore (virus)
Cough
Dizziness
Fever
Pain
Pain in the limbs
Runny nose
Sleep problems
Sore throat
Stomach pain
Fatigue
Bloating (upper abdomen)
Upper respiratory tract infections (inflammation of the nose, throat, and sinuses)
Stomach complaints
Vomiting.

Sometimes occurring side effects

(occur in less than 1 in 100 users)

Allergic reactions
Altered level of consciousness
Seizures/convulsions
Heart rhythm abnormalities
Mild to severely impaired liver function
Skin reactions (inflammation of the skin, red and itchy rash, scaly skin).

Rarely occurring side effects

(occur in less than 1 in 1000 users)

Thrombocytopenia (low platelet count)
Visual disturbances.

Children aged 1 to 12 years

Very common side effects

(occur in more than 1 in 10 users)

Cough
Nasal congestion
Vomiting.

Common side effects

(occur in less than 1 in 10 users)

Conjunctivitis (red eyes, eye discharge, or eye pain)
Ear infection and other ear problems
Headache

Nausea
Runny nose
Stomach pain
Bloating (upper abdomen)
Stomach discomfort.

Sometimes occurring side effects
(occur in less than 1 in 100 users)

Skin inflammation
Eardrum disorder.

Babies younger than 1 year

The reported side effects in babies from 0 to 12 months are generally similar to the side effects reported in older children (1 year or older). Diarrhea and diaper rash have also been reported.

If you/your child experience a lot of side effects, contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet. However,
if you or your child is repeatedly nauseous, or
if the flu symptoms worsen or the fever persists, contact your doctor immediately.

Reporting side effects

If you experience side effects, contact your doctor. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system as mentioned in Appendix V. By reporting side effects, you can help us obtain more information about the safety of this medicine.

5. How to store this medicine?

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date. You can find it on the box and blister pack after EXP. It includes a month and a year. The last day of that month is the expiry date.

Store below 25°C.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. Proper disposal of medicines ensures they are destroyed responsibly and do not enter the environment.

6. Contents of the package and other information

What substances are in this medicine?

The active substance is:

Each hard capsule contains oseltamivir phosphate equivalent to 75 mg oseltamivir

The other substances in this medicine are:

contents of the capsules: pregelatinized starch, talc, povidone, croscarmellose sodium, and sodium stearyl fumarate (see section 2 'Tamiflu contains sodium') 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 FD and C Blue 2 (indigo carmine E132).

What does Tamiflu look like and what is in a package?

The 75 mg hard capsule consists of an opaque gray lower half with the imprint "ROCHE" and an opaque light yellow upper half with the imprint "75 mg". The imprints are blue.

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

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This leaflet was last approved in {month/YYYY}

More information about this medicine is available on the website of the European Medicines Agency (<https://www.ema.europa.eu>).