

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) – 1986

(This medicine is dispensed with a doctor's prescription only)

Tamiflu 30 mg capsules	Tamiflu 45 mg capsules	Tamiflu 75 mg capsules
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Each capsule contains: **oseltamivir 30 mg**

Each capsule contains: **oseltamivir 45 mg**

Each capsule contains: **oseltamivir 75 mg**

* For information on inactive ingredients, see section 2 "Before using the medicine" and section 6 "Additional information".

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

1. What is this medicine intended for?

Tamiflu is intended for the treatment of influenza in adults and children 1 year of age or older, who have presented influenza symptoms for no more than two days.

Tamiflu is intended to prevent influenza in adults and children 1 year of age or older.

Tamiflu 75 mg capsules are intended for adults and children weighing more than 40 kg only.

Tamiflu 30 mg and 45 mg capsules are intended for adults and children one year of age and older.

Therapeutic group:

Tamiflu contains the active ingredient, oseltamivir, and belongs to a group of antiviral medicines named "neuraminidase inhibitors". These medicines prevent the flu virus from spreading inside the body and help ease or prevent symptoms of the flu virus infection.

Influenza is an infection caused by a virus. The signs of the flu generally 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 spread in the local community. When there is no outbreak of influenza, flu-like symptoms may be caused by different types of illnesses.

2. Before using the medicine**Do not use this medicine if:**

You are sensitive (allergic) to the active ingredient, oseltamivir, or to any of the other ingredients in this medicine (see section 6 - "Additional information").

Special warnings about using this medicine:

Do not use this medicine without consulting your doctor before beginning treatment:

- if you are **allergic to other medicines**
- if you suffer from **impaired kidney function**, your dose may need adjustment
- if you have a **severe medical condition**, which may require immediate hospitalization
- if your **immune system** is not working
- if you have chronic **heart disease** or chronic **respiratory disease**

During treatment with Tamiflu, **tell your doctor immediately** if you notice changes in behavior or mood (neuropsychiatric events), especially in children and adolescents. These may be signs of rare but serious side effects.

Tamiflu is not a flu vaccine: It treats infection or prevents the flu virus from spreading. A vaccine gives you antibodies against the virus. Tamiflu will not change the effectiveness of a flu vaccine, and your doctor may recommend both.

Tamiflu and other medicines

If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist.

Particularly if you are taking:

- 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)

Using Tamiflu and food

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

The medicine can be taken with or without food. However, taking the medicine with food can reduce the chance of feeling sick (nausea or vomiting).

Pregnancy, breastfeeding and fertility**Pregnancy**

You must tell your doctor if you are pregnant, if you think you are pregnant or if you are planning to become pregnant so that your doctor can decide if Tamiflu is the right medicine for you.

Breastfeeding

The effects of Tamiflu on breastfed infants are unknown. You must tell your doctor if you are breastfeeding so that your doctor can decide if Tamiflu is the right medicine for you.

Fertility

Based on preclinical studies, there is no evidence that Tamiflu affects male or female fertility.

Consult your doctor or pharmacist before taking any medicine.

Driving and using machines

Use of this medicine does not impair your ability to drive a car or operate machines.

Important information about some of the ingredients of Tamiflu

This medicine contains less than 1 mmol sodium (23 mg) per capsule and is therefore considered 'sodium-free'.

3. How to use this medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

Only your doctor will determine your dose and how you should take this medicine.

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

The standard dose is generally:

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 5-day course,** even if you start to feel better.

For adults with weak immune system function, the flu virus is shed longer than in patients who do not have weak immune system function and it may be reduced with 10 days of treatment.

To prevent the flu or after being exposed to a person who is infected with the flu, take one dose daily for 10 days. It is recommended to take the medicine in the mornings with breakfast.

In special cases, such as an outbreak of influenza in the community or for patients with a weak immune system, treatment can be continued for a period of up to 6-12 weeks.

The recommended dose is based on the patient's body weight. You must use the amount prescribed by the doctor.

Adults and adolescents 13 years and over:

Body weight	Treating flu: dose for 5 days	Preventing flu: dose for 10 days
More than 40 kg	75 mg twice daily	75 mg once daily

You can reach a dose of 75 mg by taking one 30 mg capsule plus one 45 mg capsule.

Children - aged 1 to 12 years:

Body weight	Treating flu: dose for 5 days	Preventing flu: dose for 10 days
Less than 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

You can reach a dose of 75 mg by taking one 30 mg capsule plus one 45 mg capsule.

Do not exceed the recommended dose.

If you are unable to swallow Tamiflu capsules, a liquid form of Tamiflu can be prepared from the capsules.

If you have accidentally taken a higher dose, stop taking Tamiflu and immediately contact the pharmacist or doctor. In most cases of overdose, no side effects have been reported. When side effects were reported, they were similar to those reported from normal doses, as listed in section 4 "Side effects".

Overdose cases have been reported more frequently when Tamiflu was given to children than to adults and adolescents. Be careful when preparing liquid Tamiflu for children and when having children take the medicine.

If you have taken an overdose or if a child has accidentally swallowed some medicine, immediately go to a hospital emergency room and bring the medicine package with you.

If you forget to take the medicine, do not take a double dose to make up for the forgotten one. Consult your doctor.

If you stop taking this medicine

There are no side effects when you stop Tamiflu. But if you stop taking this medicine earlier than your doctor instructed you, the symptoms of flu may come back. Adhere to the treatment as recommended by your doctor.

Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you wear them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

Like with all medicines, using Tamiflu may cause side effects in some users. Do not be alarmed by this list of side effects. You may not experience any of them. Many of the side effects listed below may also be caused by influenza.

The following side effects have been rarely reported since oseltamivir began being marketed: **Contact your doctor immediately if you suffer from one of the following serious side effects:**

- Anaphylactic reactions: severe allergic reactions, with face and skin swelling, itchy rashes, low blood pressure and breathing difficulties
- Hepatic disorders (fulminant hepatitis, hepatic function problem and jaundice): yellowing of the skin and white of the eyes, change in stool color, changes in behavior
- Angioneurotic edema: sudden and severe onset of 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 the skin, possible breathing difficulties and low blood pressure.
- Gastrointestinal bleeding: prolonged bleeding from the large intestine or spitting up blood
- Neuropsychiatric disorders, as listed below.

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

Rare but serious side effects (may affect up to 1 in 1,000 users): Seek medical treatment immediately During Tamiflu treatment, rare events have been reported that include:

- Convulsions and delirium, including altered level of consciousness
 - Confusion, abnormal behavior
 - Delusions, hallucinations, agitation, anxiety, nightmares
- The above-mentioned side effects have been reported primarily among children and adolescents and often started suddenly and resolved rapidly. A few cases resulted in self-injury, some with a 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 behavioral changes described above.

If you notice the above symptoms, especially in young people, **get medical help immediately.**

Adults and adolescents over 13 years

Very common side effects (may affect more than 1 in 10 users):

- Headache
- Nausea

Common side effects (may affect up to 1 in 10 users):

- Bronchitis
- Cold sores
- Cough
- Dizziness
- Fever
- Pain
- Pain in limbs
- Runny nose
- Sleeping difficulties
- Sore throat
- Stomachache
- Tiredness
- Upper abdominal fullness
- Upper respiratory tract infections (in the nose, throat and sinuses)
- Upset stomach
- Vomiting

Uncommon side effects (may affect up to 1 in 100 users):

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

Rare side effects (may affect up to 1 in 1,000 users):

- Low platelet count (thrombocytopenia)
- Visual disturbances

Children aged 1 to 12 years

Very common side effects (may affect more than 1 in 10 users):

- Cough
- Nasal congestion
- Vomiting

Common side effects (may affect up to 1 in 10 users):

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

Uncommon side effects (may affect up to 1 in 100 users):

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

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor. Despite this, if:

- **You or your child are repeatedly sick or**
- **The influenza symptoms get worse or the fever continues**

Contact your doctor as soon as possible.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: <https://sideeffects.health.gov.il>

5. How to store the medicine?

Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.

Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.

Do not store above 25°C.

Ask the pharmacist how to throw away medicines you no longer use in order to protect the environment.

6. Additional information

In addition to the active ingredient, this medicine also contains:

Pregelatinized starch, talc, povidone K 30, croscarmellose sodium, sodium stearyl fumarate, gelatin, titanium dioxide, iron oxide yellow, iron oxide red, iron oxide black, printing ink.

What the medicine looks like and contents of the pack:

Tamiflu 30 mg capsules are an opaque light yellow bearing the imprint "ROCHE 30 mg" in blue.

Tamiflu 45 mg capsules are an opaque gray bearing the imprint "ROCHE 45 mg" in blue.

Tamiflu 75 mg capsules are an opaque gray and opaque light yellow bearing the imprint "ROCHE 75 mg" in blue.

The capsules are available in blister packs containing 10 capsules.

Registration holder's name and address: Roche Pharmaceuticals (Israel) Ltd. 6 Hacharash, POB 6391, Hod Hasharon 4524079

Manufacturer: Hoffmann-La Roche Ltd., Basel, Switzerland

This leaflet was revised in November 2021 according to MOH guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:

Tamiflu 30 mg: 138.02.31733

Tamiflu 45 mg: 138.03.31734

Tamiflu 75 mg: 118.79.29952

