

PACKAGE LEAFLET: INFORMATION FOR THE USER

Tamiflu 30 mg hard capsules
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 paracetamol, ibuprofen or acetylsalicylic acid (Aspirin). 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.

The possible effects of Tamiflu on unborn children are unknown. 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:

Treatment

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):

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)

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):

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.

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 regular or sugar-free chocolate syrup, honey (only for children two years or older), light brown or table sugar dissolved in water, dessert toppings, sweetened condensed milk, apple sauce or yogurt 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.

Please follow these instructions to ensure proper dosing.

1. Determine the number of capsules that are needed to prepare a mixture with this procedure:

Body Weight*	Required number of capsule(s) needed to obtain the recommended doses for 5 days treatment	Required number of capsule(s) needed to obtain the recommended doses for prevention
Less than or equal to 15 kg	1 capsule of 30 mg twice daily	1 capsule of 30 mg once daily
More than 15 kg and up to 23 kg	1 capsule of 45 mg twice daily	1 capsule of 45 mg once daily
More than 23 kg and up to 40 kg	2 capsules of 30 mg twice daily	2 capsules of 30 mg once daily

* Children weighing more than 40 kg may receive medication with the adult dosage of Tamiflu 75 mg capsules twice daily for 5 days for treatment or once daily for prevention.

2. Check that you are using the correct dose according to the table above. Hold the capsule(s) over a small bowl, carefully pull the capsule(s) open and pour the powder into the bowl.
3. Add a suitable, small amount (1 teaspoon maximum) of sweetened food product (to mask the bitter taste) to the bowl and mix well.
4. Stir the mixture and give the entire contents of the bowl to the patient. The mixture must be swallowed immediately after its preparation. If there is some mixture left inside the bowl, rinse the bowl with a small amount of water and have the patient drink this remaining mixture.

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 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.

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 (30 mg and 45 mg oseltamivir in each hard capsule).
- The other ingredients are:
capsule contents, 30 mg and 45 mg: pregelatinised starch, talc, povidone, croscarmellose sodium and sodium stearyl fumarate
capsule shell, 30 mg capsules: gelatin, yellow iron oxide (E172), red iron oxide (E172) and titanium dioxide (E171)
capsule shell, 45 mg capsules: gelatin, black iron oxide (E172) and titanium dioxide (E171)
printing ink, 30 mg and 45 mg capsules: shellac (E904), titanium dioxide (E171) and FD and C Blue 2 (indigocarmine, E132).

What Tamiflu looks like and contents of the pack

30 mg hard capsule consists of a light yellow opaque body bearing the imprint "ROCHE" and a light yellow opaque cap bearing the imprint "30 mg". Imprints are blue.

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

Marketing Authorisation Holder and Manufacturer

Roche Registration Limited
6 Falcon Way
Shire Park
Welwyn Garden City
AL7 1TW
United Kingdom

Roche Pharma AG
Emil-Barell-Str. 1,
D-79639 Grenzach-Wyhlen
Germany

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder.

België/Belgique/Belgien
N.V. Roche S.A.
Tél/Tel: +32 (0) 2 525 82 11

Luxembourg/Luxemburg
(Voir/siehe Belgique/Belgien)

България
Рош България ЕООД
Тел: +359 2 818 44 44

Magyarország
Roche (Magyarország) Kft.
Tel: +36 - 23 446 800

Česká republika
Roche s. r. o.
Tel: +420 - 2 20382111

Malta
(See United Kingdom)

Danmark
Roche a/s
Tlf: +45 - 36 39 99 99

Nederland
Roche Nederland B.V.
Tel: +31 (0) 348 438050

Deutschland
Roche Pharma AG
Tel: +49 (0) 7624 140

Norge
Roche Norge AS
Tlf: +47 - 22 78 90 00

Eesti
Roche Eesti OÜ
Tel: + 372 - 6 177 380

Österreich
Roche Austria GmbH
Tel: +43 (0) 1 27739

Ελλάδα
Roche (Hellas) A.E.
Τηλ: +30 210 61 66 100

Polska
Roche Polska Sp.z o.o.
Tel: +48 - 22 345 18 88

España
Roche Farma S.A.
Tel: +34 - 91 324 81 00

Portugal
Roche Farmacêutica Química, Lda
Tel: +351 - 21 425 70 00

France
Roche
Tél: +33 (0) 1 46 40 50 00

România
Roche România S.R.L.
Tel: +40 21 206 47 01

Ireland
Roche Products (Ireland) Ltd.
Tel: +353 (0) 1 469 0700

Slovenija
Roche farmacevtska družba d.o.o.
Tel: +386 - 1 360 26 00

Ísland

Roche a/s
c/o Icepharma hf
Sími: +354 540 8000

Italia

Roche S.p.A.
Tel: +39 - 039 2471

Κύπρος

Γ.Α.Σταμάτης & Σια Λτδ.
Τηλ: +357 - 22 76 62 76

Latvija

Roche Latvija SIA
Tel: +371 - 67 039831

Lietuva

UAB "Roche Lietuva"
Tel: +370 5 2546799

Slovenská republika

Roche Slovensko, s.r.o.
Tel: +421 - 2 52638201

Suomi/Finland

Roche Oy
Puh/Tel: +358 (0) 10 554 500

Sverige

Roche AB
Tel: +46 (0) 8 726 1200

United Kingdom

Roche Products Ltd.
Tel: +44 (0) 1707 366000

This leaflet was last approved in May 2009.

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