

PACKAGE LEAFLET: INFORMATION FOR THE USER

Tamiflu 12 mg/ml powder for oral suspension 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

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

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

Tamiflu oral suspension 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). It can also be taken with a drink of water.

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.

Important information about some of the ingredients of Tamiflu

Before you take Tamiflu, make sure your prescribing doctor knows if you have hereditary fructose intolerance.

This medicine contains sorbitol which is a form of fructose.

Sorbitol can have a mild laxative effect.

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.

Always use the syringe that is provided in the box and has markings indicating the dose in mg.

Take Tamiflu as soon as you get the prescription as this will help to slow the spread of the influenza virus in the body.

➤ Infants below 12 months of age: This formulation is not suitable for dosing infants less than 12 months of age.

The usual dose is as follows:

How much Tamiflu should be given to infants 1 year of age and older and children 2 to 12 years of age)***Treatment***

You must give the amount of oral suspension to your child as prescribed by your doctor. 30 mg and 45 mg capsules can be used as an alternative to suspension.

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)

➤ Infants below 12 months of age: This formulation is not suitable for dosing infants less than 12 months of age.

Prevention

Tamiflu can also be used to prevent influenza following exposure to an infected individual, such as family members.

30 mg and 45 mg capsules can be used as an alternative to suspension.

Tamiflu should be taken once daily for 10 days. It is best to take this dose in the mornings with breakfast.

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)

Children weighing more than 40 kg and can swallow capsules may take a 75 mg dose of Tamiflu capsules once daily for 10 days.

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: This formulation is not suitable for dosing infants less than 12 months of age.

How Much Tamiflu should be given to Adolescents (13 to 17 years of age) and Adults

The suspension can be used by adults and adolescents instead of the capsule.

30 mg and 45 mg capsules can be used as an alternative to suspension.

Treatment

Usually, your doctor will prescribe a 75 mg dose of Tamiflu twice daily for 5 days.

Prevention

Usually, your doctor will prescribe a 75 mg dose of Tamiflu once daily for 10 days. Your doctor will recommend the length of time you will need to take Tamiflu.

A single 75 mg dose of Tamiflu requires two doses of the suspension: one 30 mg dose and one 45 mg dose.

a) HOW TO PREPARE THE ORAL SUSPENSION:

Your pharmacist may have prepared the oral suspension for you when you collected your prescription. However, if they have not done this, then you can do it easily yourself. **You only need to prepare the suspension once, at the beginning of your course. After that, all you need to do is shake the suspension well and draw up the appropriate recommended dose.**

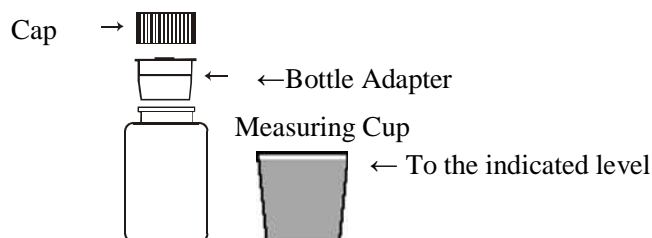


Figure 1

1. Tap the closed bottle gently several times to loosen the powder.
2. Measure 52 ml of water by filling the measuring cup to the indicated level (measuring cup included in the box). **You should always use 52 ml of water**, irrespective of the recommended dose you are taking.
3. Add all 52 ml of water into the bottle, recap the bottle and shake the closed bottle well for 15 seconds.
4. Remove the cap and push the bottle adapter into the neck of the bottle.
5. Place the cap tightly over the top of the bottle, which now includes the bottle adapter. This will make sure that the bottle adapter fits in the bottle in the right position.

b) HOW TO MEASURE AND GIVE A DOSE OF ORAL SUSPENSION

Always shake Tamiflu oral suspension well before use!

Always use the syringe with doses indicated in mg which is provided in the package.

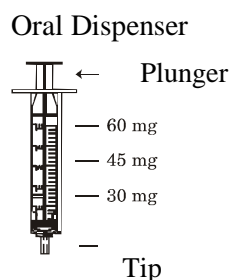


Figure 2



Figure 3

How to measure the correct amount of suspension:

1. Shake the closed bottle of Tamiflu oral suspension well before use.
2. Take the dispenser (see figure 2) and push the plunger completely down toward the tip of the dispenser. The dispenser provided with your medicine must always be used to measure to correct dose.
3. Remove the cap from the bottle of oral suspension.
4. Insert the tip of the dispenser into the bottle adapter.
5. Turn the entire unit (bottle and dispenser) upside down (see figure 3).
6. Slowly pull out the plunger to the graduation which marks the dose you need.
7. Turn the entire unit upright.
8. Slowly remove the dispenser from the bottle.

9. Push the suspension directly into the mouth by pushing down the plunger of the dispenser. Swallow the medicine. You may drink and eat something after taking the medicine.
10. Immediately after administration, take the dispenser apart and rinse both parts of the dispenser under running tap water.

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 dose.

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

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 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)

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, thrombocytopenia (low platelet count) and heart rhythm abnormalities.

Children (aged 1 to 12 years)

Other less common side effects, which may also be caused by influenza, are cough, nasal congestion, 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, thrombocytopenia (low platelet count) and heart rhythm abnormalities.

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 gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE TAMIFLU

Keep out of the reach and sight of children.

Do not use Tamiflu powder for oral suspension after the expiry date which is stated on the carton and bottle after EXP. The expiry date refers to the last day of that month.

Powder: Do not store above 30°C.

After reconstitution, the suspension can be stored either at room temperature (not above 25°C) for 10 days or in a refrigerator (2°C - 8°C) for 17 days.

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 (12 mg/ml oseltamivir after reconstitution).
- The other ingredients are sorbitol (E420), sodium dihydrogen citrate (E331[a]), xanthan gum (E415), sodium benzoate (E211), saccharin sodium (E954), titanium dioxide (E171) and flavour.

What Tamiflu looks like and contents of the pack

The powder is a granulate or clumped granulate with a white to light yellow colour.

Tamiflu 12 mg/ml powder for oral suspension is available in a bottle containing 30 g powder for mixing with 52 ml of water.

The box also contains 1 plastic measuring cup (52 ml), 1 plastic bottle adapter (to help get the drug into the dispenser) and 1 plastic oral dispenser (to give the correct amount of medicine via the mouth). Shown on the oral dispenser are marks for 30 mg, 45 mg and 60 mg of the medicine (see figures 1 and 2 above).

For details on how to prepare the oral suspension and how to measure and take the medicine, read section 3, "How to take Tamiflu".

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 - 6 7039831

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

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