

Tamiflu®

Roche

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, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

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. Storing Tamiflu
6. Further information

Tamiflu 75mg capsules, hard
Oseltamivir

- The active substance is oseltamivir phosphate (75mg oseltamivir in each hard capsule).
- The other (inactive) 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 (904), titanium dioxide (E171) and indigocarmine, (E132).

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The manufacturer responsible for batch release is:

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1. WHAT TAMIFLU IS AND WHAT IT IS USED FOR

- Tamiflu is prescribed to you for treating or preventing influenza.
- Influenza is an infection caused by the influenza virus. The signs (symptoms) of influenza include the sudden onset of fever (> 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.
- 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.

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

2. BEFORE YOU TAKE TAMIFLU

Do not take Tamiflu: if you are allergic to oseltamivir or any of the other ingredients.

Take special care with Tamiflu: before you take Tamiflu, make sure your prescribing doctor knows if you

- are allergic to other medicines,
- are taking other medicines, including those you have bought without a prescription (except paracetamol, ibuprofen or acetyl salicylic acid (Aspirin), or
- have problems with your kidneys.

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:

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.

Breast-feeding:

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 little or no effect on your ability to drive or use machines.

Taking other medicines:

Tamiflu can be taken with paracetamol, ibuprofen or acetylsalicylic acid (Aspirin). Tamiflu is not expected to alter the effect of any other medicines. If Tamiflu has been prescribed to you, you must still tell your doctor or pharmacist, if you take or have taken recently any other medicines, including those you have bought without a prescription.

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.

3. HOW TO TAKE TAMIFLU

Always take Tamiflu as your doctor has instructed you. Take Tamiflu as soon as you get the prescription as this will help to slow the spread of the influenza virus in the body.

You should ask your doctor or pharmacist if you would like to know more about this medicine.

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

Treatment

For **treatment** of influenza take one capsule as soon as you get the prescription and then take one capsule twice a day (usually it is convenient to take one in the morning and one in the evening for five days). It is important to complete the whole 5 day course, even if you start to feel better quickly.

Prevention

Tamiflu can also be used for **prevention** of influenza. When used to prevent influenza, Tamiflu should be taken once daily for 10 days. It is best to take this dose in the mornings with breakfast. Your doctor will recommend the length of time to continue taking Tamiflu, if it is prescribed to prevent influenza.

If you take more Tamiflu, than you should: Contact your doctor or pharmacist immediately.

If you have forgotten to take Tamiflu: Take the missed dose as soon as you remember, but do not take a double dose to make up for the dose you have forgotten.

Effects when use of Tamiflu is stopped: 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.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Tamiflu can have side effects.

- Common side effects of Tamiflu.

The most common side effects of Tamiflu are, nausea, vomiting and stomach ache. 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 medication is taken with food.

- Less common side effects of Tamiflu

Skin reactions and liver function disorders have been very rarely reported.

Children (aged 1 to 12 years)

Other less common side effects, which may also be caused by influenza, are diarrhoea, 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 and conjunctivitis.

Adults and adolescents (children aged 13 years and older)

Other less common side effects, which may also be caused by influenza, are nausea, diarrhoea, bronchitis, dizziness, tiredness, headache and sleeping difficulties.

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 you notice any effects not mentioned in this leaflet, please tell your doctor or pharmacist.

5. STORING TAMIFLU

Keep out of the reach and sight of children.

There are no special storage conditions.

Do not use Tamiflu after the expiry date (EXP) shown on the box.

6. FURTHER INFORMATION

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

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