PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

PRODUCT NAME(S)

Tamiflu® 30 mg Capsules

Tamiflu® 45 mg Capsules

Tamiflu® 75 mg Capsules

Tamiflu® 6 mg/mL Powder for Oral Suspension

The active substance is oseltamivir

Tamiflu Powder for Oral Suspension contains

sugar (sorbitol) and sodium benzoate 0,05 % m/v as preservative.

Read all of this leaflet carefully before you or your child start using Tamiflu

Keep this leaflet. You may need to read it again.

- If you or your child have further questions, please ask your doctor or your pharmacist.
- Tamiflu has been prescribed for you or your child personally and you or your child should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What Tamiflu is and what it is used for.
2. What you need to know before you or your child are given Tamiflu.
3. How to take Tamiflu.
4. Possible side effects.
5. How to store Tamiflu.
6. Contents of the pack and other information.

1. What Tamiflu is and what it is used for

Tamiflu contains *oseltamivir*, which belongs to a group of medicines named neuraminidase inhibitors. These medicines prevent the flu virus from spreading inside the body. They help to ease or prevent the symptoms of the flu virus infection.

Treatment of Flu

Tamiflu is used for adults, adolescents, children and infants (including full-term newborn babies) for treating flu (influenza). It can be used when you have flu symptoms, and the flu virus is known to be going round in your community.

Prevention of Flu

- Tamiflu can also be prescribed for adults, adolescents, children and infants above 1 year of age for preventing flu, on a case-by-case basis – for instance, if you have been in contact with someone who has flu.
- Tamiflu may be prescribed for adults, adolescents, children and infant (including full-term newborn babies) as preventive treatment in exceptional circumstances – for example, if there is a global epidemic of flu (a flu pandemic) and the seasonal flu vaccine may not provide sufficient protection.

Tamiflu is not a vaccine.

2. What you need to know before Tamiflu is administered to you or your child

Do not take Tamiflu

If you or your child are hypersensitive (allergic) to oseltamivir or any of the other ingredients of Tamiflu (see section 5).

If you or your child have kidney problems.

If you or your child have heart disease or respiratory disease.

If you have or you have noticed your child to have changes in behaviour or mood.

Warnings and precautions

Tell your doctor:

- If you or your child are taking other medicines, including those you or your child have bought without a prescription (except paracetamol, ibuprofen or acetylsalicylic acid (aspirin)), or
- If you or your child have problems with your kidneys.

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 or your child, Tamiflu may be prescribed by your doctor.

Taking Tamiflu with food and drink

Swallow Tamiflu capsules 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 Breastfeeding

The possible effects of Tamiflu on unborn children are unknown. You must tell your doctor if you are pregnant or if you think you, may be pregnant. There is not enough information on the use of Tamiflu in pregnancy. Your doctor will decide whether it is safe to give you Tamiflu if you are pregnant, depending on your condition.

The effects on breastfed infants are unknown. You must tell your doctor if you are breastfeeding. You should not breastfeed your baby if you are taking Tamiflu unless your doctor says you may.
If you are pregnant or breastfeeding your baby while taking Tamiflu, please consult your doctor or pharmacist for advice before taking Tamiflu.

Driving and using machinery

It is not known whether taking Tamiflu will affect your, or your child's, ability to drive or use machines. However if you, or your child, experience symptoms such as delirium or fever while you are taking Tamiflu, do not drive or use machines until the symptoms disappear.

Important information about some of the ingredients of Tamiflu Powder for Oral Suspension

Tamiflu Powder for Oral Suspension contains sorbitol and may have a laxative effect.

Tamiflu contains sorbitol. If you, or your child, have been told that you have an intolerance to some sugars, you, or your child, should not take Tamiflu powder for oral suspension.

Other medicines and Tamiflu

Always tell your healthcare professional if you, or your child, are taking any other medicine. (This includes complementary or traditional 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 for you, or your child, you must still tell your doctor or pharmacist if you, or your child, take or have recently taken any other medicines, including those you have bought without a prescription.

3. How to take Tamiflu

Always take Tamiflu as your doctor has instructed you, or to your child. You should check with your doctor or pharmacist if you are unsure.

Take Tamiflu within two days you, or your child, started having flu symptoms, as this will help to slow the spread of the influenza virus in the body.

The recommended doses

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

For patients with a weak immune system, treatment will continue for 10 days.

For preventing flu or after being exposed to an infected person, take one dose daily for 10 days. It is best to take this in the mornings with breakfast.

Your doctor will prescribe the appropriate dose according to your, or your child's, condition.

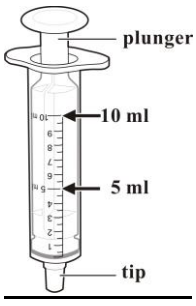
Method of administration

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

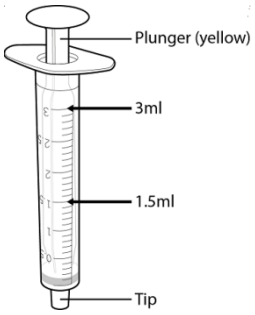
How to take Tamiflu 6 mg/mL oral suspension

1. Shake the closed bottle of Tamiflu 6 mg/mL oral suspension well before use.
2. Take the syringe dispenser (see Figure 1) and push the plunger completely down toward the tip of the dispenser.

Figure 1

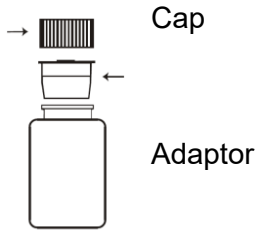


OR



3. Remove the cap from the bottle of oral suspension.
4. Insert the bottle adaptor into the neck of the bottle (see Figure 2).

Figure 2



5. Insert the tip of the syringe dispenser into the bottle adaptor.
6. Turn the entire unit (bottle and dispenser) upside down (see Figure 3).

Figure 3



7. Slowly pull out the plunger to the graduation marks in mL which your doctor or pharmacist has instructed you to take or has instructed your child to take.
8. Turn the entire unit upright.
9. Slowly remove the dispenser from the bottle.

10. Push the suspension in the syringe dispenser directly into the mouth by pushing down the plunger of the dispenser. Swallow the medicine. You, or your child, may drink and eat something after taking the medicine.
11. Immediately after administration, take the syringe dispenser apart and rinse both parts of the dispenser under running tap water. Air dry prior to next use.

When Tamiflu Powder for Oral Suspension is not available

During situations when commercially manufactured Tamiflu Powder for 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 yoghurt to mask the bitter taste. Your healthcare professional may prepare and mix the preparation for you or your child. Before you or your child take the mixture, you must stir it and drink all the contents immediately.

If you or your child take more Tamiflu than you should

In the event of overdosage, consult your, or your child's doctor or pharmacist. If neither is available, contact the nearest hospital or poison control center.

If you or your child forget to take Tamiflu

Take the missed dose as soon as you, or your child, remember, but do not take a double dose to make up for the dose you, or your child, have forgotten.

Effects when treatment with 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, or your child, the symptoms of influenza may re-occur.

4. Possible side effects

Tamiflu can have side effects.

Not all side effects reported for Tamiflu are included in this leaflet. Should your or your child's general health worsen or if you, or your child, experience any untoward effects while taking Tamiflu, please consult your, or your child's, doctor, pharmacist or other health care provider for advice.

The following side effects reported after Tamiflu has been marketed:

- Neuropsychiatric events such as convulsions, abnormal and inappropriate behaviour, including abnormal motor behaviour, disturbances in consciousness, hallucinations and delirium (sometimes resulting in accidental self-injury and death).
- Erythema multiforme, Stevens-Johnson syndrome, and toxic epidermal necrolysis: complicated possibly life-threatening allergic reaction, severe inflammation of the outer and possibly the inner skin, initially with fever, sore throat, and fatigue, skin rashes, leading to blisters, peeling, shedding of large areas of skin, possible breathing difficulties and low blood pressure.
- Anaphylactic/anaphylactoid reactions (severe allergic reactions, with face and skin swelling, itchy rashes, low blood pressure and breathing difficulties).
- Allergy.
- Face oedema (swelling of the face).
- Hypersensitivity reactions such as allergic skin reactions including dermatitis, rash, eczema, urticaria (hives).
- Hepatitis and elevated liver enzymes (yellowing of the skin and white of the eyes, changes in stool colour).
- Gastrointestinal bleedings, prolonged bleeding from the large bowel or spitting up blood.

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

If you are or your child is, often sick, you should inform your doctor. You should also tell your doctor if the influenza symptoms get worse or the fever continues.

The most frequently (very common and common) reported side effects of Tamiflu are feeling or being sick (nausea, vomiting), stomach ache, stomach upset, headache and pain. These side effects mostly occur after 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 effects: get medical help at once

(These may affect up to 1 in 1,000 people)

During Tamiflu treatment, rare events have been reported that include

- Convulsions and delirium (sometimes resulting in accidental self-injury and death)
- Confusion, abnormal and inappropriate behaviour
- Delusions, hallucinations, agitation, anxiety, nightmares
- Patients, especially children and adolescents, should be closely monitored for the behavioural changes

Very common side effects *(may affect more than 1 in 10 people)*

- Headache
- Nausea

Common side effects *(may affect up to 1 in 10 people)*

- Bronchitis
- Cold sore virus
- Cough
- Dizziness
- Fever

- Pain
- Pain in limb
- Runny nose
- Sleeping difficulties
- Sore throat
- Stomach ache
- Tiredness
- Upper abdominal fullness
- Upper respiratory tract infections (inflammation of the nose, throat and sinuses)
- Upset stomach
- Vomiting

Uncommon side effects *(may affect up to 100 people)*

- Altered level of consciousness
- Seizures
- Irregular heartbeat
- Mild to severe liver disease
- Skin reactions

Rare side effects *(may affect up to 1,000 people***)**

- Low number of platelets in the blood (thrombocytopenia)
- Vision problems
- Mental disorders
- Allergic reactions

The frequency of these effects is reduced if the medication is taken with food.

Infants less than 1 year

The reported side effects in infants 1 to 12 months old are mostly similar to side effects reported for children 1 year and older.

Additional frequent side effects of Tamiflu – Infants aged 0 to 12 months:

- vomiting
- diarrhoea
- nappy rash

If you or your child notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of Tamiflu.

5. How to store Tamiflu

Store all medicines out of reach of children.

Tamiflu 30 mg, 45 mg and 75 mg Capsules:

Store at or below 25 °C. Protect from light. Keep blisters in outer carton until required for use.

Do not use Tamiflu Capsules after the expiry date shown on the box.

Tamiflu 6 mg/mL Powder for Oral Suspension:

Store at or below 25 °C. Protect from light. Keep bottle tightly closed.

After reconstitution, store the suspension at or below 25 °C and use within 10 days, or at 2 °C - 8 °C (in a refrigerator) and use within 17 days.

Shake the reconstituted suspension well before use.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What Tamiflu contains

Tamiflu 30 mg, 45 mg and 75 mg. Capsules

- The active substance is oseltamivir.
- The other ingredients are pregelatinised starch, povidone sodium croscarmellose, sodium stearyl fumarate and talc.
- The capsule shell contains gelatin, yellow iron oxide (E172), red iron oxide (E172) and titanium dioxide (E171). The printing ink contains shellac (904), titanium dioxide (E171) and FD and C Blue 2 (indigocarmine, E132).

Tamiflu 6 mg/mL Powder for Oral Suspension

- The active substance is oseltamivir.
- Preservative of constituted suspension: sodium benzoate 0,05 % m/v
- Tamiflu Powder for Oral Suspension contains sorbitol.
- Tamiflu 6 mg/mL: reconstitution with 55 mL water results in a retrievable volume of 64,7 mL which is equivalent to 10 doses of 60 mg.

The other ingredients are saccharin sodium, sodium benzoate, sodium dihydrogen citrate, sorbitol, titanium dioxide (E171), tutti frutti flavour and xanthan gum.

What Tamiflu looks like and contents of the pack

Tamiflu 30 mg Capsules: Light yellow opaque hard gelatin capsules. "ROCHE" and “30 mg” is printed in blue ink.

Tamiflu 45 mg Capsules: Grey opaque hard gelatin capsules. "ROCHE" and “45 mg” is printed in blue ink.

Tamiflu 75 mg Capsules: Grey/light yellow opaque hard gelatin capsules. "ROCHE" is printed in blue ink on the grey body and "75 mg" is printed in blue ink on the light yellow opaque cap.

Tamiflu 6 mg/mL Powder for Oral Suspension: White to light yellow granules. After reconstituting the 13 g of Tamiflu Powder for Oral suspension with 55 mL of water it will appear as a white to light yellow, opaque suspension.

PRESENTATION OF TAMIFLU

Tamiflu 30 mg, 45 mg and 75 mg Capsules: Boxes containing 10 capsules in blister pack. Blister packs are composed of transparent plastic (PVC/PE/PVDC) and aluminium foil.

Tamiflu 6 mg/mL: Powder for Oral Suspension: Carton containing a 100 mL amber glass bottle with a child-resistant white polypropylene plastic screw cap, a press-in oral adaptor and a 10 mL plastic oral dispenser (transparent polypropylene barrel with a white polypropylene plunger). After reconstitution with 55 mL of water, the usable volume of oral suspension allows for the retrieval of a total of 10 doses of 60 mg oseltamivir.

Holder of Certificate of Registration

Roche Products (Pty) Ltd

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Building E, Vorna Valley, Midrand

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Roche Ethical Assistance Line (REAL) toll-free: 0800 21 21 25

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19 February 2025

Registration number(s)

Tamiflu 30 mg Capsules: 42/20.2.8/1020

Tamiflu 45 mg Capsules: 42/20.2.8/1021

Tamiflu 75 mg Capsules: A40/20.2.8/0578

Tamiflu 6 mg/mL Powder for Oral Suspension: 47/20.2.8/1194