PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

Tamiflu® 30 mg Capsules

Tamiflu® 45 mg Capsules

Tamiflu® 75 mg Capsules

Tamiflu® 6 mg/mℓ Powder for Oral Suspension

Read all of this leaflet carefully before you start using Tamiflu

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

WHAT TAMIFLU CONTAINS

Tamiflu 30 mg, 45 mg & 75 mg. Capsules

- The active substance is oseltamivir.
- The other ingredients are pregelatinised starch, povidone sodium croscarmellose, sodium stearyl fumarate and talc.
- The capsule sh
- ell 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 IS USED FOR

Tamiflu is prescribed to you for treating or preventing influenza.

BEFORE YOU TAKE TAMIFLU

Tamiflu should not be used in children under 12 months of age.

Do not take Tamiflu

If you are hypersensitive (allergic) to oseltamivir or any of the other ingredients of Tamiflu.

Take special care with Tamiflu

Tell your doctor:

- If you are taking other medicines, including those you have bought without a prescription (except paracetamol, ibuprofen or acetylsalicylic acid (aspirin)), or
- If you 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 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 are pregnant. There is not enough information on the use of Tamiflu in pregnancy.

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.

If you are pregnant or breastfeeding your baby, 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 ability to drive or use machines. However if you 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 have been told that you have an intolerance to some sugars, you should not take Tamiflu Powder for Oral suspension.

Taking other medicines with Tamiflu

Always tell your healthcare professional if you 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, you must still tell your doctor or pharmacist if you take or have recently taken any other medicines, including those you have bought without a prescription.

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.

HOW TO TAKE TAMIFLU

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

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.

Your doctor will prescribe the appropriate dose according to your condition.

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 will prepare and mix the preparation for you. Before you take the mixture, you must stir it and drink all the contents immediately.

If you take more Tamiflu than you should

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

If you forget 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 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 the symptoms of influenza may re-occur.

POSSIBLE SIDE EFFECTS

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

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 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. 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.

If you 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.

Tamiflu can have side effects.

Frequent side effects of Tamiflu:

- nausea
- vomiting
- diarrhoea
- stomach ache
- headache

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

Less frequent side effects of Tamiflu - Children (aged 1 to 12 years):

- 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

Less frequent side effects - Adults and adolescents (children aged 13 years and older):

- 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

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

STORING AND DISPOSING OF TAMIFLU

Store all medicines out of reach of children.

Tamiflu 30 mg, 45 mg & 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).

PRESENTATION OF TAMIFLU

Tamiflu 30 mg, 45 mg & 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 adapter 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.

IDENTIFICATION OF TAMIFLU

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.

REGISTRATION NUMBERS

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

NAME AND ADDRESS OF REGISTRATION HOLDER

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DATE OF PUBLICATION

Registration: 75 mg capsules – 17 Feb 2006

30 mg & 45 mg capsules – 26 Nov 2010

6 mg/mℓ powder for oral suspension: 11 Jun2018

Last revision: 22 July 2022