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## **Tamiflu®**

**Capsules 30 mg, 45 mg, 75 mg**

*contains the active ingredient oseltamivir*

### **Consumer Medicine Information**

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#### **What is in this leaflet**

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This leaflet answers some common questions about TAMIFLU capsules.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking TAMIFLU against the benefits they expect it will have for you.

**If you have any concerns about taking this medicine, ask your doctor or pharmacist.**

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#### **What TAMIFLU is used for**

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TAMIFLU is used for the treatment and prevention of influenza (an infection caused by the influenza virus). It has no effect on the common cold or other respiratory virus infections.

TAMIFLU belongs to a group of medicines called neuraminidase inhibitors. These medicines prevent the influenza virus from spreading inside your body and so help to ease or prevent the symptoms arising from the influenza virus infection.

You will also be less likely to develop complications of influenza, such as bronchitis, pneumonia and sinusitis.

Typical symptoms of influenza include sudden onset of fever (> 38°C, cough, headaches, runny or stuffy nose, muscle aches and often extreme fatigue).

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#### **Before you take TAMIFLU**

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##### ***When you must not take***

Do not take TAMIFLU if you are allergic (hypersensitive) to oseltamivir or any other ingredients of Tamiflu.

##### ***Use in the elderly***

Same dose is recommended in elderly patients unless they have severe kidney impairment, kidney failure.

##### ***Use in children***

**Do not give TAMIFLU to children under 1 year of age, unless you have been instructed to do so by your doctor.**

##### ***Before you start to take it***

**Tell your doctor if:**

**1. You are pregnant or plan to become pregnant**

It is not known whether TAMIFLU is harmful to an unborn baby when taken by a pregnant woman. If there is a need to take TAMIFLU when you are pregnant your doctor will discuss the risks and benefits to you and the unborn baby.

**2. You are breast-feeding or plan to breast-feed**

It is not known whether TAMIFLU passes into breast milk. Your doctor will discuss the risks and benefits of using TAMIFLU if you are breast-feeding.

**3. You have any other health problems, especially the following:**

kidney failure, kidney impairment or kidney disease.

**4. You are allergic to any other medicines, foods, dyes or preservatives**

##### ***Taking other medicines***

**Tell your doctor if you are taking any other medicines, including medicines obtained without a prescription.**

TAMIFLU can be taken with aspirin, paracetamol, ibuprofen and cough medicines.

However, medical advice should be sought before giving aspirin to children with viral illness.

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#### **How to take TAMIFLU**

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**Follow all directions given to you by your doctor or pharmacist carefully.**

They may differ from the information contained in this leaflet.

The earlier you start treatment with TAMIFLU, the shorter will be the duration of your influenza.

##### ***How much to take***

###### **Treatment of influenza**

###### **Adults**

The recommended oral dose of TAMIFLU for adults and adolescents (13-17 years of age) is 75 mg twice a day for 5 days.

###### **Children (1-12 years of age)**

For children less than 12 years of age, take the dose of TAMIFLU as directed by the doctor.

###### **Prevention of influenza**

For prevention of influenza TAMIFLU is taken once a day at the recommended dose while protection is required. Safety and effectiveness have been shown in patients taking TAMIFLU long term for up to 6 weeks.

###### **Adults**

The recommended oral prevention dose of TAMIFLU for adults and adolescents (13-17 years of age) and adolescents is 75 mg once a day for 10 days.

**Children (1-12 years of age)**

For children less than 12 years of age, take the dose of TAMIFLU as directed by the doctor.

**How to take it**

**Swallow capsules whole with a glass of water with or without food.**

It does not matter whether you take TAMIFLU with food or not. However, if TAMIFLU upsets your stomach, it is better to take TAMIFLU with food.

**Do not break or chew the capsules before swallowing.**

**If you cannot swallow the capsule**

It is recommended that TAMIFLU powder for oral suspension be constituted by a pharmacist prior to dispensing to the patient.

**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.

**When to take it**

**If you have been prescribed TAMIFLU, treatment with TAMIFLU should be started as soon as possible, but no later than 48 hours after the first symptoms of influenza.**

For influenza treatment, TAMIFLU should be taken in the morning and in the evening.

For influenza prevention, TAMIFLU should be taken once a day.

**How long to take it**

Do not stop your treatment course of TAMIFLU unless instructed by your doctor or if you experience bothersome side effects (see 'Undesirable effects').

Contact your doctor if you experience bothersome side effects from TAMIFLU

**If you forget to take it**

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember and then go back to taking it as you would normally.

**Overdose**

**You should discontinue the treatment in the event of overdose and contact or consult your doctor for medical advice.**

The following are some symptoms of overdose which may or may not occur:

- nausea (feeling like vomiting)
- vomiting
- dizziness

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**Undesirable effects**

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**Like all medicine, TAMIFLU can cause undesirable effects, although not everybody gets them.**

The most common undesirable effects of TAMIFLU are:

- nausea (feeling like vomiting)
- vomiting
- stomach ache
- diarrhoea
- headache

Mostly these effects are mild.

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.

Taking TAMIFLU with food may reduce the potential for some or all of these adverse effects.

People with influenza, including those taking TAMIFLU may be at an increased risk of seizures, confusion, hallucinations, and/or abnormal behaviour during their illness. These events may occur shortly after beginning TAMIFLU or may occur when influenza is not treated. These events are uncommon but may result in accidental injury to the patient.

Patients, especially children and adolescents, should be closely monitored and their healthcare professional should be contacted immediately if the patient shows any signs of unusual behaviour.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

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**Important things to note**

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- Do not stop taking TAMIFLU or change the dose without first checking with your doctor.
- Do not give TAMIFLU to anyone else even when they have the same condition as you.

- Do not use TAMIFLU to treat other complaints unless directed by your doctor.

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#### How to store TAMIFLU

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**Keep your capsules in the blister pack until it is time to take them.**

If you take the capsules out of the blister pack they may not keep well.

**Keep TAMIFLU in a cool dry place where the temperature stays below 25°C.**

Heat and dampness can destroy some medicines.

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#### Product description

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##### ***Availability***

TAMIFLU capsules are available in the following strengths: 30 mg, 45 mg and 75 mg.

TAMIFLU comes in blister packs containing 10 capsules.

##### ***What TAMIFLU looks like***

TAMIFLU 30 mg hard gelatin capsules have a light yellow/opaque cap and a light yellow/opaque body. "ROCHE" is printed in blue ink on the light yellow body and "30 mg" is printed in blue ink on the light yellow cap.

TAMIFLU 45 mg hard gelatin capsules have a grey/opaque cap and a grey/opaque body. "ROCHE" is printed in blue ink on the grey body and "45 mg" is printed in blue ink on the grey cap.

TAMIFLU 75 mg hard gelatin capsules have a light yellow/opaque cap and a grey/opaque body. "ROCHE" is printed in blue ink on the grey body and "75 mg" is printed in blue ink on the light yellow cap.

Current at June 2020.

