

## Oseltamivir 30mg/45mg/75mg Capsules USP

### Package Leaflet: Information for the user

Oseltamivir 30mg/45mg/75mg capsules

oseltamivir

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any of the side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

### What is in this leaflet

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

#### 1. What Oseltamivir is and what it is used for

- Oseltamivir 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.

- Oseltamivir 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.
- Oseltamivir 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.

Oseltamivir 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.

Influenza, usually called flu, is an infection caused by a virus. The signs of flu often include a sudden fever (more than 37.8 °C), cough, runny or stuffy nose, headaches, muscle aches and extreme tiredness. These symptoms can also be caused by other infections. True influenza infection only occurs during annual outbreaks (*epidemics*) when flu viruses are spreading in the local community. Outside epidemic periods, flu-like symptoms are usually caused by a different type of illness.

#### 2. What you need to know before you take Oseltamivir

**Do not take Oseltamivir:**

- **if you are allergic** (*hypersensitive*) to oseltamivir or any of the other ingredients of Oseltamivir listed in section 6.

**Talk to your doctor** if this applies to you. **Do not take Oseltamivir.**

#### **Warnings and precautions:**

Before you take Oseltamivir, make sure the prescribing doctor knows

- if you are **allergic to other medicines**
- if you have **problems with your kidneys**. If so, your dose may need adjustment
- if you have a **severe medical condition**, which may require immediate hospitalisation
- if your **immune system** is not working
- if you have chronic **heart disease** or **respiratory disease**.

During treatment with Oseltamivir, **tell a doctor immediately:**

- if you notice changes in behaviour or mood (*neuropsychiatric events*), especially in children and adolescents). These may be signs of rare but serious side effects.

#### **Oseltamivir is not a flu vaccine**

Oseltamivir is not a vaccine: it treats infection, or prevents the flu virus spreading. A vaccine gives you antibodies against the virus. Oseltamivir will not change the effectiveness of a flu vaccine, and you might be prescribed both by your doctor.

#### **Other medicines and Oseltamivir**

Tell your doctor or pharmacist if you are taking any other medicines, or have recently taken any. This includes medicines obtained without a prescription. The following medicines are particularly important:

- chlorpropamide (used to treat diabetes)
- methotrexate (used to treat e.g. rheumatoid arthritis)
- phenylbutazone (used to treat pain and inflammation)
- probenecid (used to treat gout)

#### **Pregnancy and breast-feeding**

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 Oseltamivir is right for you.

The effects on breast-fed infants are unknown. You must tell your doctor if you are breast-feeding so that your doctor can decide if Oseltamivir is right for you.

Ask your doctor or pharmacist for advice before taking this medicine.

#### **Driving and using machines**

Oseltamivir has no effect on your ability to drive or use machines.

### **3. How to take Oseltamivir**

Take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Take Oseltamivir as soon as possible, ideally within two days of the flu symptoms starting.

#### **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 adult 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.

In special situations, such as widespread flu or for patients with a weak immune system, treatment will continue for up to 6 or 12 weeks.

**The recommended dose is based on the patient's body weight.** You must use the amount of oral capsules or suspension prescribed by the doctor.

#### **Adults, and adolescents 13 years and over**

For adults and adolescents 13 years and over and weighing 40 kg or more, the recommended dose for treating flu is 75mg twice daily for 5 days.

For adults and adolescents 13 years and over and weighing 40 kg or more, the recommended dose for preventing flu is 75mg once daily for 10 days.

A 75mg dose can be made up of a 30mg capsule plus a 45mg capsule.

#### **Children 1 to 12 years**

For children aged 1 to 12 years and weighing 10 kg to 15 kg, the recommended dose for treating flu is 30mg twice daily for 5 days.

For children aged 1 to 12 years and weighing 10 kg to 15 kg, the recommended dose for preventing flu is 30mg once daily for 10 days.

For children aged 1 to 12 years and weighing more than 15 kg and up to 23 kg, the recommended dose for treating flu is 45mg twice daily for 5 days.

For children aged 1 to 12 years and weighing more than 15 kg and up to 23 kg, the recommended dose for preventing flu is 45mg once daily for 10 days.

For children aged 1 to 12 years and weighing more than 23 kg and up to 40 kg, the recommended dose for treating flu is 60mg twice daily for 5 days.

For children aged 1 to 12 years and weighing more than 23 kg and up to 40 kg, the recommended dose for preventing flu is 60mg once daily for 10 days.

For children aged 1 to 12 years and weighing more than 40 kg, the recommended dose for treating flu is 75mg twice daily for 5 days.

For children aged 1 to 12 years and weighing more than 40 kg, the recommended dose for treating flu is 75mg once daily for 10 days.

A 75mg dose can be made up of a 30mg capsule plus a 45mg capsule.

#### **Infants less than 1 year (0 to 12 months)**

Giving Oseltamivir to infants less than 1 year old for preventing flu during flu pandemic should be based upon the judgment of a doctor after considering the potential benefit versus any potential risk to the infant.

For infants aged between 0 and 12 months and weighing between 3 kg to 10 kg and

above, the recommended dose for treating flu is 3mg per kg of body weight, twice daily for 5 days.

For infants aged between 0 and 12 months and weighing between 3 kg to 10 kg and above, the recommended dose for preventing flu is 3mg per kg of body weight, twice daily for 10 days.

mg/kg equals mg per kilogram of infant body weight. For example if a 6 month old weighs 8 kg then the dose is 8 kg x 3mg per kg = 24mg.

#### **Method of administration**

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

Oseltamivir can be taken with or without food, although taking it with food can reduce the chance of feeling or being sick (nausea or vomiting).

**People who find it hard to take capsules** can use a liquid medicine, *Oseltamivir oral suspension*. If you need Oseltamivir oral suspension, but it's not available from your pharmacy, you can make a liquid form of Oseltamivir from these capsules. **See *Making liquid Oseltamivir at home***, over the page.

#### **If you take more Oseltamivir than you should**

Stop taking Oseltamivir and contact a doctor or pharmacist immediately.

In most cases of overdose, people have not reported any side effects. When side effects were reported, they were similar to those from normal doses, as listed in section 4.

Overdose has been reported to have occurred more frequently when Oseltamivir

was given to children than to adults and adolescents. Caution should be exercised when preparing liquid Oseltamivir for children and when administering Oseltamivir capsules or liquid Oseltamivir to children.

#### **If you forget to take Oseltamivir**

Do not take a double dose to make up for a forgotten capsule.

#### **If you stop taking Oseltamivir**

There are no side effects when you stop Oseltamivir. But if Oseltamivir is stopped earlier than your doctor told you, the symptoms of flu may come back. Always complete the course that your doctor prescribed.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

#### **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them. Many of the side effects listed below may also be caused by influenza.

The following serious side effects have been rarely reported since oseltamivir has been marketed:

- Anaphylactic and anaphylactoid reactions: severe allergic reactions, with face and skin swelling, itchy rashes, low blood pressure and breathing difficulties
- Hepatic disorders (fulminant hepatitis, hepatic function disorder and jaundice): yellowing of the skin and white of the eyes, change in stool color, changes in behaviour

- Angioneurotic oedema: sudden onset of severe swelling of the skin mainly around the head and neck area, including eyes and tongue, with difficulties breathing
- Stevens-Johnson syndrome and toxic epidermal necrolysis: complicated, possibly life-threatening allergic reaction, severe inflammation of the outer and possibly inner skin, initially with fever, sore throat, and fatigue, skin rashes, leading to blisters, peeling, shedding of larger areas of skin, possible breathing difficulties and low blood pressure
- Gastrointestinal bleeding: prolonged bleeding from the large bowel or spitting up blood
- Neuropsychiatric disorders, as described below.

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

The most frequently (very common and common) reported side effects of Oseltamivir 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 medicinal product is taken with food.

**Rare but serious effects: get medical help at once**

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

During Oseltamivir treatment, rare events have been reported that include

- Convulsions and delirium, including altered level of consciousness

- Confusion, abnormal behaviour
- Delusions, hallucinations, agitation, anxiety, nightmares

These are reported primarily among children and adolescents and often started suddenly and resolved rapidly. A few cases resulted in self-injury, some with fatal outcome. Such neuropsychiatric events have also been reported in patients with influenza who were not taking Oseltamivir.

- Patients, especially children and adolescents, should be closely monitored for the behavioural changes described above.

**If you notice any of these symptoms, especially in younger people, get medical help immediately.**

**Adults and adolescents 13 and over**

**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 1 in 100 people)*

- Allergic reactions
- Altered level of consciousness
- Convulsion
- Heart rhythm abnormalities
- Mild to severe liver function disorders
- Skin reactions (inflammation of the skin, red and itchy rash, scaling skin).

#### **Rare side effects**

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

- Thrombocytopenia (low platelet count)
- Visual disturbances.

#### **Children 1 to 12 years**

#### **Very common side effects**

*(may affect more than 1 in 10 people)*

- Cough
- Nasal congestion
- Vomiting.

#### **Common side effects**

*(may affect up to 1 in 10 people)*

- Conjunctivitis (red eyes and discharge or pain in the eye)
- Ear inflammation and other ear disorders
- Headache
- Nausea
- Runny nose
- Stomach ache
- Upper abdominal fullness
- Upset stomach.

#### **Uncommon side effects**

*(may affect up to 1 in 100 people)*

- Inflammation of the skin
- Tympanic membrane (eardrum) disorder.

#### **Infants less than 1 year**

The reported side effects in infants 0 to 12 months old are mostly similar to the side effects reported for older children (1 year old or older). Additionally, diarrhoea and diaper rash have been reported.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, tell your doctor or pharmacist.

However,

- if you or your child are repeatedly sick, or
- if the influenza symptoms get worse or the fever continues

Tell your doctor as soon as possible.

### Reporting of side effects

If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet.

### 5. How to store Oseltamivir

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

Do not store above 25 °C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

### 6. Contents of the pack and other information

#### What Oseltamivir contains

- Each hard capsule contains oseltamivir equivalent to 30mg/45mg/75mg of oseltamivir
- The other ingredients are:  
capsule contents: pregelatinised starch, talc, povidone, croscarmellose sodium

and sodium stearyl fumarate capsule shell: gelatin, yellow iron oxide, red iron oxide and titanium dioxide  
printing ink: shellac, titanium dioxide and FD and C Blue 2 (indigo carmine).

#### What Oseltamivir looks like and contents of the pack

hard capsule.

Oseltamivir 30mg/45mg/75mg hard capsules are available in blister packs of 10.

#### 7. Manufactured By:

**Taj Pharmaceuticals Ltd.**

at: Plot. No. 220, Mahagujarat

Industrial Estate, At & Post-Moraiya,

Tal-Sanand, Dist- Ahmedabad Gujarat (India)