

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

OSELTREX, 75 mg, tablets

Oseltamivir

Sugar free

Read all of this leaflet carefully before you start taking OSELTREX

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- OSELTREX 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 is in this leaflet

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

1. What OSELTREX is and what it is used for

OSELTREX contains oseltamivir, which belongs to a group of medicines that prevent the flu virus from spreading inside the body. They help to ease or prevent the symptoms of the flu virus infection.

OSELTREX is used to treat or prevent flu (influenza) in adults. It can also be used in children who weigh 40 kg or more and who are able to swallow tablets.

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 seasonal 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 OSELTREX

Do not take OSELTREX:

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

Warnings and precautions

Take special care

- If you notice changes in behaviour, mood, awareness of your surroundings, seeing/hearing things that do not exist, or having convulsions, especially in children and adolescents. These may be signs of rare but serious side effects called neuropsychiatric events.
- If you have problems with your kidneys. If so, your dose may need to be adjusted, which means that your doctor may prescribe a different medicine (that also contains oseltamivir but at a different strength) that is appropriate for people with kidney problems.

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

Children and adolescents

OSELTREX can be given to children and adolescents weighing 40 mg or more, who are able to swallow tablets.

The safety and efficacy of oseltamivir, the active ingredient of OSELTREX, in children under the age of 1 year old have not been established.

Other medicines and OSELTREX

Always tell your health care provider if you are taking any other medicine.

(This includes all complementary or traditional medicines.)

Tell your doctor if you are taking any of the following medicines:

- Chlorpropamide (used to treat diabetes).
- Methotrexate (used to treat e.g. rheumatoid arthritis).
- Phenylbutazone (used to treat pain and inflammation).

Your doctor might monitor the concentrations of these medicines more closely.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine. The possible effects of OSELTREX on unborn or breastfed babies are unknown. You should therefore not use OSELTREX while you are pregnant or breastfeeding your baby.

Driving and using machines

It is not always possible to predict to what extent OSELTREX may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of how OSELTREX affects you.

OSELTREX can have side effects e.g. changes in your level of consciousness, convulsions or you may experience a short spell of flashing or shimmering of light in your sight, that can influence your ability to drive or use machines.

3. How to take OSELTREX

Do not share medicines prescribed for you with any other person.

Always take OSELTREX exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose for adults and adolescents 13 years and older:

- For treating flu, take one OSELTREX tablet twice daily for 5 days. It is usually convenient to take one tablet 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.
- For preventing flu or after being exposed to an infected person, take one OSELTREX tablet once daily for 10 days. It is best to take this in the mornings with breakfast.
- In special situations, such as widespread flu, take one OSELTREX tablet once daily for up to 6 weeks to prevent flu.
- For patients with a weak immune system, one OSELTREX tablet can be taken once daily for up to 12 weeks to prevent flu.

Your doctor will prescribe the dose that is appropriate for you.

The recommended dose for children, weighing 40 kg or more and who can swallow a tablet:

- For treating flu, one OSELTREX tablet twice a day for 5 days. It is usually convenient to give your child one tablet in the morning and one in the evening. It is important to complete the whole 5 day course, even if your child starts to feel better.
- For preventing flu or after being exposed to an infected person, give one OSELTREX tablet daily for 10 days. It is best to take this in the mornings with breakfast.

Method of administration

Take the tablets with water. Do not break or chew the tablets.

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

If you take more OSELTREX than you should

In the event of overdosage, stop taking OSELTREX and consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take OSELTREX

Take it as soon as you remember unless it is nearly time for your next dose. Do not take a double dose to make up for forgotten individual doses.

If you stop taking OSELTREX

There are no side effects when you stop taking OSELTREX. But if OSELTREX 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

OSELTREX can have side effects.

Not all side effects reported for OSELTREX are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking OSELTREX, please consult your health care provider for advice.

If any of the following happens, stop taking OSELTREX and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Anaphylactic and anaphylactoid reactions: severe allergic reactions, with face and skin swelling, itchy rashes, low blood pressure and difficulty breathing.
- Liver disorders (fulminant hepatitis, hepatic function disorder and jaundice): yellowing of the skin and white of the eyes, changes in stool colour, 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 breathing difficulties.
- 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: bleeding from the gastrointestinal tract, that is from the mouth to the bowels. Symptoms may include vomiting red blood, vomiting black blood, bloody stools, or black stools.
- Neuropsychiatric disorders: changes in behaviour, mood, awareness of your surroundings, seeing/hearing things that do not exist, or convulsions (fits). These are reported primarily among children and adolescents and often start suddenly and clear up 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 OSELTREX. Patients, especially children and adolescents, should be closely monitored for the behavioural changes described above.

If you have them, you may have had a serious reaction to OSELTREX. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Bronchitis, a chest infection causing shortness of breath and/or wheezing, a cough with phlegm (mucous) which can range in colour from clear, white, yellow or green, or rarely, streaked with blood. You may also experience tiredness, fever and/or chills, headache, body aches and a sore throat.
- Cold sore.
- Nasopharyngitis (swelling of the throat and blocked nose).
- Upper respiratory tract infections, causing symptoms like coughing, sore throat, hoarse voice, runny or blocked nose, tiredness or lack of energy.
- Sinusitis (infection of your sinuses), causing a runny or stuffy nose with yellow or green mucous, fever, facial pressure (particularly around your nose, eyes and forehead) which might get worse when you move your head around or bend over, headache, postnasal drip (mucus dripping down your throat), pressure or pain in your teeth, ear pressure or pain, and tiredness.
- Infection in the ear, causing symptoms like ear pain, fluid draining from the ear or hearing trouble. In children, symptoms may include fever, loss of appetite (not wanting to eat), pulling at the ear, crying more than usual or fussiness and trouble sleeping.
- Pneumonia (inflammation and infection of the lungs), causing symptoms like coughing, tiredness, chest pain when you breathe or cough, shortness of breath, fever, sweating or chills and tiredness.
- Headache.
- Conjunctivitis (red eyes, excess fluid in the eye and pain in the eye).
- Earache.
- Insomnia (sleeplessness).
- Cough.
- Asthma or worsening of asthma.
- Sore throat.
- Rhinorrhoea (runny nose).
- Blocked nose.
- Nose bleeds.

- Nausea.
- Vomiting.
- Pain in the abdominal (stomach).
- Dyspepsia (indigestion).
- Diarrhoea.
- Back pain.
- Muscle and joint pain.
- Menstrual pain.
- Pain.
- Dizziness (feeling lightheaded, faint and/or loss of balance).
- Fatigue (feeling tired).
- Pyrexia (fever).
- Pain in your limbs.
- Dermatitis (skin itchiness, redness and a rash).

Less frequent side effects:

- Unexplained bruising or bleeding.
- Visual disturbance (when you experience a short spell of flashing or shimmering of light in your sight).
- Cardiac dysrhythmia (your heart beats irregular).
- Haemorrhagic colitis (infection of the large intestine that can cause bloody diarrhoea and other serious complications).
- Eczema (itchy, red skin).
- Rash.
- Urticaria (red, itchy welts that result from a skin reaction).
- Erythema multiforme (skin immune reaction, which is a rash on the body where each mark resembles a bullseye).
- Swollen enlarged lymph nodes most commonly found in the neck.

- Problems with the eardrum such as pain, feeling like your ears are blocked or difficulty hearing.

If you 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 or pharmacist. 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 OSELTREX.

5. How to store OSELTREX

Store all medicines out of reach of children.

- Store at or below 25 °C.
- Do not use after the expiry date stated on the blister or carton.

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 OSELTREX contains

- The active substance is oseltamivir.

Each tablet contains 75 mg oseltamivir as oseltamivir phosphate.

- The other ingredients are crospovidone type A (E 1202), microcrystalline cellulose type 101 and 102 (E 460), magnesium stearate (E 572), povidone K30 (E 1201), silica colloidal anhydrous (E 551).

What OSELTREX looks like and contents of the pack

OSELTREX is white, round, biconvex tablets.

OSELTREX tablets are packed in carton boxes containing 10, 20 or 30 tablets, packed in blisters of OPA/Aluminium/PVC and Aluminium foil.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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