APPROVED PATIENT INFORMATION LEAFLET FOR OZETIR

SCHEDULING STATUS

S4

OZETIR 6 mg/mL powder for oral suspension

Each ml of reconstituted suspension contains 6 mg oseltamivir

Contains sugar sorbitol

Read all of this leaflet carefully before you start taking OZETIR

- 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.
- OZETIR 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 OZETIR is and what it is used for

- The active substance is oseltamivir phosphate, which belongs to group of medicines named

neuraminidase inhibitors.

- These medicines are used to prevent flu virus from spreading inside the body.
- OZETIR is used for adults, adolescents, children and infants (including full-term new-born babies) for treating flu(influenza). It can be used when you have flu symptoms, and the flu virus is known to be going around in your community.
- OZETIR 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.
- OZETIR may be prescribed for adults, adolescents, children and infants (including full-term new-born 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

2. What you need to know before you take OZETIR

Do not take OZETIR:

- If you are hypersensitive (allergic) to (oseltamivir phosphate) or any of the other ingredients of OZETIR (listed in Section 6)

Warnings and precautions

Take special care with OZETIR:

- If you have problems with your kidneys. If so, your dose may need adjustment.
- If you have chronic heart disease or respiratory disease.
- If you realise you lost consciousness (black outs).
- OZETIR is not a substitute for influenza vaccination.

Children and adolescents

- 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.
- If OZETIR is meant for your child of 6-12 months of age. In this case OZETIR is only to be used during a widespread influenza outbreak throughout the country or the world.

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Other medicines and OZETIR

Always tell your health care provider if you are taking any other medicine (This includes complementary or traditional medicines).

Tell your health care provider 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)
- probenecid (used to treat gout)

OZETIR with food, drink and alcohol

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

Pregnancy and 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.

Safety in pregnancy has not been established.

The effects on breastfed infants are unknown.

Mothers who are taking OZETIR should not breastfeed their babies.

Driving and using machines

OZETIR may impair your ability to drive and use machinery.

Do not drive, operate machinery, or do anything else that could be dangerous until you know how OZETIR affects you.

OZETIR contains sorbitol. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this OZETIR.

3.How to take OZETIR

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

Always take OZETIR exactly as your doctor has told you.

Check with your doctor or pharmacist if you are unsure.

Take **OZETIR as** soon as possible, ideally within two

days of the flu symptoms starting.

Your doctor will tell you how long your treatment with OZETIR will last. Do not stop treatment early because OZETIR will only be effective while you are using it.

If you take more OZETIR than you should

In the event of overdosage, consult your doctor or pharmacist. If

neither is available, contact the nearest hospital or poison centre.

If you forget to take OZETIR

If you have missed your dose by only a few hours, take the missed dose as soon as you remember. If it is almost time for your next dose, skip the missed dose and take OZETIR at the next regularly scheduled time.

Do not take a double dose to make up for forgotten individual doses

If you stop taking OZETIR

Do not stop taking OZETIR without talking to your doctor first.

If you have diabetes, your blood sugar may increase without this medicine.

4. Possible side effects

OZETIR can have side effects.

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

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

- 'swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in

swallowing or breathing',

- 'rash or itching',
- 'fainting'
- Jaundice (yellowing of the skin and white of the eyes)

These are all very serious side effects. If you have them, you may have had a serious reaction to OZETIR. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at

your nearest hospital if you notice any of the following:

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

Frequent:

- Conjunctivitis (red eyes and discharge or pain in the eye).
- (Mostly in children 1 to 12 years)
- Ear inflammation and other ear disorders (Mostly in children 1 to 12 years)
- nausea, vomiting
- headache and pain.
- Diarrhoea
- Stomach ache

Less frequent:

- 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 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 (convulsions and delirium, including altered level of consciousness, confusion, abnormal behaviour, delusions, hallucinations, agitation, anxiety, nightmares)
- Heart rhythm abnormalities
- Mild to severe liver function disorders
- Tympanic membrane (eardrum) disorder (Mostly in children 1 to 12 years)

These are all serious side effects. You may need urgent medical attention.

Tell your doctor as soon as possible if you notice any of the following:

Frequent:

- Feeling or being sick (nausea, vomiting), stomach ache,stomach upset
- Headache and pain
- Bronchitis
- Cold sore virus
- Cough
- Dizziness
- Fever
- Pain in limbs
- Runny nose
- Sleeping difficulties

- Sore throat
- Tiredness
- Upper abdominal fullness
- Upper respiratory tract infections (inflammation of the nose,throat and sinuses)
- Upset stomach
- Upper abdominal fullness

Less frequent:

- Allergic reactions
- Skin reactions (inflammation of the skin, red and itchy rash,scaling skin).
- Thrombocytopenia (low platelet count)
- Visual disturbances

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 **"6.04 Adverse Drug Reaction Reporting Form"**, found online under SAHPRA's

publications: https://www.sahpra.org.za. or to the Holder of certificate of registration through the mail:

pvg.cdma@heterogroups.com. By reporting side effects, you can help provide more information on the safety of OZETIR.

5. How to store OZETIR

- Store at or below 25 °C

- Store the suspension in the original container until required for
- Store all medicines out of reach of children.
- Protect from moisture / light.
- Do not use after the expiry date stated on the label / carton / bottle.
- 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 OZETIR contains

Monosodium citrate anhydrous

Dehydrated alcohol

Sodium benzoate

Titanium dioxide

Tutti-frutti Flavor

What OZETIR looks like and contents of the pack

White to pale yellow, tutti-frutti flavored granular or clumped

granular powder.

Contents of the pack

100 ml Amber glass bottle (type-III (SGD)) with a child-resistant plastic caps with Expended PE wad, 28 mm

Holder of Certificate of Registration

Hetero Drugs South Africa (Pty) Ltd

Waterfall Corporate

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Registration number(s)

OZELET 6 mg/mL:56/20.8/1086

Access to the corresponding Professional Information

Hetero Drugs South Africa (Pty) Ltd

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2066