PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S2

ESOCID OTC 20 mg gastro-resistant tablets

Esomeprazole

Contains sugar.

Each tablet contains 19,3 mg sucrose.

Read all of this leaflet carefully before you start taking ESOCID OTC.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, nurse or other health care provider.
- ESOCID OTC 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 ESOCID OTC is and what it is used for
2. What you need to know before you take ESOCID OTC
3. How to take ESOCID OTC
4. Possible side effects
5. How to store ESOCID OTC
6. Contents of the pack and other information.

1. What ESOCID OTC is and what it is used for

Esomeprazole belongs to a group of medicines called proton pump inhibitors. They work by reducing the amount of acid that your stomach produces.

ESOCID OTC is used for the temporary, short-term relief of heartburn and increased acid

(hyperacidity) of the stomach.

2. What you need to know before you take ESOCID OTC

Do not take ESOCID OTC:

- If you are hypersensitive (allergic) to esomeprazole or any of the other ingredients of ESOCID OTC (listed in section 6).
- If you are allergic to any other proton pump inhibitors.
- If you are taking medicine for human immunodeficiency virus (HIV) treatment (atazanavir or nelfinavir).

Warnings and precautions

Tell your doctor or health care provider before taking ESOCID OTC:

- If you have been experiencing indigestion.
- If you develop kidney problems such as blood in the urine caused by acute interstitial nephritis (AIN).
- If you have been on continuous medication for longer than a year.
- If you have been taking a medication that contains clopidogrel (used in the treatment of blood clots).
- If you are due to have a specific blood test (chromogranin A).
- If you have had previous intestinal conditions.
- If you develop severe diarrhoea with watery stools, abdominal pain and fever.
- If you are taking ESOCID OTC when necessary and your symptoms change.
- If you have a vitamin B_{12} deficiency.
- If you develop tiredness, dizziness, tremor and muscle problems (hypomagnesaemia).
- If you have been diagnosed with osteoporosis (brittle bones) or are at risk of breaking your bones.
- If you develop ‘butterfly rash’ with sensitivity to sunlight (subacute cutaneous lupus erythematosus).

If any of these applies to you, tell your doctor or nurse before you are given ESOCID OTC.

Children

ESOCID OTC should not be used in children younger than 1 year.

Other medicines and ESOCID OTC

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

It is particularly important that you mention the following:

- Itraconazole, ketoconazole or voriconazole, used in the treatment of fungal infections.
- Diazepam, used in the treatment of anxiety.
- Medicines used to prevent fitting (phenytoin).
- Medicines used to prevent blood clotting (warfarin or clopidogrel).
- Medicine used to help the symptoms of intermittent claudication (aching pain in your legs when you walk or exercise, that goes away when you rest) (cilostazol).
- Medicines used to speed up stomach emptying (cisapride).
- Digoxin, used in the treatment of heart problems.
- Rifampicin, used for the treatment of tuberculosis (TB).
- St John's wort – used to treat depression, or certain types of anti-malignancy medicines (such as erlotinib) or another anti-malignancy medicine from the same class.
- ESOCID OTC should not be taken at the same time as some medicines for HIV, such as atazanavir and nelfinavir, as ESOCID OTC may reduce the blood levels of your antiretroviral medicine.
- Tipranavir, used to treat HIV.
- Clarithromycin, an antibiotic.
- If you are taking a high dose of methotrexate (a chemotherapy medicine in which high doses are used to treat cancer). ESOCID OTC may need to be temporarily withdrawn.

Pregnancy and breastfeeding

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 ESOCID OTC.

You should not take ESOCID OTC if you are pregnant or breastfeeding your baby.

Driving and using machines

ESOCID OTC may cause dizziness and blurred vision, thereby affecting the ability to drive or use machinery.

ESOCID OTC contains sugar in the form of sucrose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking ESOCID OTC.

3. How to take ESOCID OTC

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

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

Take one ESOCID OTC tablet once daily, for a maximum treatment period of 14 days.

Do not take more than 20 mg (one ESOCID OTC tablet) daily.

The tablets should be swallowed whole with liquid. The tablets should not be chewed or crushed.

Your doctor will tell you how long your treatment with ESOCID OTC will last. Do not stop treatment early because you feel better.

If you have the impression that the effect of ESOCID OTC is too strong or too weak, tell your doctor or pharmacist.

If you take more ESOCID OTC than you should

In the event of overdosage, consult your doctor or pharmacist without delay. If neither is available, contact the nearest hospital or poison centre.

If you forget to take ESOCID OTC

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

If it is almost time for your next dose, do not take the missed dose, and just take the next dose on time.

4. Possible side effects

ESOCID OTC can have side effects.

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

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

- Sudden wheezing, swelling of your lips, tongue and throat or body, rash, fainting or difficulties in swallowing (severe allergic reaction).
- Rash or itching in the form of reddening of the skin with blisters or peeling. There may also be severe blisters and bleeding in the lips, eyes, mouth, nose and genitals. This could be Stevens-Johnson syndrome or toxic epidermal necrolysis (TEN).
- Yellow skin, dark urine and tiredness, which can be symptoms of liver problems.

These are all very serious side effects. If you have them, you may have had a serious reaction to ESOCID OTC. 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:

- Tightening of chest accompanied with severe coughing (bronchospasm).
- Loss or decreased vision.
- Abdominal swelling (may be an indication of liver failure).
- Excessive sweating.

- Blood in the urine (nephritis).
- Significant reduction in the amount of urine with shortness of breath. (This could be a sign of kidney failure.)

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Stomach pain.
- Diarrhoea.
- Nausea/vomiting.
- Constipation.
- Headache.

Less frequent side effects:

- Muscle weakness/pain.
- Fever.
- Development of breast tissue in males.
- Joint pain.
- Hair loss.
- Dry mouth.
- Inflammation of the mouth and lips.
- Dizziness.
- Blurred vision.
- Tingling sensation.
- Loss of balance.
- Taste disturbance.
- Sleepiness.
- Inability to sleep.
- Confusion.

- Depression.
- Agitation.
- Hallucination.
- Low blood cell count.

Side effects of which the frequency is unknown:

- Decreased levels of calcium.
- Decreased levels of magnesium.
- 'Butterfly rash' that lasts hours to days.

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/Publications/Index/8

By reporting side effects, you can help provide more information on the safety of ESOCID OTC.

5. How to store ESOCID OTC

- Store at or below 25 °C.
- Store in a dry place.
- Keep the blister strips in the outer carton until required for use.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry stated on the carton/blister.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What ESOCID OTC contains

The active substance is esomeprazole magnesium dihydrate.

Each tablet contains esomeprazole magnesium dihydrate equivalent to 20 mg esomeprazole.

The other ingredients are copovidone, crospovidone, glycerol monostearate, hydroxypropyl cellulose (E463), hypromellose (E464), magnesium oxide (light), magnesium stearate (E572), mannitol (E421), methacrylic acid ethyl acrylate polymer, microcrystalline cellulose [E460(i)], microcrystalline cellulose (silicified) [E460(i)], Opadry Pink [containing hydroxypropyl cellulose (E463), hypromellose (E464), iron oxide red (E172), talc (E553b) and titanium dioxide (E171)], polyethylene glycol 8 000, polysorbate 80 (E433), povidone, sugar spheres, talc (E553b) and triethyl citrate (E1505).

What ESOCID OTC looks like and contents of the pack

Pink coloured, oval shaped, biconvex, bevelled edge, film-coated tablets, plain on both sides.

Silver aluminium/aluminium blister strips placed in an outer carton with a desiccant. Each blister strip contains 7 tablets.

Pack size: 14 tablets.

Holder of certificate of registration

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