

ESOZ 20/40

(Esomeprazole Gastro Resistant Tablets 20/40 mg)

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

Keep this leaflet with the medicine.

You may need to read it again.

What ESOZ 20/40 is used for

ESOZ 20/40 is used to treat the following conditions:

- ‘Gastroesophageal reflux disease’ (GERD). This is where acid from the stomach escapes into the gullet (the tube which connects your throat to your stomach) causing pain, inflammation and heartburn.
- Ulcers in the stomach or upper part of the gut (intestine) that are infected with bacteria called ‘*Helicobacter pylori*’. If you have this condition, your doctor may also prescribe antibiotics to treat the infection and allow the ulcer to heal. It also helps to stop the ulcers from coming back or relapsing.
- Stomach ulcers caused by medicines called NSAIDs (Non-Steroidal Anti-Inflammatory Drugs). **ESOZ 20/40** can also be used to stop stomach ulcers from forming if you are taking NSAIDs.
- Too much acid in the stomach caused by a growth in the pancreas (Zollinger-Ellison syndrome).

How ESOZ 20/40 works

ESOZ 20/40 contains a medicine called esomeprazole. Esomeprazole belongs to a group of medicines called ‘proton-pump inhibitors’. It works by

decreasing the amount of acid made by the stomach to relieve symptoms and allow healing to take place. This does not stop food being digested in the normal way.

Before you take ESOZ 20/40

When you must not take it

Do not take ESOZ 20/40:

- If you are allergic (hypersensitive) to esomeprazole or any of the other ingredients of this medicine.
- If you are allergic to other proton pump inhibitor medicines (e.g. pantoprazole, lansoprazole, rabeprazole, omeprazole).
- If you are taking a medicine containing nelfinavir (used to treat HIV infection).

Do not take this medicine after the expiry date printed on the pack

The expiry date refers to the last day of that month. If it has expired or is damaged, return it to your pharmacist for disposal.

Before you start to take it

Talk to your doctor or pharmacist before taking ESOZ 20/40.

- If you have severe liver problems.
- If you have severe kidney problems
- If you have ever had a skin reaction after treatment with a medicine similar to **ESOZ 20/40** that reduces stomach acid.
- If you are due to have a specific blood test (Chromogranin A).

ESOZ 20/40 may hide the symptoms of other. Therefore, if any of the following happen to you before you start taking **ESOZ 20/40** or while you are taking it, talk to your doctor straight away:

- You lose a lot of weight for no reason and have problems swallowing.
- You get stomach pain or indigestion.
- You begin to vomit food or blood.
- You pass black stools (blood-stained faeces).

If you have been prescribed **ESOZ 20/40** “on demand” you should contact your doctor if your symptoms continue or change in character.

Taking a proton pump inhibitor like **ESOZ 20/40**, especially over a period of more than one year, may slightly increase your risk of fracture in the hip, wrist or spine. Tell your doctor if you have osteoporosis or if you are taking corticosteroids (which can increase the risk of osteoporosis).

If you get a rash on your skin, especially in areas exposed to the sun tell your doctor as soon as you can, as you may need to stop your treatment with **ESOZ 20/40**. Remember to also mention any other ill-effects like pain in your joints.

ESOZ 20/40 contains sucrose

ESOZ 20/40 contains sugar spheres which contain sucrose, a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, talk to your doctor before taking this medicine.

Children and adolescents

ESOZ 20/40 is not recommended for children less than 12 years old.

Taking other medicines

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines obtained without a prescription including herbal medicines. This is because **ESOZ 20/40** can affect the way some other medicines work. Also, some other medicines can affect the way **ESOZ 20/40** works. Some medicines and **ESOZ 20/40** may interfere with each other. These include:

- Atazanavir (used to treat HIV infection).
- Clopidogrel (used to prevent blood clots).
- Ketoconazole, itraconazole or voriconazole (used to treat infections caused by a fungus).
- Erlotinib (used to treat cancer).

- Citalopram, imipramine or clomipramine (used to treat depression).
- Diazepam (used to treat anxiety, relax muscles or in epilepsy).
- Phenytoin (used in epilepsy). If you are taking phenytoin, your doctor will need to monitor you when you start or stop taking **ESOZ 20/40**.
- Medicines that are used to thin your blood, such as warfarin. Your doctor may need to monitor you when you start or stop taking **ESOZ 20/40**.
- Cilostazol (used to treat intermittent claudication – a pain in your legs when you walk which is caused by an insufficient blood supply).
- Cisapride (used for indigestion and heartburn).
- Digoxin (used for heart problems).
- Methotrexate (a chemotherapy medicine used in high doses to treat cancer) – if you are taking a high dose of methotrexate, your doctor may temporarily stop your **ESOZ 20/40** treatment.
- Tacrolimus (organ transplantation).
- Rifampicin (used for treatment of tuberculosis).
- St. John's wort (*Hypericum perforatum*) (used to treat depression).

If your doctor has prescribed the antibiotics amoxicillin and clarithromycin as well as esomeprazole to treat ulcers caused by *Helicobacter pylori* infection, it is very important that you tell your doctor about any other medicines you are taking.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking **ESOZ 20/40**.

How to take ESOZ 20/40

How much to take

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

The recommended dose of **ESOZ 20/40** is usually 20 mg or 40 mg a day depending on what condition you are being treated for and how severe it is.

Children

Esomeprazole should not be used in children younger than 12 years.

Liver problems

If you have liver problems, your doctor will decide the right dose for you.

How to take it

Swallow **ESOZ 20/40** whole with a glass of water. **Do not crush or chew the tablets.**

If the tablets are chewed or crushed they will not work properly.

If you forget to take it

- If you forget to take a dose, take it as soon as you remember it. However, if it is almost time for your next dose, skip the missed dose.
- Do not take a double dose (two doses at the same time) to make up for a forgotten dose.

If you take too much (overdose)

If you are taking more than the recommended dose of **ESOZ 20/40**, please contact your doctor or pharmacist

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Take the medicine pack with you. This is so the doctor knows what you have taken.

While you are using ESOZ 20/40

Things you must do

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Your doctor will decide whether you can take **ESOZ 20/40** during this time.

It is not known if **ESOZ 20/40** passes into breast milk. Therefore, you should not take **ESOZ 20/40** if you are breastfeeding.

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

Things you must not do

- Do not take **ESOZ 20/40** to treat any other complaints unless your doctor tells you to.

- Do not give your medicine to anyone else, even if they have the same condition as you.
- Do not stop taking your medicine because you are feeling better, unless advised by your doctor.

Things to be careful of

ESOZ 20/40 is not likely to affect you being able to drive or use any tools or machines. However, side effects such as dizziness and blurred vision may uncommonly or rarely occur. If affected, you should not drive or use machines.

Side Effects

Like all medicines, ESOZ 20/40 can have side effects, although not everybody gets them.

Serious side effects

If any of the following happens, stop taking **ESOZ 20/40** and tell your doctor immediately or go to the casualty department at your nearest hospital immediately.

- Rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing (anaphylaxis, angioedema).
- Irregular red patches on the skin of the hands and arms (erythema multiforme)
- Severe skin disease with painful red areas, large blisters and ends with peeling of layers of skin. It is accompanied by fever and chills, aching muscles and generally feeling unwell (toxic epidermal necrolysis)
- Rare skin condition with severe blisters and bleeding in the lips, eyes, mouth, nose and genitals (Stevens-Johnson syndrome).
- Yellow skin, dark urine and tiredness which can be symptoms of liver problems.

Other side effects

Tell your doctor if you notice any of the following:

- Headache
- Diarrhoea, stomach pain, constipation, wind (flatulence).
- Feeling sick (nausea)/vomiting
- Benign polyps in the stomach

Tell your doctor if you notice anything else that is making you feel unwell.

Other side effects not listed above may also occur in some people.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of ESOZ 20/40

Storage

Store below 30°C, protected from moisture.

Keep out of the reach and sight of children.

Disposal

Return any unused or expired medicine to your doctor, pharmacist or health care professional for safe disposal.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

What ESOZ 20/40 looks like

ESOZ 20/40 20 mg gastro-resistant tablets

Ingredients

Active ingredient: esomeprazole

Inactive ingredients:

Sugar spheres, Hydroxyl propyl cellulose, Crospovidone, Povidone, Macrogol 400, Purified talc, Isopropyl alcohol, Hypromellose phthalate(HP-55S), Hypromellose phthalate(HP-50), Diethylphalate, Acetone, Macrogol 6000, Methylene chloride, Microcrystalline cellulose PH101, Microcrystalline cellulose PH112, Sodium stearyl fumarate Macrogol 4000, and Opadry 03B86651 brown(HPMC 2910/Hypromellose 6cP,Titanium dioxide,Macrogol/PEG 400,Talc, Iron oxide red).

Manufacturer

Sun Pharmaceutical Industries Ltd.
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Paonta Sahib 173 025,
District Sirmour, Himachal Pradesh.
INDIA.

Product Registration Holder

RANBAXY (Malaysia) SDN. BHD.
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MALAYSIA

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