Package leaflet: Information for the patient

Esocor 20 Tablets

Esocor 40 Tablets

Esomeprazole

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 any 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 side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

1. What Esocor is and what it is used for
2. Before you take Esocor
3. How to take Esocor
4. Possible side effects
5. How to store Esocor
6. Further information

1. WHAT ESOCOR IS AND WHAT IT IS USED FOR

Esocor contains a medicine called esomeprazole magnesium. This belongs to a group of medicines called 'proton pump inhibitors'. They work by reducing the amount of acid that your stomach produces.

Esocor is used to treat the following conditions:

Adults

- '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.
- Stomach ulcers caused by medicines called NSAIDs (Non-Steroidal Anti-Inflammatory Drugs). Esocor 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).
- Prolonged treatment after prevention of re-bleeding of ulcers with intravenous Esocor.

Adolescents aged 12 years and above

- '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.

2. BEFORE YOU TAKE ESOCOR

Do not take Esocor:

- If you are allergic to esomeprazole or any of the other ingredients of this medicine (listed in section 6).

- 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 Esocor if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Esocor.

Take special care with Esocor:

Talk to your doctor or pharmacist before taking Esocor:

- 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 Esocor that reduces stomach acid.
- If you are due to have a specific blood test (Chromogranin A).

Esocor may hide the symptoms of other diseases. **Therefore, if any of the following happen to you before you start taking Esocor 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 Esocor "on demand" you should contact your doctor if your symptoms continue or change in character.

Taking a proton pump inhibitor like Esocor, 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).

Rash and skin symptoms

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 Esocor. Remember to also mention any other ill-effects like pain in your joints.

Serious skin rashes have occurred in patients taking esomeprazole (see also section 4). The rash can involve ulcers of the mouth, throat, nose, genitals and conjunctivitis (red and swollen eyes). These serious skin rashes often come after flu-like symptoms such as fever, headache and body ache. The rash may cover large parts of the body with blistering and peeling of the skin.

If at any time during the treatment (even after several weeks) you develop a rash or any of these skin symptoms, stop taking this medicine and contact your doctor immediately.

Children under the age of 12 years

Esocor gastro-resistant tablets are not recommended for children less than 12 years old.

Other medicines and Esocor

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription. This is because Esocor can affect the way some medicines work and some medicines can have an effect on Esocor.

Do not take Esocor Tablets if you are taking a medicine containing nelfinavir (used to treat HIV infection).

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

- 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 Esocor.
- Medicines that are used to thin your blood, such as warfarin. Your doctor may need to monitor you when you start or stop taking Esocor.
- 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 Esocor 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 Esocor to treat ulcers caused by Helicobacter pylori infection, it is very important that you tell your doctor about any other medicines you are taking.

This medicine may affect the way that your body absorbs vitamin B12, particularly if you need to take it for a long time. Please contact your doctor if you notice any of the following symptoms, which could indicate low levels of Vitamin B12:

- Extreme tiredness or lack of energy
- Pins and needles
- Sore or red tongue, mouth ulcers
- Muscle weakness
- Disturbed vision
- Problems with memory, confusion, depression

Esocor with food and drink

You can take your tablets with food or on an empty stomach.

Driving and using machines

Esocor 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 (see section 4). If affected, you should not drive or use machines.

3. HOW TO TAKE ESOCOR

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

- If you are taking this medicine for a long time, your doctor will want to monitor you (particularly if you are taking it for more than a year).
- If your doctor has told you to take this medicine as and when you need it, tell your doctor if your symptoms change.

How much to take

Your doctor will tell you how many tablets to take and how long to take them for. This will depend on your condition, how old you are and how well your liver works.

The recommended doses are given below.

Use in adults aged 18 and above

To treat heartburn caused by gastroesophageal reflux disease (GERD):

- If your doctor has found that your food pipe (gullet) has been slightly damaged, the recommended dose is one Esocor 40 mg gastro-resistant tablet once a day for 4 weeks. Your doctor may tell you to take the same dose for a further 4 weeks if your gullet has not yet healed.
- The recommended dose once the gullet has healed is one Esocor 20 mg gastro-resistant tablet once a day
- If your gullet has not been damaged, the recommended dose is one Esocor 20 mg gastro-resistant tablet each day. Once the condition has been controlled, your doctor may tell you to take your medicine as and when you need it, up to a maximum of one Esocor 20 mg gastro-resistant tablet each day.
- If you have severe liver problems, your doctor may give you a lower dose.

To treat ulcers caused by Helicobacter pylori infection and to stop them coming back:

- The recommended dose is one Esocor 20 mg gastro-resistant tablet twice a day for one week.
- Your doctor will also tell you to take antibiotics for example amoxicillin and clarithromycin.

To treat stomach ulcers caused by NSAIDs (Non-Steroidal Anti-Inflammatory Drugs):

- The recommended dose is one Esocor 20 mg gastro-resistant tablet once a day for 4 to 8 weeks.

To prevent stomach ulcers if you are taking NSAIDs (Non-Steroidal Anti-Inflammatory Drugs):

- The recommended dose is one Esocor 20 mg gastro-resistant tablet once a day.

To treat too much acid in the stomach caused by a growth in the pancreas (Zollinger Ellison syndrome):

- The recommended dose is Esocor 40 mg twice a day.
- Your doctor will adjust the dose depending on your needs and will also decide how long you need to take the medicine for. The maximum dose is 80 mg twice a day.

Prolonged treatment after prevention of re-bleeding of ulcers with intravenous Esocor:

- The recommended dose is one Esocor 40 mg tablet once a day for 4 weeks.

Use in adolescents aged 12 or above

To treat heartburn caused by gastroesophageal reflux disease (GERD):

- If your doctor has found that your food pipe (gullet) has been slightly damaged, the recommended dose is one Esocor 40 mg gastro-resistant tablet once a day for 4 weeks. Your doctor may tell you to take the same dose for a further 4 weeks if your gullet has not yet healed.
- The recommended dose once the gullet has healed is one Esocor 20 mg gastro-resistant tablet once a day.
- If your gullet has not been damaged, the recommended dose is one Esocor 20 mg gastroresistant tablet each day.
- If you have severe liver problems, your doctor may give you a lower dose.

Taking this medicine

- You can take your tablets at any time of the day.
- You can take your tablets with food or on an empty stomach.
- Swallow your tablets whole with a drink of water. Do not chew or crush the tablets. This is because the tablets contain coated pellets which stop the medicine from being broken down by the acid in your stomach. It is important not to damage the pellets.

What to do if you have trouble swallowing the tablets

- If you have trouble swallowing the tablets:
  - Put them into a glass of still (non-fizzy) water. Do not use any other liquids.
  - Stir until the tablets break up (the mixture will not be clear). Then drink the mixture straight away or within 30 minutes. Always stir the mixture just before drinking it.
  - To make sure that you have drunk all of the medicine, rinse the glass very well with half a glass of water and drink it. The solid pieces contain the medicine - do not chew or crush them.
- If you cannot swallow at all, the tablet can be mixed with some water and put into a syringe. It can then be given to you through a tube directly into your stomach ('gastric tube').

Use in children under the age of 12 years

Esocor gastro-resistant tablets are not recommended for children less than 12 years old.

Information on dosing for children aged 1 to 11 years is provided in Esocor sachet product information (ask your doctor or pharmacist if you require further information).

Elderly

Dose adjustment is not required in the elderly.

If you take more Esocor than you should

If you take more Esocor than prescribed by your doctor, talk to your doctor or pharmacist straight away.

If you forget to take Esocor

- 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 stop Esocor

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.

If you notice any of the following serious side effects, stop taking Esocor and contact a doctor immediately:

- Yellow skin, dark urine and tiredness which can be symptoms of liver problems.
  These effects are rare, and may affect up to 1 in 1,000 people.
- Sudden wheezing, swelling of your lips, tongue and throat or body, rash, fainting or difficulties in swallowing (severe allergic reaction).
  These effects are rare, and may affect up to 1 in 1,000 people.
- Sudden onset of a severe rash or reddening of the skin with blisters or peeling may occur even after several weeks of treatment. There may also be severe blisters and bleeding in the lips, eyes, mouth, nose and genitals. The skin rashes may develop into serious widespread skin damage (peeling of the epidermis and superficial mucous membranes) with life threatening consequences. This could be 'erythema multiforme', 'Stevens-Johnson syndrome', 'toxic epidermal necrolysis' or 'drug reaction with eosinophilia and systemic symptoms'. These effects are very rare, and might affect up to 1 in 10,000 people.

Other side effects include:

Common (may affect up to 1 in 10 people)

- Headache.
- Effects on your stomach or gut: diarrhoea, stomach pain, constipation, wind (flatulence).

- Feeling sick (nausea) or being sick (vomiting).
- Benign polyps in the stomach.

Uncommon (may affect up to 1 in 100 people)

- Swelling of the feet and ankles.
- Disturbed sleep (insomnia).
- Dizziness, tingling feelings such as "pins and needles", feeling sleepy.
- Spinning feeling (vertigo).
- Dry mouth.
- Changes in blood tests that check how the liver is working.
- Skin rash, lumpy rash (hives) and itchy skin.
- Fracture of the hip, wrist or spine (if Esocor is used in high doses and over long duration).

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

- Blood problems such as a reduced number of white cells or platelets. This can cause weakness, bruising or make infections more likely.
- Low levels of sodium in the blood. This may cause weakness, being sick (vomiting) and cramps.
- Feeling agitated, confused or depressed.
- Taste changes.
- Eyesight problems such as blurred vision.
- Suddenly feeling wheezy or short of breath (bronchospasm).
- An inflammation of the inside of the mouth.
- An infection called "thrush" which can affect the gut and is caused by a fungus.
- Liver problems, including jaundice which can cause yellow skin, dark urine, and tiredness.
- Hair loss (alopecia).
- Skin rash on exposure to sunshine.
- Joint pains (arthralgia) or muscle pains (myalgia).
- Generally feeling unwell and lacking energy.
- Increased sweating.

Very rare (may affect up to 1 in 10,000 people)

- Changes in blood count including agranulocytosis (lack of white blood cells)
- Aggression.
- Seeing, feeling or hearing things that are not there (hallucinations).
- Severe liver problems leading to liver failure and inflammation of the brain.
- Sudden onset of a severe rash or blistering or peeling skin. This may be associated with a high fever and joint pains (Erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms).
- Muscle weakness.
- Severe kidney problems.
- Enlarged breasts in men.

Not known (frequency cannot be estimated from the available data)

- If you are on Esocor for more than three months it is possible that the levels of magnesium in your blood may fall. Low levels of magnesium can be seen as fatigue, involuntary muscle contractions, disorientation, convulsions, dizziness or increased heart rate. If you get any of these symptoms, please tell your doctor promptly. Low levels of magnesium can also lead to a reduction in potassium or calcium levels in the blood. Your doctor may decide to perform regular blood tests to monitor your levels of magnesium.
- Inflammation in the gut (leading to diarrhoea).
- Rash, possibly with pain in the joints.

Esocor may in very rare cases affect the white blood cells leading to immune deficiency. If you have an infection with symptoms such as fever with a severely reduced general condition or fever with symptoms of a

local infection such as pain in the neck, throat or mouth or difficulties in urinating, you must consult your doctor as soon as possible so that a lack of white blood cells (agranulocytosis) can be ruled out by a blood test. It is important for you to give information about your medication at this time.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE ESOCOR

- Keep out of the reach and sight of children.
- Store below 30°C. Protect from light and moisture.
- Do not use this medicine after the expiry date which is stated on the carton after Exp. Date. The expiry date refers to the last day of that month.
- Store this medicine in the original package (blister) to protect from moisture.
- 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. FURTHER INFORMATION

What Esocor contains

- The active substance is Esomeprazole. Esocor tablets come in two strengths containing 20 mg or 40 mg of Esomeprazole (As Magnesium Trihydrate).
- The other ingredients are Crospovidone, Mannitol, Sodium Carbonate, Povidone, Purified water, Magnesium Stearate, Dichloromethane (Methylene Dichloride), Isopropyl Alcohol;
  Polacrilin Potassium (Kyron T-314) & Easy Coat ECM (Yellow Oxide of Iron) (in Esocor 20) / Purified Talc & Easy Coat ECM (Red Oxide of Iron) (in Esocor 40).

What Esocor looks like and contents of the pack

- Esocor 20 Tablets are yellow coloured, round shaped, biconvex, enteric coated tablets plain on both sides.
- Esocor 40 Tablets are brick red coloured, round shape, biconvex, enteric coated tablets plain on both sides.

Marketing Authorisation Holder and Manufacturer

Name of Marketing Authorization Holder: Corona Remedies Pvt. Ltd.

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