

ZELOMAC

Consumer Medication Information Leaflet (RiMUP)

Esomeprazole Magnesium Trihydrate 20 mg and 40 mg Gastro Resistant Tablet

What is in this leaflet

1. What Zelomac Tablets is used for
2. How Zelomac Tablets works
3. Before you use Zelomac Tablets
4. How to use Zelomac Tablets
5. While you are using it
6. Side effects
7. Storage and Disposal of Zelomac Tablets
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision
11. Serial number

What is Zelomac Tablets used for

Zelomac Tablets is used to treat and prevent relapse of the following conditions:

- Adults and young people 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.
- 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.

Adults

- Stomach ulcers caused by medicines called NSAIDs (Non-Steroidal Anti Inflammatory Drugs). Zelomac Tablets 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 rebleeding of ulcers with Esomeprazole injection.

How Zelomac Tablets works

Zelomac Tablets contains a medicine called esomeprazole. This belongs to a group of medicines called 'proton

pump inhibitors'. They work by reducing the amount of acid that your stomach produces.

Before you use Zelomac Tablets

-When you must not use it

- If you are allergic 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).

If you are not sure, talk to your doctor or pharmacist before taking Zelomac Tablets.

-Before you start to use it

Check with your doctor or pharmacist before taking Zelomac Tablets if you have:

- severe liver problems.
- severe kidney problems.

Zelomac Tablets may hide the symptoms of other diseases. Therefore, if any of the following happen to you before you start taking Zelomac tablets 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).

Treatment with proton pump inhibitors may lead to slightly increased risk of gastrointestinal infections.

If you have been prescribed Zelomac Tablets "on demand", you should contact your doctor if your symptoms continue or change in character.

Please inform your doctor if you have been diagnosed with osteoporosis (brittle bone disease).

Tell your doctor before taking this medicine, if you are due to have a specific blood test (Chromogranin A).

-Taking other medications

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

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 Zelomac Tablets.
- Medicines that are used to thin your blood, such as warfarin. Your doctor may need to monitor you when you start or stop taking Zelomac Tablets.
- 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

ZELOMAC

Consumer Medication Information Leaflet (RiMUP)

Esomeprazole Magnesium Trihydrate 20 mg and 40 mg Gastro Resistant Tablet

cancer) – if you are taking a high dose of methotrexate, your doctor may temporarily stop your Zelomac Tablets 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 Zelomac Tablets to treat ulcers caused by Helicobacter pylori infection, it is very important that you tell your doctor about any other medicines you are taking.

How to use Zelomac Tablets

-How much to use

The usual doses are given below.

Adults and children aged 12 or above:

To treat erosive reflux esophagus inflammation and prevent relapse:

The usual dose is one Zelomac 40 mg 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 (esophagus) has not yet healed.

To treat gastroesophageal reflux disease (GERD) symptoms:

The usual dose once the gullet has healed is one Zelomac tablets 20 mg tablet once a day. If your gullet is not inflamed, the usual dose is one Zelomac 20 mg tablet each day. Once the condition has been controlled, your doctor may tell you to take your medicine as and when you need it, of one Zelomac tablets 20 mg 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 from coming back:

Adults: the usual dose is one Zelomac 20 mg tablet twice a day for one week. Your doctor will also tell you to take

with antibiotics for example amoxicillin and clarithromycin.

To treat stomach ulcers caused by NSAIDs:

Adults: the usual dose is one Zelomac 20 mg tablet once a day for 4 to 8 weeks.

To prevent stomach ulcers if you are taking NSAIDs:

Adults: the usual dose is one Zelomac 20 mg tablet once a day.

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

Adults: the usual dose is Zelomac 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 rebleeding of ulcers with Esomeprazole injection:

The usual dose is one Zelomac tablets 40 mg tablet once a day for 4 weeks.

Zelomac tablets are not recommended for children less than 12 years old

-When to use it

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 glass 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.

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.

If you cannot swallow at all, the tablet can be mixed with some non-fizzy water and put into a syringe. It can then be given to you through a tube directly into your stomach ('gastric tube').

-How long to use it

Always take Zelomac tablets exactly as your doctor has told you. You should 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.

-If you forget to use 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 use too much (overdose)

If you take more Zelomac Tablets than prescribed by your doctor, talk to your doctor or pharmacist straight away. The symptoms connected with overdose are gastrointestinal symptoms and weakness.

While you are using it

-Things you must do

Take your medication daily as prescribed.

If your doctor prescribed antibiotics for you together with Zelomac Tablets, ensure that you complete the whole course of medication as advised.

-Things you must not do

Do not take other medications together with Zelomac Tablets

ZELOMAC

Consumer Medication Information Leaflet (RiMUP)

Esomeprazole Magnesium Trihydrate 20 mg and 40 mg Gastro Resistant Tablet

without speaking to your doctor or pharmacist first.

-Things to be careful of

Pregnancy and breast-feeding:

Before taking Zelomac Tablets, tell your doctor if you are pregnant or trying to get pregnant. Your doctor will decide whether you can take Zelomac Tablets during this time. It is not known if Zelomac Tablets passes into breast milk. Therefore, you should not take Zelomac Tablets you are breastfeeding.

Driving and using machines:

Zelomac tablet is not likely to affect you being able to drive or use any tools or machines.

Zelomac tablets contain sucrose, which is 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.

Zelomac tablets contain less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodiumfree'.

Side effects

Like all medicines, Zelomac tablets can cause side effects, although not everybody gets them.

When you are taking this medicine, your doctor will want to monitor you (especially if you are taking it for long term). Hence, you should report any new and exceptional symptoms and circumstances whenever you see your doctor. Please tell your doctor promptly if you get any of the symptoms below:

- Rash (especially in areas exposed to the sun), possibly with pain in the joints (Subacute Cutaneous Lupus Erythematosus, SCLE)
- Fever, extreme tiredness, pus/blood in urine
- Involuntary muscle contractions, disorientation, convulsions, dizziness, increased heart rate
- Fracture in the hip, wrist or spine
- Watery stool, stomach pain and fever that do not go away

- Anemic (pale skin, weakness, tiredness or lightheadedness), shortness of breath, a smooth tongue, nerve problems (numbness or tingling, muscle weakness and problems walking), vision loss and mental problems (depression, memory loss or behavioral changes)

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

- Sudden wheezing, swelling of your lips, tongue and throat or body, rash, fainting or difficulties in swallowing (severe allergic reaction). These effects are rare, affecting less than 1 in 1,000 people.

Other side effects include:

Common (affects less than 1 in 10 people)

- Headache.
- Effects on your stomach or gut: diarrhea, stomach pain, constipation, wind (flatulence).
- Feeling sick (nausea) or being sick (vomiting).
- Fundic gland polyps (benign polyps in the stomach).

Uncommon (affects less than 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. Tell your doctor if you have osteoporosis or if you are taking corticosteroids (which can increase the risk of osteoporosis).

Rare (affects less than 1 in 1,000 people)

- Blood problems such as a reduced number of white cells or platelets. This can cause bruising or make infections more likely

- Low levels of sodium in the blood. This may cause being sick (vomiting) and cramps.
- Feeling agitated, confused or depressed.
- Taste changes.
- Blurred vision.
- Suddenly feeling short of breath
- An inflammation of the inside of the mouth.
- An infection called "thrush" which can affect the gut and is caused by a fungus.
- Hair loss
- High skin reactivity to light
- Joint pains or muscle pains
- Generally feeling unwell and lacking energy.
- Increased sweating.
- Liver inflammation, including jaundice which can cause yellow skin, dark urine, and tiredness.

Very rare (affects less than 1 in 10,000 people)

- Aggression.
- Seeing, feeling or hearing things that are not there (hallucinations).
- Severe liver problems leading to liver failure and affecting the brain.
- Sudden onset of a severe rash or blistering or peeling skin. This may be associated with a high fever and joint pain (Erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, acute generalised exanthematous pustulosis, drug reaction with eosinophilia and systemic symptoms)
- Muscle weakness.
- Severe kidney problems (interstitial nephritis).
- Enlarged breasts in men.
- If you are on Zelomac tablets, it is possible that the levels of magnesium in your blood will fall. Low levels of magnesium can be seen as fatigue, involuntary muscle contractions, disorientation, convulsions or increased heart rate. Low magnesium can also lead to reduction of potassium or calcium levels in the body. If you get any of these symptoms, please tell your doctor promptly.

ZELOMAC

Consumer Medication Information Leaflet (RiMUP)

Esomeprazole Magnesium Trihydrate 20 mg and 40 mg Gastro Resistant Tablet

- Inflammation in the gut (leading to diarrhoea).

Unknown frequency (cannot be estimated from available data)

- Subacute cutaneous lupus erythematosus (SCLE).
- Hypomagnesaemia. Low levels of magnesium can also lead to a reduction in potassium or calcium levels in the blood.
- Inflammation in the large bowel, that causes persistent watery diarrhea.

Other possible side effects include Clostridium difficile diarrhea [Severe diarrhoea which may be caused by an infection (Clostridium difficile) in your intestines] and Vitamin B12 deficiency.

Zelomac tablets 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.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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

Storage and Disposal of Zelomac Tablets

-Storage

Keep out of the reach and sight of children.

Do not store above 30°C.

Keep this medicine in the original container (blister).

Do not take your tablets after the expiry date (EXP) shown on the carton or blister foil. The expiry date refers to the last day of that month.

-Disposal

Remember to return any unused medicine to your pharmacist (chemist).

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 it looks like

40 mg: Pink, oblong shaped, biconvex (approx.16.15 mm × 8.15 mm) film-coated tablets engraved '40' on one side and plain on other.

20 mg: Pink, oblong shaped, biconvex (approx.12.15 mm × 6.15 mm) film-coated tablets engraved '20' on one side and plain on other.

-Ingredients

- Active ingredient(s)
The active substance is Esomeprazole. Zelomac Tablets come in two strengths containing 20 mg or 40 mg of Esomeprazole (as magnesium trihydrate).
- Inactive ingredient(s)
Sugar spheres, Hydroxypropyl Methyl Cellulose, Polysorbate 80, Sodium Hydroxide Pellets, Hydroxypropyl Cellulose, Talc, Magnesium Stearate, Methacrylic Acid - Ethyl Acrylate Copolymer Dispersion 30%, Triethyl citrate, Glycerol Monostearate, Silica colloidal anhydrous, Silicified Microcrystalline Cellulose, Sieved Lactose Monohydrate,

Crospovidone, Povidone K 30, Croscarmellose Sodium, Microcrystalline Cellulose Pellets, Sodium Stearyl Fumarate and Opadry Pink.

-MAL number

Zelomac 20: MAL24036022AZ

Zelomac 40: MAL24036021AZ

Manufacturer

M/s. Lee Pharma Limited,

Plot No. V, Phase-II, VSEZ,

Duvvada, Sabbavaram (M),

Visakhapatnam District - 530049,

Andhra Pradesh, India.

Product Registration Holder

Healol Pharmaceuticals Sdn. Bhd.

74-3 Jalan Wangsa Delima 6, KLSC Wangsa Maju, 53300 Kuala Lumpur, Malaysia

Date of revision

04/09/2024

Serial Number

NPRA (R2) 23/027