

EMANERA

Esomeprazole gastro-resistant capsules, hard (20 mg and 40 mg)

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What *Emanera* is used for

Emanera is used to treat the following conditions:

- "Gastro-oesophageal reflux disease" (GORD). 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 (acid indigestion with a burning sensation in the chest).
- 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). *Emanera* can also be used to stop stomach ulcers from forming if you are taking NSAIDs.
- Prolonged treatment after prevention of rebleeding of ulcers with intravenous esomeprazole.
- Too much acid in the stomach caused by a growth in the pancreas (Zollinger-Ellison syndrome).

How *Emanera* works

Emanera 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 *Emanera*

- When you must not use it

- If you are allergic (hypersensitive) to esomeprazole or any of the other ingredients of *Emanera*.
- If you are allergic to other proton pump inhibitor medicines.
- If you are taking atazanavir (a medicine used to treat HIV).

Do not take *Emanera* if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking *Emanera*.

- Before you start use it

Check with your doctor or pharmacist before taking *Emanera* if:

- You have severe liver problems.
- You have severe kidney problems.
- Tell your doctor before taking this medicine, if you are due to have a specific blood test (Chromogranin A).

Emanera may hide the symptoms of other diseases. **Therefore, if any of the following happen to you before you start taking *Emanera* or while you are taking them, 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 (dyspepsia or upset stomach).
- You begin to vomit food or blood.
- You pass black stools (blood-stained faeces).

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

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy from a pharmacy, supermarket or health food shop without a prescription.

Emanera can affect the way some medicines work and some medicines can have an effect on *Emanera*.

Do not take *Emanera* if you are taking the following medicine:

- Atazanavir (used to treat HIV).

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

- Ketoconazole, itraconazole or voriconazole (used to treat infections caused by a fungus).
- 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 *Emanera*.

- Medicines that are used to thin your blood, such as warfarin. Your doctor may need to monitor you when you start or stop taking *Emanera*.
- Cisapride (used for indigestion and heartburn).

If your doctor has prescribed the antibiotics amoxicillin and clarithromycin as well as *Emanera* 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 *Emanera*

- How much to use

Your doctor will tell you how many capsules 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 usual doses are given below:

To treat heartburn caused by gastro-oesophageal reflux disease (GERD):

Adults and children aged 12 or above:

- If your doctor has found that your food pipe (gullet) has been slightly damaged, the usual dose is one *Emanera* 40 mg gastro-resistant capsules 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 usual dose once the gullet has healed is one *Emanera* 20 mg gastro-resistant capsule once a day.
- If your gullet has not been damaged, the usual dose is one *Emanera* 20 mg gastro-resistant capsule 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 *Emanera* 20 mg gastro-resistant capsule 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:

- Adults aged 18 or above: the usual dose is one *Emanera* 20 mg gastro-resistant capsule twice a day for one week.
- Your doctor will also tell you to

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take antibiotics called amoxicillin and clarithromycin.

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

- Adults aged 18 and above: the usual dose is one *Emanera* 20 mg gastro-resistant capsule once a day for 4 to 8 weeks.

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

- Adults aged 18 and above: the usual dose is one *Emanera* 20 mg gastro-resistant capsule once a day.

Prolonged treatment after prevention of rebleeding of ulcers with intravenous esomeprazole:

- Adults aged 18 and above: the usual dose is one *Emanera* 40 mg capsules once a day for 4 weeks.

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

- Adults aged 18 and above: the usual dose is one *Emanera* 40 mg gastro-resistant capsule 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.

- When to use it

You can take your capsules at any time of the day.

- How long to use it

Continue taking *Emanera* for as long as your doctor recommends.

If you are taking this medicine for a long time, your doctor might 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

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do

not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

- Things you must do

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

Before taking *Emanera*, tell your doctor if you are pregnant or trying to get pregnant. Ask your doctor or pharmacist for advice before taking any medicine. Your doctor will decide whether you can take *Emanera* during this time.

- Things you must not do

Swallow your capsules whole with a drink of water. Do not chew or crush the capsules. This is because the capsules 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.

It is not known if *Emanera* passes into breast milk. Therefore, you should not take *Emanera* if you are breastfeeding.

Do not take *Emanera* if you are taking atazanavir (used to treat HIV).

- Things to be careful of

If you have trouble swallowing the capsules:

- Open the capsule and empty the pellets into half a glass of still (non-fizzy) water. Do not use any other liquids.
- 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 pellets can be mixed with some water and put into a syringe. They can then be given

to you through a tube directly into your stomach ('gastric tube').

Side effects

Like all medicines, *Emanera* can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

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

- Sudden wheezing (a continuous, coarse, whistling sound produced in the lungs during breathing), swelling of your lips, tongue and throat or body, rash, fainting or difficulties to swallow (severe allergic reaction).
- 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".
- Yellow skin, dark urine and tiredness which can be symptoms of liver problems.

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, nerver problems (numbness or tingling, muscle weakness and

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problems walking), vision loss and mental problems (depression, memory loss or behavioral changes)

Other side effects include:

Common

- 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

- 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

- 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 (upset), 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" (candidiasis) 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

- 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).
- Muscle weakness.
- Severe kidney problems (interstitial nephritis)
- Enlarged breasts in men.

Not known

- Subacute Cutaneous Lupus Erythematosus (SCLE)
- Hypomagnesaemia. Low levels of magnesium can also lead to a reduction in potassium or calcium levels in the blood.
- Severe diarrhoea which may be caused by an infection (*Clostridium difficile*) in your intestines.
- Proton pump inhibitors may cause vitamin B12 deficiency.
- Inflammation in the large bowel, that causes persistent watery diarrhea.

Emanera 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.

If any of the side effects gets serious, or if you notice any side effects not listed

in this leaflet, please tell your doctor or pharmacist.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking this medicine, even if you think the problems are not connected with the medicine.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

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

Storage and Disposal of *Emanera*

- Storage

Keep out of the reach and sight of children.

Do not store above 30°C.

Store in original package in order to protect from moisture.

Do not use your medicine after the expiry date which is stated on the pack after 'EXP'. The expiry date refers to the last day of that month.

- 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 it looks like

20 mg capsules: the body and the cap are slightly pink (body and cap); the capsules contain white to almost white pellets.

40 mg capsules: the body and the cap are off-pink (body and cap); the capsules contain white to almost white pellets.

Supply

Blister packs: 14 and 28 gastro-resistant capsules, hard, in a box.

Not all pack sizes may be marketed.

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- *Ingredients*

Active ingredient

Each gastro-resistant capsule, hard, contains 20 mg esomeprazole (as esomeprazole magnesium dihydrate).

Each gastro-resistant capsule, hard, contains 40 mg esomeprazole (as esomeprazole magnesium dihydrate).

Inactive ingredients

sugar spheres (sucrose and maize starch), povidone K30, sodium laurilsulfate, poly(vinyl alcohol), titanium dioxide (E171), macrogol, talc (E553b), heavy magnesium carbonate, polysorbate 80 (E433) and methacrylic acid – ethyl acrylate copolymer (1:1) dispersion 30 per cent in pellets in the capsule, and gelatine (E441), titanium dioxide (E171) and red iron oxide (E172) in the capsule shell.

- *MAL numbers:*

Emanera 20 mg : MAL19071009AZ

Emanera 40 mg : MAL19071010AZ

Manufacturer

KRKA, d.d., Novo mesto
Šmarješka cesta 6,
8501 Novo mesto, Slovenia

Product Registration Holder

PAHANG PHARMACY SDN. BHD.,
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