

# Esomeprazole 20mg and 40mg Gastro-resistant Capsules

**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. see section 4.
- The full name of this medicine is Esomeprazole 20mg and 40mg Gastro-resistant Capsules but within the leaflet it will be referred to as Esomeprazole capsules.

## What is in this leaflet:

- 1 What Esomeprazole capsules are and what they are used for**
- 2 What you need to know before you take Esomeprazole capsules**
- 3 How to take Esomeprazole capsules**
- 4 Possible side effects**
- 5 How to store Esomeprazole capsules**
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### 1 What Esomeprazole capsules are and what they are used for

Esomeprazole capsules contain 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.

Esomeprazole capsules are used to treat the following conditions:

#### Adults and adolescents aged 12 years and above

- **'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
- **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). Esomeprazole capsules 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 intravenous esomeprazole

### 2 What you need to know before you take Esomeprazole capsules

#### Do not take Esomeprazole capsules if you

- are **allergic** to esomeprazole or any of the other ingredients of this medicine (listed in Section 6)
- are **allergic to other proton pump inhibitor medicines** (e.g. pantoprazole, lansoprazole, rabeprazole, omeprazole)
- are taking a medicine containing **nelfinavir** (used to treat HIV infection).

Do not take Esomeprazole capsules if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Esomeprazole capsules.

#### Warnings and precautions

Talk to your doctor or pharmacist before taking Esomeprazole capsules if you:

- have **severe liver** problems
- have **severe kidney** problems

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

Talk to your doctor if you experience severe or persistent diarrhoea; esomeprazole has been associated with a small increased risk of infectious diarrhoea.

Taking a proton pump inhibitor like Esomeprazole Capsules, 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).

#### Children under the age of 12 years

Esomeprazole Capsules should not be used in children younger than 12 years. More appropriate pharmaceutical forms of this medicine may be available.

#### Other medicines and Esomeprazole capsules

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because Esomeprazole capsules can affect the way some medicines work and some medicines can have an effect on Esomeprazole capsules.

**Do not take** Esomeprazole capsules 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 or saquinavir** (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 Esomeprazole capsules.
- medicines that are used to thin your blood, such as **warfarin**. Your doctor may need to monitor you when you start or stop taking Esomeprazole capsules.
- **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 Esomeprazole capsules 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 capsules to treat ulcers caused by *Helicobacter pylori* infection, it is very important that you tell your doctor about any other medicines you are taking.

#### Pregnancy, breast-feeding and fertility

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 Esomeprazole capsules during this time.

It is not known if Esomeprazole capsules passes into breast milk. Therefore, you should not take Esomeprazole capsules if you are breast-feeding.

#### Driving and using machines

Esomeprazole capsules is not likely to affect your ability 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.

#### Esomeprazole capsules contain sucrose and parahydroxybenzoates (E216 and E218)

Esomeprazole capsules contain sugar spheres which contain sucrose, a type of sugar, propyl-p-hydroxybenzoate (E216) and methyl-p-hydroxybenzoate (E218):

- If you have been told by your doctor that you have an intolerance to some sugars, talk to your doctor before taking this medicine.
- Parahydroxybenzoates may cause allergic reactions (possibly delayed).

### 3 How to take Esomeprazole capsules

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 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 recommended doses are given below.

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

Adults and adolescents aged 12 years or above:

- If your doctor has found that your food pipe (gullet) has been slightly damaged, the recommended dose is one capsule of Esomeprazole 40mg 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 capsule of Esomeprazole 20mg once a day
- If your gullet has not been damaged, the recommended dose is one capsule Esomeprazole 20mg 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 capsule of Esomeprazole 20mg 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 and young people aged 12 or above:

- The recommended dose is one capsule of Esomeprazole 20mg 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):

Adults aged 18 and above:

- The recommended dose is one capsule of Esomeprazole 20mg once a day for 4 to 8 weeks

The following information is intended for healthcare professionals only:

#### Administration through gastric tube

1. Add the contents of a capsule into approximately 25 ml or 50 ml of water. (For some tubes, dispersion in 50 ml water is needed to prevent the granules from clogging the tube). Stir.
2. Draw the suspension into a syringe and add approximately 5 ml of air.
3. Immediately shake the syringe for approximately 2 minutes to disperse the granules.
4. Hold the syringe with the tip up and check that the tip has not clogged.
5. Attach the syringe to the tube whilst maintaining the above position.

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

Adults aged 18 and above:

- The recommended dose is one capsule of Esomeprazole 20mg once a day.

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

Adults aged 18 and above:

- The recommended dose is one capsule of Esomeprazole 40mg 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 80mg twice a day.

### To be used as prolonged treatment after prevention of rebleeding of ulcers with intravenous Esomeprazole:

Adults aged 18 years and above:

-The recommended dose is one capsule of Esomeprazole 40mg once a day for 4 weeks.

### Taking this medicine

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

### What to do if you have trouble swallowing the capsules

- If you have trouble swallowing the capsules:
- Open the capsule carefully above half a glass of still (non-fizzy) water and empty the content of the capsule (granules) into the glass. Do not use any other liquids.
- Stir. 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 content of the capsule 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').

### Children under the age of 12 years

Esomeprazole capsules should not be used in children younger than 12 years. More appropriate pharmaceutical forms of this medicine may be available.

### Older people

Dose adjustment is not required in the elderly.

### If you take more Esomeprazole capsules than you should

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

### If you forget to take Esomeprazole capsules

- 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 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 Esomeprazole capsules 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, seen rarely)
- 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 'erythema multiforme', 'Stevens-Johnson syndrome' or 'toxic epidermal necrolysis', seen very rarely
- yellow skin, dark urine and tiredness which can be symptoms of liver problems, seen rarely.

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)

#### 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 Esomeprazole capsules 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
- 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) (see \*below)
- aggression
- seeing, feeling or hearing things that are not there (hallucinations)
- severe liver problems leading to liver failure and inflammation of the brain
- muscle weakness
- severe kidney problems
- enlarged breasts in men

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

- inflammation in the gut (leading to diarrhoea)
- If you are on Esomeprazole capsules 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, 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.

\*Esomeprazole capsules 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. You can also report side effects directly via the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)

By reporting side effects you can help provide more information on the safety of this medicine.

## 5 How to store Esomeprazole capsules

- Keep this medicine out of the sight and reach of children.
- Do not store above 25°C.
- Keep this medicine in the original container (blister) or keep the container tightly closed (bottle) in order to protect from moisture.
- Do not use this medicine after the expiry date which is stated on the carton, bottle or blister foil after 'EXP'. The expiry date refers to the last day of that month.
- After opening the bottle, the capsules should be used within 3 months.
- 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 Contents of the pack and other information

### What Esomeprazole capsules contain

- The active substance is esomeprazole. Esomeprazole capsules come in two strengths containing 20mg or 40mg of esomeprazole (as magnesium dihydrate).

- The other ingredients are:

Capsule content: sugar spheres (sucrose and maize starch), hypromellose, dimethicone emulsion 35% (containing dimethicone, propyl-p-hydroxybenzoate (E216), methyl-p-hydroxybenzoate (E218), sorbic acid, sodium benzoate, polyethylene glycol sorbitan monolaureate, octylphenoxy polyethoxy ethanol and propylene glycol), polysorbate 80, mannitol, diacetylated monoglycerides, talc, methacrylic acid-ethyl acrylate copolymer (1:1) dispersion 30 % (containing copolymer of methacrylic acid and ethyl acrylate, sodium lauryl sulfate and polysorbate 80, triethyl citrate and stearyl macroglycerides.

Capsule shell: black iron oxide (E 172), shellac, gelatin, yellow iron oxide (E 172) and titanium dioxide (E 171).

### What Esomeprazole capsules look like and contents of the pack

- Esomeprazole 20mg capsules have an opaque yellow cap and an opaque white body. "20mg" is printed in black both on the cap and on the body.
- Esomeprazole 40mg capsules have an opaque yellow cap and an opaque yellow body. "40mg" is printed in black both on the cap and on the body.

- Your capsules will come in packs of 28 capsules

### Marketing Authorisation Holder

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6. Shake the syringe and position it with the tip pointing down. Immediately inject 5-10 ml into the tube. Invert the syringe after injection and shake (the syringe must be held with the tip pointing up to avoid clogging of the tip).
7. Turn the syringe with the tip down and immediately inject another 5-10 ml into the tube. Repeat this procedure until the syringe is empty.
8. Fill the syringe with 25 ml of water and 5 ml of air and repeat step 6 if necessary to wash down any sediment left in the syringe. For some tubes, 50 ml is needed.



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