

# Esvin® Capsules

(Esomeprazole) USP

اليسون كپسولز

#### Composition:

Esvin® Capsules 20 mg: Each capsule contains:  
Esomeprazole Magnesium Trihydrate, MDM equivalent to Esomeprazole ..... 20 mg

Esvin® Capsules 40 mg: Each capsule contains:  
Esomeprazole Magnesium Trihydrate, MDM equivalent to Esomeprazole ..... 40 mg

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 further questions, ask your doctor or your pharmacist.
- This medicine has been prescribed for you only. Do not pass it onto 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?

- What is Esvin® Capsule?
- What are the indications for Esvin® Capsule?
- What should be the dose of Esvin® Capsule?
- What are the contraindications of Esvin® Capsule?
- What are the adverse effects of Esvin® Capsule?

#### What is Esvin® Capsule?

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

#### What are the indications for Esvin® Capsule?

Esvin® 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.
- 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). Esvin® 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.

#### What should be the dose of Esvin® Capsule?

Always take Esvin® exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- Esvin® capsules are not recommended for children less than 12 years old.
- 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.

#### 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 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.

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

- 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').

#### 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 usual doses are given below.

#### To treat heartburn caused by gastroesophageal reflux disease (GORD):

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 Esvin® 40 mg capsule 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 Esvin® 20 mg capsule once a day.
- If your gullet has not been damaged, the usual dose is one Esvin® 20 mg 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 Esvin® 20 mg 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 Esvin® 20 mg capsule twice a day for one week.
- Your doctor will also tell you to 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 Esvin® 20 mg 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 Esvin® 20 mg capsule 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 usual dose is one Esvin® 40 mg 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.

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

Adults aged 18 and above:

- The usual dose is one Esvin® 40 mg capsule once a day for 4 weeks.

#### If you take more Esvin® than you should

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

#### If you forget to take Esvin®

- 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 product, ask your doctor or pharmacist.

#### What are the contraindications of Esvin® Capsule?

Do not take Esvin® if:

- You are allergic (hypersensitive) to esomeprazole or any of the other ingredients of this medicine.
  - You are allergic to other proton pump inhibitor medicines.
  - You are taking a medicine containing nelfinavir (used to treat HIV).
- Do not take Esvin® if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Esvin®.

#### Take special care with Esvin®

Check with your doctor or pharmacist before taking Esvin® if:

- You have severe liver problems.
- You have severe kidney problems.

Esvin® may hide the symptoms of other diseases.

Therefore, if any of the following happen to you before you start taking Esvin® 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 Esvin® "on demand" you should contact your doctor if your symptoms continue or change in character.

If diarrhoea occurs during the treatment with Esvin® contact your doctor immediately, as treatment with proton pump inhibitors may lead to a slightly increased risk of gastrointestinal infections such as Salmonella and Campylobacter.

#### Taking other medicines

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

Do not take Esvin® Capsules if you are taking a medicine containing nelfinavir (used to treat HIV).

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

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

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

#### Pregnancy and breast-feeding

Before taking Esvin®, 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 Esvin® during this time.

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

#### Taking Esvin® with food and drink

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

#### Driving and using machines

Esvin® is not likely to affect you being able to drive or use any tools or machines.

#### What are the adverse effects of Esvin® Capsule?

Like all medicines, Esvin® can cause side effects, although not everybody gets them. Side effects are classified into the following groups in order of frequency.

If you notice any of the following serious side effects, stop taking Esvin® 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).
- 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.

These effects are rare, affecting less than 1 in 1,000 people.

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).

#### 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 of the hip, wrist or spine.

#### 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, 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

- 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.
- Enlarged breasts in men.

#### Effects

Esvin® 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.

Do not be concerned by this list of possible side effects. You may not get any of them. 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.

#### PRESENTATION

Esvin Capsules 20 mg: Pack of 14's  
Esvin Capsules 40 mg: Pack of 14's

#### STORAGE

Store below 30 °C

Protect from light, heat and moisture.

Keep all medicines out of the reach of the children.

موجودگی سبھی گریڈ سے کم درجہ حرارت پر رکھیں۔  
روشنی، گرمی اور نمی سے محفوظ رکھیں۔  
تمام دواؤں بچوں کی پہنچ سے دور رکھیں۔

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Martin Dow Marker Ltd

7, Jail Road, Quetta, Pakistan.

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