

Eso TAD[®] 20 mg gastro-resistant capsules, hard

Eso TAD[®] 40 mg gastro-resistant capsules, hard

Esomeprazole

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- 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.

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1. What Eso TAD is and what it is used for
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1. WHAT ESO TAD IS AND WHAT IT IS USED FOR

Eso TAD contains an active substance called esomeprazole magnesium dihydrate. The medicine belongs to the group of so called "proton pump inhibitors". They work by reducing the amount of acid that your stomach produces.

Eso TAD is used to treat the following conditions:

- Gastro-esophageal 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). Eso TAD 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. BEFORE YOU TAKE ESO TAD

Taking Eso TAD with food and drink

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

Pregnancy and breast-feeding

Before taking Eso TAD, 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 Eso TAD during this time. It is not known if Eso TAD passes into breast milk. Therefore, you should not take Eso TAD if you are breast-feeding.

Driving and using machines

Eso TAD is not likely to affect you being able to drive or use any tools or machines.

Important information about some of the ingredients of Eso TAD

Eso TAD gastro-resistant capsules 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.

3. HOW TO TAKE ESO TAD

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

- Eso TAD gastro-resistant 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 medical conditions change.



Do not take Eso TAD if:

- You are allergic (hypersensitive) to the active substance esomeprazole or any of the other ingredients of this medicinal product (listed in section 6: Further information).
- You are allergic to other proton pump inhibitors.
- You are taking a medicinal product containing nelfinavir (used to treat HIV infection).

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

Take special care with Eso TAD

Check with your doctor or pharmacist before taking Eso TAD if:

- You have a severe hepatic dysfunction.
- You have a severe renal dysfunction.

Eso TAD may hide the symptoms of other diseases. **Therefore, if any of the following happen to you before you start taking Eso TAD or while you are taking it, talk to your doctor immediately:**

- You lose a lot of weight for no reason and have difficulties in 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 Eso TAD "on demand" you should contact your doctor if your symptoms continue or change in character.

If diarrhoea occurs during the treatment with Eso TAD 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, including medicines obtained without a prescription. This is because Eso TAD can affect the way some medicines work and some medicines can have an effect on Eso TAD.

Do not take Eso TAD 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 infection).
- 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 Eso TAD.
- Medicines that are used to thin your blood, such as warfarin. Your doctor may need to monitor you when you start or stop taking Eso TAD.
- Cisapride (used for indigestion and heartburn).

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

Taking this medicine

- You can take the capsules at any time of the day.
- You can take the 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 immediately 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. The medicine 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 the type of your disease, how old you are and how well your liver works.
- The usual doses are given below.

To treat heartburn caused by gastro-esophageal 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 Eso TAD 40 mg gastro-resistant 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 Eso TAD 20 mg gastro-resistant capsule once a day.
- If your gullet has not been damaged, the usual dose is one Eso TAD 20 mg gastro-resistant capsule each day. Once the disease has been controlled, your doctor may tell you to take your medicine as and when you need it, up to a maximum of one Eso TAD 20 mg gastro-resistant capsule each day.
- If you have severe hepatic dysfunctions, your doctor may give you a lower dose.

To treat ulcers caused by *Helicobacter pylori* infection and to prevent relapse:

- Adults aged 18 or above: the usual dose is one Eso TAD 20 mg gastro-resistant 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 Eso TAD 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 Eso TAD 20 mg gastro-resistant 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 Eso TAD 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.

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

Adults aged 18 and above: the usual dose is one Eso TAD 40 mg capsule once a day for 4 weeks.

If you take more Eso TAD than you should

If you take more Eso TAD than prescribed by your doctor, talk immediately to your doctor or pharmacist.

If you forget to take Eso TAD

- 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.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Eso TAD can cause side effects, although not everybody gets them.

Side effects are classified into the following groups in order of frequency:

Very common:	Affects more than 1 user in 10
Common:	Affects 1 to 10 users in 100
Uncommon:	Affects 1 to 10 users in 1,000
Rare:	Affects 1 to 10 users in 10,000
Very rare:	Affects less than 1 user in 10,000
Not known:	Frequency cannot be estimated from available data

If you notice any of the following serious side effects, stop taking Eso TAD 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 hepatic dysfunctions.

These effects are rare, affecting less than 1 in 1,000 patients treated with Eso TAD.

Other side effects include:

Common

- Headache.

5. HOW TO STORE ESO TAD

Keep out of the reach and sight of children.

Do not use Eso TAD after the expiry date which is stated on the packaging. The expiry date refers to the last day of that month.

This medicinal product does not require any special temperature storage conditions.

Store in the original package in order to protect from moisture.

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.

6. FURTHER INFORMATION

What Eso TAD contains

The active substance is esomeprazole. Each gastro-resistant capsule, hard, contains 20 mg or 40 mg esomeprazole (as esomeprazole hemimagnesium 1 H₂O).

The other ingredients are sugar spheres (sucrose and maize starch), povidone K30, sodium lauryl sulphate, polyvinyl 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.

What Eso TAD looks like and contents of the pack

The body and cap of the 20 mg gastro-resistant capsules, hard, are slightly pink. The capsules contain white to almost white pellets.

The body and cap of the 40 mg gastro-resistant capsules, hard, are dark pink. The capsules contain white to almost white pellets.

The capsules are available in boxes of 14 capsules in blister packs.

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- 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 to check the function of the liver.
- Skin rash, lumpy rash (hives) and itchy skin.

Rare

- Blood problems such as a reduced overall 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 muscle 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 gastro-intestinal tract and is caused by a fungus.
- Hepatic dysfunctions, 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 hepatic dysfunctions 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 renal dysfunctions.
- Enlarged breasts in men.

Eso TAD 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 as soon as possible by a blood test. It is important to inform your doctor 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.