

ESORAL® 20 mg, Gastro-resistant capsule
ESORAL® 40 mg, Gastro-resistant capsule
Esomeprazole

Use in adolescents (12 years of age and older)

Treatment of symptoms of gastroesophageal reflux (burns and acid reflux)
 • If your doctor diagnoses inflammation of the esophagus, the recommended dose is 40 mg ESORAL once daily for 4 weeks. Additional 4 weeks of treatment may be required to achieve complete recovery.
 • The recommended dose after scarring of the esophagus is one ESORAL 20 mg capsule once a day.
 • If your esophagus does not have inflammation, the recommended dose is one 20 mg capsule of ESORAL once daily.

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 symptoms are the same as yours.
 - A stomach ulcer is not the same as a stomach ache.
- 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.

What is in this leaflet?

1. What is ESORAL, Gastro-resistant capsule, and in which case is it used?
2. What you need to know before you take ESORAL, Gastro-resistant capsule?
3. How to take ESORAL, Gastro-resistant capsule?
4. Possible side effects?
5. How to store ESORAL, Gastro-resistant capsule?
6. Content of the packaging and other information.

1. WHAT IS ESORAL, Gastro-resistant capsule, AND IN WHICH CASE IS IT USED ?
 Pharmacotherapeutic class - A1C code - code A02BA05
 ESORAL contains a substance called esomeprazole. This medicine belongs to the class of medications called proton pump inhibitors. It decreases the amount of acid produced by the stomach.

ESORAL 20 mg, Gastro-resistant capsule is used in the treatment of the following diseases :
Adults
 • Gastroesophageal reflux disease (GERD) when stomach acid rises to the level of the esophagus (the tube that connects the throat to the stomach) and causes pain, inflammation and burns.
 • The stomach or duodenum (small intestine) ulcer in case of infection by a bacteria called Helicobacter pylori. If you are in this situation your doctor may also prescribe antibiotics to treat the infection and allow the ulcer to heal.

• Treatment of ulcers associated with taking nonsteroidal anti-inflammatory drugs (NSAIDs).
 ESORAL can also be used to stop the formation of ulcers if you take non-steroidal anti-inflammatory drugs.
 • An excess of acid in the stomach due to Zollinger-Ellison syndrome.

Adolescents aged 12 and over
 • Gastroesophageal reflux disease (GERD) when stomach acid rises to the level of the esophagus (the tube that connects your throat to your stomach) and causes pain, inflammation, and burns.
 • The stomach or duodenum (small intestine) ulcer in case of infection by bacteria called Helicobacter pylori. If you are in this situation your doctor may also prescribe antibiotics to treat the infection and allow the ulcer to heal.
ESORAL 40 mg, Gastro-resistant capsule, is used in the treatment of the following disease

Adults
 • Treating erosive reflux esophagitis when stomach acid rises to the level of the esophagus (the tube that connects your throat to your stomach) and causes pain, inflammation, and burns.
 • Excess acid in the stomach due to Zollinger-Ellison syndrome.
 • Continuation of treatment after prevention with ESORAL intravenously of the hemorrhagic recurrence of a peptic ulcer.

Adolescents aged 12 and over
 • Gastroesophageal reflux disease (GERD) when stomach acid rises to the level of the esophagus (the tube that connects your throat to your stomach) and causes pain, inflammation, and burns.
2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ESORAL, gastro-resistant capsule ?
Never take ESORAL, gastro-resistant capsule :

- If you are allergic (hypersensitive) to esomeprazole or to any other components contained in this medicine listed in section 6.
- If you are allergic to another proton pump inhibitor (ex : pantoprazole, lansoprazole, rabeprazole, omeprazole).
- If you take medicines containing nefeline/used in the treatment of HIV infection.
- If you are in any of the situations described above, do not take ESORAL. If you are not sure, talk to your doctor or pharmacist before any administration of ESORAL.

Warnings and precautions
 • Tell your doctor or pharmacist before you take ESORAL, gastro-resistant capsule.
 • If you have severe liver problems.
 • If you have severe kidney problems.
 • If you have never had a skin reaction after treatment with a medication similar to ESORAL that reduces stomach acid.

• If you need to have a specific blood test (Chromogranin A).
ESORAL can hide symptoms of other illnesses. If you take ESORAL you should tell your doctor immediately if :

- You lose weight for no reason or if you have problems swallowing.
 - You have stomach pain or indigestion.
 - You vomit food or blood.
 - You have blood stained black stools.
- If prescribed "on demand" treatment as needed, you should contact your doctor if the symptoms persist or change. Taking a proton pump inhibitor like ESORAL, especially over a period of more than a year, may slightly increase the risk of hip, wrist, or vertebral fractures. Tell your doctor if you have osteoporosis or if you are taking corticosteroids (which may increase the risk of osteoporosis).

If you develop a rash, especially in areas exposed to the sun, consult your doctor as soon as possible, as you may need to stop taking ESORAL. Do not forget to mention any other side effect, such as pain in your joints.
Other medicines and ESORAL, gastro-resistant capsule.
 Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. ESORAL can interact with the functioning of other medicines and vice versa.

You should not take ESORAL if you are taking the following medicines :
 • nefeline/ur (used to treat HIV infection).
 • Tell your doctor or pharmacist if you are taking any of the following medicines :
 • atazanavir (used to treat HIV infection) ;
 • ciprofloxacin (used to prevent blood clots) ;
 • ketoconazole, itraconazole or voriconazole (used in the treatment of fungal infections) ;
 • erlotinib (used in the treatment of cancer) ;
 • citalopram, escitalopram or clomipramine (used in the treatment of depression) ;
 • diazepam, lorazepam, oxcarbazepine, epilepsy or as a muscle relaxant) ;
 • phenytoin (used in epilepsy) ; if you are taking phenytoin, monitoring by your doctor will be necessary at the start and end of administration of ESORAL, gastro-resistant capsule ;
 • anti-coagulant medicines to thin the blood such as warfarin, monitoring by your doctor may be necessary at the start and stop of administration of ESORAL, gastro-resistant capsule ;
 • painkillers used to treat intermittent claudication - pain in the legs when walking that is caused by insufficient blood supply) ;
 • cisapride (used in case of indigestion or heartburn) ;
 • digoxin (used for heart problems) ;
 • methotrexate (medicine used in high dose chemotherapy to treat cancer) ; if you are taking a high dose of methotrexate, your doctor may temporarily stop your treatment with ESORAL ;
 • tacrolimus (organ transplant) ;
 • rifampicine (used to treat tuberculosis) ;
 • millepertuis (Hypericum perforatum) (used to treat depression).

ESORAL, gastro-resistant capsule, with food and drinks
 Capsules may be taken with or without food.
Pregnancy, breastfeeding and fertility
 • If you are pregnant or breastfeeding, if you think you are pregnant or planning pregnancy, ask your doctor or pharmacist before taking this medicine.
 • Your doctor will tell you if you can take ESORAL during this period.
 It is not known if ESORAL passes into breast milk; therefore, you should not use ESORAL while breastfeeding.

Driving and using machines
 ESORAL does not enter the blood or affect the ability to drive and use machines. However, side effects such as dizziness and blurred vision may occur infrequently or rarely (see section 4). If you are affected by any of these effects, you should not drive or use machines.
ESORAL, gastro-resistant capsule, contains saccharides
 ESORAL, gastro-resistant capsule contains spheres of sucrose-based sugars (a type of sugar). Its use is not recommended in patients with intolerance to sucrose (rare hereditary disease). If your doctor has told you that you have an intolerance, contact your doctor before taking this medicine.

3. HOW TO TAKE ESORAL, gastro-resistant capsule ?
Always take this medicine exactly as your doctor or pharmacist has told you. Ask your doctor or pharmacist for advice if necessary.
 • If you have been taking this medicine for a long time (especially for more than a year), your doctor will have to monitor you.
 • If your doctor has told you to take this medication "on demand" as needed, you should tell them if your symptoms change.

Dosage
 Your doctor will tell you the number of capsules to take and the duration of treatment. This will depend on your health, your age and how your liver is working.
 The recommended doses are mentioned below :

Use in adults 18 years of age and older:
Treatment of symptoms of gastroesophageal reflux (burns and acid reflux)
 • If your doctor diagnoses inflammation of the esophagus, the recommended dose is 40 mg ESORAL once daily for 4 weeks. Additional 4 weeks of treatment may be required to achieve complete recovery.
 • The recommended dose after scarring of the esophagus is one ESORAL 20 mg capsule once a day.
 • If your esophagus does not have inflammation, the recommended dose is one 20 mg capsule of ESORAL once a day.
 Once symptom control is obtained, your doctor may recommend that you take one ESORAL 20 mg capsule once a day, depending on your needs.

• If you have severe liver problems, your doctor may give you a lower dose.
In case of infection with the bacteria called Helicobacter pylori, treatment of duodenal ulcer and prevention of recurrence of stomach ulcer or duodenum.
 The recommended dose is one 20 mg capsule of ESORAL twice a day for one or two weeks.
 • If you have an intolerance to sucrose, for example amoxicillin and clarithromycin.

Treatment of stomach ulcers associated with taking nonsteroidal anti-inflammatory drugs
 • The recommended dose is one 20 mg ESORAL capsule once a day for 4 to 8 weeks.
Prevention of ulcers associated with taking nonsteroidal anti-inflammatory drugs
 • The recommended dose is one 20 mg ESORAL capsule once daily.

Treatment of excess stomach acid due to Zollinger-Ellison syndrome.
 • The recommended dose is ESORAL 40 mg twice daily.
 • Your doctor will tell you the dose and duration of treatment according to your needs. The maximum dose is 80 mg twice a day.

Continuation of treatment after prevention with an intravenous proton pump inhibitor of recurrent hemorrhagic ulcer of peptic ulcer.
 The recommended dose is one 40 mg capsule once daily for 4 weeks.

Administration mode
 • You can take your capsules at any time of the day.
 • You can take your capsules with or without meals.



Swallow your capsules with a glass of water. The capsules must not be chewed or crunched. Indeed, the capsules are made up of film-coated granules protecting the medicine from the acidity of the stomach which must not be damaged.

Use in children under 12 years of age

ESORAL, gastro-resistant capsule, is not recommended for children under the age of 12.

Elderly
 Dose adjustment is not necessary in the elderly.
If you take more ESORAL, gastro-resistant capsule, than you should:
 Consult immediately your doctor or pharmacist.

If you forget to take ESORAL, gastro-resistant capsule :
 • Take it as soon as possible. However, if you are close to when to take the next dose, do not take the missed dose.
 • Do not take a double dose to make up for the dose you forgot to take.
 • If you have any further questions on the use of this medicine, ask your doctor or pharmacist for more information.

4. POSSIBLE SIDE EFFECTS ?
 Like any medicine, this medication can cause side effects, but they do not occur systematically in everyone.
Do not take the following side effects, these are rare but serious, stop taking ESORAL, gastro-resistant capsule, and contact immediately a doctor :
 • Sudden onset of wheezing, swelling of the lips, tongue and throat or body, rash, loss of consciousness or difficulty swallowing (severe allergic reactions).
 • Redness of the skin with bubbles or desquamation. Sometimes, the bubbles can be significant and be accompanied by bleeding in the lips, eyes, mouth, nose and genitals. This may be Stevens-Johnson syndrome or toxic epidermal necrolysis.

• Jaundice, dark urine and fatigue can be symptoms of liver problems. These effects are rare and may affect up to 1 in 1,000 people.
Other side effects are
Common side effects (may affect up to 1 in 10 people)

- Headache
- Effects on the stomach or intestine : diarrhea, stomach pain, constipation, flatulence.
- Nausea, vomiting.
- Mild polyps in the stomach
- Swelling of the feet and ankles.
- Sleep disorders (insomnia).
- Diarrhea, tingling, drowsiness.
- Dizziness.
- Dry mouth.
- Increased liver enzymes in the blood.
- Skin rash, hives and itching.
- Fracture of the hip, wrist or vertebrae (if ESORAL, gastro-resistant capsule, is used in high doses and over a long period).

Rare side effects (may affect up to 1 in 10,000 people)
 • Blood disorders such as a decrease in the number of white blood cells or platelets. These effects can cause weakness, bruising and facilitate the onset of infections.
 • Decrease in the sodium level in the blood. This can cause weakness, nausea, vomiting and cramps.

- etes crampes.
- Restlessness, confusion, depression.
- taste disorders.
- Vision problems, such as blurred vision.
- Wheezing or shortness of breath (bronchospasm).
- Inflammation of the inside of the mouth.
- Bowel infection linked to a fungus (gastrointestinal candidiasis).
- Liver problems including jaundice, which can cause yellow skin, dark urine and fatigue.
- Hair loss (alopecia).
- Skin rash when exposed to the sun.
- Joint (arthritis) or muscle pain (myalgia).
- Sensation of weakness and lack of energy.
- Increased sweating.

Very rare side effects (may affect up to 1 in 10,000 people)
 • Change in the number of blood cells including agranulocytosis (white blood cell deficiency).
 • Aggressiveness.

Side effects of unknown frequency (cannot be estimated from the available data).
 • If you take ESORAL, gastro-resistant capsule, for more than three months, the level of magnesium in your blood may decrease. Low levels of magnesium can lead to fatigue, involuntary muscle contractions, disorientation, convulsions, irregular, increased heart rate. If you have any of these symptoms, please tell your doctor immediately. Low levels of magnesium can also cause low potassium or calcium levels in the blood. Your doctor may decide to perform regular blood tests to monitor your magnesium levels.
 • Inflammation of the intestine (leading to diarrhea)
 • Skin rash, potentially accompanied by joint pain.

ESORAL can in very rare cases affect white blood cells resulting in an immune deficiency. You should see your doctor as soon as possible if you have an infection with symptoms such as fever with very general tiredness and symptoms of local infection such as pain in the neck, throat, mouth, or difficulty urinating. If you have these symptoms, a deficit of white blood cells (agranulocytosis) can be eliminated by a blood test. It is important that you give information about your medicines in this case.

Reporting side effects
 If you get any side effects, talk to your doctor or pharmacist. This also applies to any side effect not mentioned in this leaflet. You can also report side effects directly via the national reporting system :
 Centre National de Pharmacovigilance CNPV.
 By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE ESORAL, gastro-resistant capsule ?
 Keep this medicine out of the sight and reach of children.
 Do not use this medicine after the expiry date which is stated on the carton and the bottle after EXP. The expiration date refers to the last day of the month indicated.
 Store at a temperature not exceeding 30 °C.
 Store in the original packaging.
 Do not throw away any medicines via wastewater or household waste. Ask your pharmacist to dispose of the medicines you no longer use. These measures will help protect the environment.

6. CONTENT OF THE PACKAGING AND OTHER INFORMATION
What ESORAL, gastro-resistant capsule contains

	ESORAL 20 mg, gastro-resistant capsule	ESORAL 40 mg, gastro-resistant capsule
Active substance	20 mg esomeprazole	40 mg esomeprazole
Excipients	Cetyl alcohol, Titanium dioxide, hydroxypropylmethylcellulose, hydroxypropylmethylcellulose phthalate, Lactyl sodium sulfate, disodium phosphate, croscarmellose, sugar spheres	

What does ESORAL look, gastro-resistant capsule, and content of the other packaging
 This medicine is in the form of gastro-resistant capsules in Alu / Alu blisters packaged in boxes of 08, 16 and 28 capsules.
Prescription and supply conditions: List II

M. A. N° :
 ESORAL 20mg, box of 08 : 9233561
 ESORAL 20mg, box of 16 : 9233561
 ESORAL 20mg, box of 28 : 9233562
 ESORAL 40mg, box of 08 : 9233566
 ESORAL 40mg, box of 16 : 9233563
 ESORAL 40mg, box of 28 : 9233564

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 ESORAL, gastro-resistant capsule, is a registered trademark of es Laboratories Médix.
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THIS IS A MEDICINE
 • A medicine is a product but not like any other product.
 • A medicine is a tool to help you improve your health. If it's not used properly, it can be health threatening.
 • Strictly adhere to the prescription of your Doctor and to its instructions prescribed, follow your pharmacist advice.
 • Your doctor and your pharmacist know the medicine, its use and side effect.
 • Don't stop the use of the treatment on your own during the prescribed time.
 • Don't retake, don't increase the doses without doctor's advice.

KEEP THE MEDICINES OUT OF REACH OF CHILDREN

