

Package leaflet: Information for the patient

Lafaxid-10

Lafutidine Tablets 10 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 any further questions, ask your doctor, pharmacist or nurse.
- 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.

What is in this leaflet

1. What Lafaxid-10 is and what it is used for
2. What you need to know before you take **Lafaxid-10**
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1. What Lafaxid-10 is and what it is used for

Lafaxid-10 contains Lafutidine which belongs to a group of medicines called H₂-receptor antagonists. These work by reducing the amount of acid you produce in your stomach. It can be used to relieve the symptoms of indigestion and heartburn caused by too much acid in the stomach.

Lafutidine is used to treat the following:

- Ulcer in your duodenum, stomach.
- Gastroesophageal reflux disease (GERD) occurs when stomach acid repeatedly flows back into the tube connecting your mouth and stomach (esophagus)
- Gastric mucosal lesions (erosion, hemorrhage, redness or edema) associated with gastritis

2. What you need to know before you take Lafaxid-10

Do not take Lafutidine if:

- You are allergic to Lafutidine, other H₂-receptor antagonists or any of the other ingredients of this medicine

- If you are under 6 years' old
- If you are pregnant, breastfeeding, or trying to become pregnant, unless your doctor tells you to.

Warnings and precautions

! Talk to your pharmacist or doctor:

- If you have any of the following symptoms – these may be a sign of a more serious problem that needs different treatment
 - You have an ulcer in your stomach or intestine, or you think you may have one
 - You are middle aged or older and this is the first time you have had these symptoms, or
- your symptoms have recently changed
 - You have lost weight without trying, difficulty in swallowing, stomach pain
- If you have liver or kidney problems
- If you have regular medical appointments for any reason
- If you have any other illness, or take any medicines on a regular basis (including medicines prescribed by your doctor, and any you have bought for yourself)
- If you are taking any non-steroidal anti-inflammatory drugs, e.g. ibuprofen or aspirin, especially if you are elderly
- If you have a condition called porphyria (a rare blood disease) or you have ever had this condition
- There is a possibility of a malignant growth (tumour) being present in your stomach
- You have been taking a high dose of Lafutidine for a long time. Your doctor may monitor your blood count and liver function

Other important information

Information about some of the ingredients in this medicine: Castor oil may cause a stomach upset or diarrhoea.

Do not drink alcohol (wine, beer, spirits) whilst taking this medicine.

If you take other medicines

Before you take these tablets, make sure that you tell your pharmacist about ANY other medicines you might be using at the same time, particularly the following:

- Non-steroidal anti-inflammatory drugs
- Antacids (for indigestion)
- Sucralfate (for ulcers)
- Procainamide (for abnormal heartbeats)
- Theophylline (for asthma)
- Ketoconazole (for fungal infections)
- Glipizide (for diabetes)

If you take other antacids for indigestion, or sucralfate to treat ulcers and your doctor tells you that you can take this medicine as well, you must separate the times when you take

them. You must take these tablets at least two hours before the antacid or sucralfate.

If you are unsure about interactions with any other medicines, talk to your pharmacist. This includes medicines prescribed by your doctor and medicine you have bought for yourself, including herbal and homeopathic remedies.

Pregnancy and breast-feeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

This product should only be used during pregnancy and breast-feeding only considered essential.

Driving and using machines

These tablets have no known effects on ability to drive or operate machinery.

3. How to take Lafaxid

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

- The recommended dose is one tablet once or twice daily according to age and severity of disease symptoms.
- Swallow one tablet with glass of water as soon as you have symptoms. If symptoms persist or recur take another tablet. Do not take more than 2 tablets in one day.
- The score line is only there to help you break the tablet if you have difficulty swallowing it whole.
- Lafutidine can be taken with or without food.

Patients with Kidney disorders/on dialysis

- If you suffer from kidney disorders, your doctor is likely to reduce your dose.
- Lafutidine should be administered at the end of dialysis or after since some of the active ingredient is removed by dialysis.

Use in children

Lafutidine can be used in children.

If you take more Lafutidine than you should

If you accidentally take too many tablets, contact your doctor or nearest hospital emergency department immediately for advice. Remember to take this leaflet or any remaining tablets with you.

If you forget to take your Lafutidine

Take it as soon as you remember, unless it is nearly time for your next dose. If you miss a dose, do not take a double dose to make up for a forgotten dose.

If you stop taking Lafutidine

It is important that you keep taking Lafutidine for as long as your doctor has told you to. In case of long-standing ulcer disease, abrupt withdrawal after symptom relief should be avoided. 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.

Some side effects are mentioned below:

Constipation, diarrhea, drug rash, nausea or vomiting and dizziness are the adverse reactions observed during clinical trials.

Other adverse effects of unknown frequency include abnormal changes in laboratory tests, hypersensitivity reactions (itching, redness of the skin, skin rash)

! If you get any of these serious side effects, stop taking the tablets. See a doctor at once:

- Difficulty in breathing, swelling of the face, neck, tongue or throat, chest pain, unexplained
- fever, fainting (severe allergic reactions)
- Fast, slow or irregular heartbeat
- Severe stomach pain (this may be caused by a swollen pancreas)

These effects are rare and happen to one person in 1000 to 10,000 who take this medicine

Reporting of side effects

If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly: Website: www.zuventus.co.in and click the tab “Safety Reporting” located on the top right end of the home page.

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

5. How to store Lafaxid

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 blister after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special temperature storage conditions.

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

Do not use this medicine if you notice that the pack is damaged or shows signs of tampering.

Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Lafaxid contains

- The active substances are lafutidine.

Each film-coated tablet contains:

Lafutidine.....10 mg.

Excipients.....q. s

Color: Titanium Dioxide I P

Pack size:

3 composite blister strips of 3 × 10 tablets each.

Marketing Authorisation Holder

Zuventus Healthcare Limited

Zuventus House, Plot Y2, CTS No.: 358/A2,

Near Nahur Railway Station,

Nahur (W), Mumbai, 400078 Maharashtra, India.

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