

Package leaflet: Information for the patient

Lobetron™-0.5

[Lobeglitazone Sulfate Tablets 0.5 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 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.

What is in this leaflet

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2. What you need to know before you take Lobetron™-0.5
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1. What Lobetron™-0.5 is and what it is used for

Lobetron™-0.5 tablets contain Lobeglitazone.

- It is an anti-diabetic medicine used to treat type 2 (non-insulin dependent) diabetes mellitus in adults, when metformin is not suitable or has failed to work adequately. This is the diabetes that usually develops in adulthood.
- Lobeglitazone tablets help control the level of sugar in your blood when you have type 2 diabetes by helping your body make better use of the insulin it produces. Your doctor will check whether Lobeglitazone is working 3 to 6 months after you start taking it.
- Lobeglitazone tablets may be used on their own in patients who are unable to take metformin, and where treatment with diet and exercise has failed to control blood sugar or may be added to other therapies (such as insulin, sulphonyl urea) which have failed to provide sufficient control in blood sugar.

2. What you need to know before you take Lobetron™-0.5

Do not take Lobetron™-0.5 if:

- you are allergic to Lobeglitazone or any of the other ingredients of this medicine,
- you have heart failure or have had heart failure in the past,
- you have liver disease,
- you have had diabetic ketoacidosis (a complication of diabetes causing rapid weight loss, nausea or vomiting),
- you have severe kidney disease,
- you have blood in your urine that your doctor has not checked.
- Serious infection or trauma

Warnings and precautions

Talk to your doctor or pharmacist before taking Lobeglitazone:

- If you retain water (fluid retention) or have heart problems in particular if you are over 75 years old. If you take non-steroidal anti-inflammatory medicines which can also cause water (fluid retention) and swelling, including celecoxib or etoricoxib, you must also tell your doctor.
- If you have ever had blood in your urine. If you find blood in your urine or have other problems urinating while taking Lobeglitazone, you should contact your doctor.
- If you smoke (or have smoked in the past), have received chemotherapy or radiotherapy (for cancer treatment).
- If you have a special type of diabetic eye disease called macular oedema (swelling of the back of the eye with worsening of your vision).
- If you have cysts on your ovaries (polycystic ovary syndrome). There may be an increased possibility of becoming pregnant because you may ovulate again when you take Lobeglitazone. If this applies to you, use appropriate contraception to avoid the possibility of an unplanned pregnancy.
- If you have a problem with your liver or heart. Before you start taking Lobeglitazone you will have a blood sample taken to check your liver function. This check may be repeated at intervals. Some patients with long-standing type 2 diabetes mellitus and heart disease or previous stroke who were treated with Lobeglitazone and insulin experienced the development of heart failure. Inform your doctor as soon as possible if you experience signs of heart failure such as unusual shortness of breath or rapid increase in weight or localised swelling (oedema).
- Broken bones, a higher number of bone fractures was seen in patients, particularly women taking Lobeglitazone. Your doctor will take this into account when treating your diabetes.
- If you take Lobeglitazone with other medicines for diabetes, it is more likely that your blood sugar could fall below the normal level (hypoglycaemia).
- You may also experience a reduction in blood count (anaemia).

Pediatric population

Use in children is not recommended.

Other medicines and Lobeglitazone

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. You can usually continue to take other medicines whilst you are being treated with Lobeglitazone tablets.

Pregnancy and breast-feeding

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.

You should not take Lobeglitazone in pregnancy as it is unsure whether the medicine can affect the growth of your baby.

You should not take Lobeglitazone if you are breast-feeding as it is not known whether it may be present in the milk.

Driving and using machines

Lobeglitazone will not normally affect your ability to drive or use machines but take care if you experience abnormal vision.

3. How to take Lobetron™-0.5

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual recommended dose is 1 tablet (0.5 mg) of Lobeglitazone taken once daily. Swallow your tablet with a glass of water with or without food.

If necessary, your doctor may tell you to take a different dose. When Lobeglitazone tablets are taken in combination with other medicines used to treat diabetes (such as insulin, metformin, glibenclamide, gliclazide) your doctor will tell you whether you need to take a smaller dose of your medicines.

Your doctor will ask you to have blood tests periodically during treatment with Lobeglitazone. This is to check that your liver is working normally.

If you are following a diabetic diet, you should continue with this while you are taking Lobeglitazone.

Your weight should be checked at regular intervals; if your weight increases, inform your doctor.

If you take more Lobeglitazone tablets than you should

If you accidentally take too many tablets, or if someone else or a child takes your medicine, contact your doctor or hospital emergency department **immediately**. Your blood sugar could fall below the normal level and can be increased by taking sugar. It is recommended that you carry some sugar lumps, sweets, biscuits or sugary fruit juice.

If you forget to take Lobeglitazone tablets

Take Lobeglitazone daily as prescribed. However, if you miss a dose, just carry on with the next dose as normal. **Do not** take a double dose to make up for a forgotten dose.

If you stop taking Lobeglitazone tablets

Lobeglitazone should be used every day to work properly. If you stop using Lobeglitazone, your blood sugar may go up. Talk to your doctor before stopping this treatment.

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 side effects, stop taking this medicine and contact your doctor or go to the nearest hospital casualty department straight away.

- Heart failure (when taking Lobeglitazone in combination with insulin): symptoms are unusual shortness of breath or rapid increase in weight or localised swelling (oedema).
- Signs and symptoms include blood in your urine.
- Localised swelling (oedema) (when taking Lobeglitazone in combination with insulin).
- Broken bones (this has been reported in both female and male patients).
- Blurred vision due to swelling (or fluid) at the back of the eye. Also, if you already have blurred vision and the symptom gets worse, talk to your doctor as soon as possible.
- Allergic reactions: symptoms of a serious allergic reaction include hives and swelling of the face, lips, tongue, or throat that may cause difficulty in breathing or swallowing.

Other possible side effects:

Common

- abnormal vision
- respiratory infection
- weight gain
- numbness

Uncommon

- inflammation of the sinuses (sinusitis)
- difficulty sleeping (insomnia).

Not known: frequency cannot be estimated from the available data

- increase in liver enzymes
- allergic reactions

The following additional side effects have been experienced by some patients when Lobeglitazone is taken with other antidiabetic medicines.

Very common

- decreased blood sugar (hypoglycaemia)

Common

- headache
- dizziness
- joint pain
- impotence
- back pain
- shortness of breath
- small reduction in red blood cell count (anemia)
- flatulence
- increase in enzyme levels

Uncommon

- sugar in urine, proteins in urine
- spinning sensation (vertigo)
- sweating
- tiredness
- increased appetite

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: Website:

www.zuventus.co.in and click the tab “Safety Reporting” located on the top end of the home page.

By reporting side effects, you can help provide more information on the safety of this medicine. You can also report the side effects with the help of your treating physician.

5. How to store Lobetron™-0.5

Store protected from light & moisture at a temperature not exceeding 30°C. 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 blister, carton, bottle after EXP. The expiry date refers to the last day of that month.

6. Content of the pack and other information

What Lobetron™-0.5 contains

The active substance is Lobeglitazone. Each tablet contains 0.5 mg of Lobeglitazone (as Sulfate).

What Lobetron™-0.5 looks like and contents of the pack

Alu-Alu blister strip of 10 tablets.

Marketing Authorisation Holder

Zuventus Health care LTD

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TM - Trade Mark Owners.

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