LODOZ TABLET

Lodoz 2.5 mg / 6.25 mg: 2.5 mg bisoprolol fumarate & 6.25 mg hydrochlorothiazide
Lodoz 5 mg / 6.25 mg: 5 mg bisoprolol fumarate & 6.25 mg hydrochlorothiazide

What is in this leaflet

What Lodoz is used for

The active substances are bisoprolol and hydrochlorothiazide. This medicine is recommended in the treatment of high blood pressure in patients whose blood pressure is not sufficiently controlled by bisoprolol or hydrochlorothiazide alone.

How does Lodoz works

Bisoprolol belongs to the family of medicines called beta-blockers and it is used to decrease blood pressure. Bisoprolol slows down the heart rate and makes the heart more efficient at pumping blood around the body Hydrochlorothiazide belongs to the family of medicines called thiazide diuretics (also known as "water tablets"). Hydrochlorothiazide helps to lower blood pressure by increasing the elimination of urine.

Before you take Lodoz

– *When you must not take it*

If you,

- are allergic to bisoprolol, hydrochlorothiazide, other thiazides, sulphonamides (substances chemically related to hydrochlorothiazide) or any of
- the other ingredients of this
- medicine.
- suffer from acute weakness of the
- heart muscle (acute heart failure) or
- if your heart muscle weakness is not
- under control (decompensated heart failure)
- suffer from shock due to a heart attack (cardiogenic shock)
- have major disturbances of heart rhythm (2nd and 3rd degree AV block, sick sinus syndrome, sinoatrial block)
- have a severely slowed heart rate
- suffer from severe forms of asthma or any other breathing problems such as chronic respiratory disorders
- have severe circulatory disorders affecting the limbs (such as Raynaud's syndrome that could result in pallor, blueing or tingling of the fingers and toes)
- have untreated phaeochromocytoma (rare adrenal tumour)
- have an increase in blood acid concentration (metabolic acidosis) due to a serious disease
- have severe kidney or liver disorders
- have low blood potassium levels that do not respond to treatment
- are breastfeeding
- have a severe sodium deficiency (hyponatraemia)
- have raised calcium levels in your blood (hypercalcaemia)
- suffer from gout

– *Before you start to take it*

Tell your doctor or pharmacist before taking Lodoz if you:

- have had skin cancer or if you develop an unexpected skin lesion during the treatment. Treatment with hydrochlorothiazide, particularly long-term use with high doses, may increase the risk of some types of skin and lip cancer (non-melanoma skin cancer). Protect your skin from sun exposure and UV rays while taking Lodoz
- have heart failure. This medicine may cause potassium deficiency. Low levels of potassium might cause heart rhythm problems and sometimes may be fatal. Your doctor will have to carefully adjust your dose of bisoprolol before you start taking Lodoz.
- are planning to undergo surgery. Your heart rate and blood pressure can change when anaesthetics are taken together with Lodoz. Tell the anaesthetist that you are taking Lodoz
- suffer from asthma or any other chronic respiratory disorders which may cause symptoms of difficulty in breathing or tightening of the windpipe (bronchospasms). In such cases your doctor might increase your dose of your existing respiratory medicines or add some more medicines for respiratory problems.
- have diabetes, Lodoz may hide the symptoms of low blood sugar (hypoglycaemia)
- are fasting and undertake physically strenuous activities
- have a tumour of the adrenal medulla (phaeochromocytoma) which is being treated; Lodoz must only be used in combination with certain medicinal products (alpha-blockers)
- are receiving treatment for allergic reactions. Lodoz may increase the severity of your allergic reactions. Your normal treatment may also be less effective.
- thyroid disorder (bisoprolol can hide the symptoms of an overactive thyroid).
- suffer from a heart conduction disorder (1st degree atrio-ventricular (AV) block).
- suffer from a tight, painful feeling in the chest at rest (Prinzmetal angina). Lodoz may increase the number and the duration of the attacks.
- suffer (or have suffered) from a recurrent skin disorder involving a scaling, dry skin rash (psoriasis).
- suffer from blood circulation problems in the fingers, toes, arms and legs or a cramp like pain in the calves brought on by exercise or walking. The complaints may be worse, particularly at the beginning of the treatment.
- have reduced blood volume (hypovolaemia).
- have mild to moderate kidney or liver problems.

- suffer from high uric acid levels in your blood (hyperuricaemia), since Lodoz has a tendency to increase the risk of gout attacks.
- you are elderly.
- plan to expose yourself to the sun or artificial UV light, given that certain patients have presented a skin rash after sun exposure. In that case, you must protect your skin during treatment with Lodoz.
- If you wear contact lenses Lodoz may reduce tear production, which can cause irritation.
- If you have experienced decrease in viusion or eye pain. These could be symptoms of fluid accumulation in the vascular layer of the eye (choroidal effusion) or an increase of pressure in your eye and can happen within hours to a week of taking this medicine. This can lead to permanent vision loss, if not treated. If you earlier have had a penicillin or sulfonamide allergy, you can be at higher risk of developing this.
- If you experienced breathing or lung problems (including inflammation or fluid in the lungs) following hydrochlorothiazide intake in the past. If you develop any severe shortness of breath or difficulty breathing after taking this medicine, seek medical attention immediately.

Full benefits from urine inducing medicines (hydrochlorothiazide) for blood pressure are obtained only when kidneys are functioning properly. There can be a decrease in renal function in patients with pre-existing renal problems.

– *Taking other medicines*

Tell your doctor or pharmacist if you are taking, have recently taken, or might use any other medicines.
Tell your doctor if you are already taking or using any of the following as they may interact with your medicine:
Do not take Lodoz with:

- sultopride, used to treat schizophrenia.

Take special care with Lodoz and

- some medicines used to treat hypertension, angina or cardiac arrhythmia (e.g. verapamil, diltiazem, bepridil, amlodipine, felodipine) which may increase the risk of cardiac rhythm disorders or can cause low blood pressure.
- medicines to treat high blood pressure (clonidine, moxonidine, amlodipine, methyldopa, reserpine, ACE inhibitors)
- other medicines used to treat certain psychiatric conditions (lithium, trycyclic, phenothiazines)
- medicines to treat an irregular heartbeat (quinidine, disopyramide, amiodarone, sotalol)
- medicines to control the speed of
- your heartbeat (digitalis glycosides)
- medicines to treat aches, swelling or redness (anti-inflammatory
- medicines)
- topical beta-blockers e.g. eye drops to treat glaucoma
- insulin and oral treatments for
- diabetes
- if you are to undergo surgery that requires anaesthetic tell your doctor you are taking Lodoz
- medicines to treat depression (tricyclic antidepressants)
- medicines that affect you nervous
- system e.g. epinephrine, norepinephrine (sympathomimetics)
- medicines to reduce uric acid levels in the blood
- medicines that affect or can be affected by potassium blood levels, such as digoxin, a medicine to control the heart rhythm, some antipsychotic medicines
- corticosteroid, amphotericin, furosemide, laxatives. These medicines may lead to a potassium deficiency
- methyldopa. This medicine may lead to problems with your blood pressure.
- mefloquine to prevent malaria, it may slow your heart rate

How to take Lodoz

– *How much to take*

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. The recommended dose is one Lodoz 2.5/6.25 mg tablet to be taken once daily. If the effect is not sufficient your doctor may increase the dosage to one Lodoz 5/6.25 mg tablet to be taken once daily. If latter proves to be ineffective, the dosage may be increased to one Lodoz 10/6.25 mg tablet once daily.

Use in children
The use of Lodoz is not recommended as there is insufficient experience with the use of this medicinal product in children.

Use in the elderly
No dosage adjustment is normally required. It is recommended to start with the lowest possible dose.
Impaired kidney function in patients with mild to moderately impaired kidney function the doctor may instruct use of a lower dose. Lodoz tablets must not be taken, if the patient has severely impaired kidney function (see also 'When you must not take it').

– *When to take it*

For oral use. The tablets must be taken in the morning, with food. The tablets may be swallowed with some liquid and must not be chewed. The tablet(s) should be taken once daily.

– *How long to take it*

The treatment duration is not limited and depends on the severity of the disease. The duration of therapy will be determined by your doctor. Stopping treatment must be discussed with your doctor

– *If you forget to take it*

Do not take a double dose to make up for a forgotten dose. Take the next dose on time. If you miss several doses, contact your doctor.

– *If you take too much (overdose)*

If you take more Lodoz than you should contact your doctor or casualty department immediately. Take the container and any remaining tablets with you. The common signs of overdose are light-headedness, feeling faint, feeling sick, feeling drowsy, and slow/irregular heart rate

While you are using Lodoz

– *Things you must do*

Pregnancy, breast-feeding and fertility:
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. Usually, your

doctor will advise you to take another medicine instead of Lodoz, as Lodoz is not recommended during pregnancy. This is because both hydrochlorothiazide and bisoprolol cross the placenta and their use during pregnancy may harm your baby.

Tell your doctor if you are breast-feeding or about to start breast-feeding. Lodoz should not be used in mothers who are breast-feeding. Hydrochlorothiazide may affect your milk production.

– *Things you must not do*

- Do not use this medicine to treat any other complaints unless your doctor or pharmacist tells you to. Do not give this medicine to anyone else, even if they have the same condition as you. Do not stop taking Lodoz, or change the dosage, without checking with your doctor. Treatment should not be stopped suddenly, especially if you suffer from certain ischemic heart diseases (for example, angina).

– *Things to be careful of*

Lodoz does not normally affect the ability to drive or use machines. However, the way you react to your medicine may have an effect on your concentration or your reactions. In that case, do not drive and do not use machines.

If you stop taking Lodoz
Do not stop taking this medicine unless told to by your doctor. Your condition may worsen considerably if you stop. If you must interrupt the treatment, your doctor will generally tell you to decrease the dose gradually. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

Lodoz acts by influencing the saltwater balance of the body. Your doctor will monitor it regularly. These tests are particularly important if you suffer from other diseases that may be aggravated if the water-electrolyte balance is perturbed. Your doctor may also wish to verify occasionally the lipids, potassium, sodium, calcium, uric acid, urea or glucose concentrations in your blood.

Side effects
Like all medicines, this medicine can cause side effects, although not everybody gets them.

Common side effects (affecting fewer than 1 in 10 people):

- Dizziness* or headaches*
- sensation of cold or numbing in the
- hands and feet
- nausea, vomiting, diarrhoea or
- constipation
- glucose in the urine
- feeling tired or weak*

*Symptoms which occurs in the beginning of treatment and usually disappear after 1-2 weeks of treatment begins

Uncommon side effects (affecting fewer than 1 in 100 people)

- abnormal body fluid and electrolyte levels (increased triglycerides, increased cholesterol, hypokalaemia, hypomagnesaemia, hyponatraemia, hypochloraemia, hypercalcaemia)
- loss of appetite
- sleep disorders, depression
- slow heartbeat, abnormal heart rhythm, worsening of heart failure feeling dizzy or lightheaded when you stand up
- difficulty breathing in people with asthma or lung disease
- abdominal pains
- increase in amylases (enzymes involved in digestion)
- muscular weakness and cramps
- increase in the levels of creatine and urea in the blood
- loss of physical strength.

Frequency ‘not known’

- Skin and lip cancer (non-melanoma skin cancer)

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting thewebsite npra.gov.my (Consumer → Reporting Side Effects to Medicines (ConSERF or Vaccines (AEFI))

Storage and Disposal of Lodoz
– *Storage*
Keep this medicine out of the sight and reach of children.
Do not store above 30°C.
Do not use this medicine after the expiry date. The expiry date refers to the last day of that month.

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

Product Description
– *What it looks like*
Lodoz 2.5 mg/6.25 mg, film-coated tablet:
Film coated tablet, yellow, round, biconvex upper side embossed heart, downside embossed 2.5.
Lodoz 5 mg/6.25 mg, film-coated tablet:
Film coated tablet, pastel-pink, round, biconvex, upper side embossed heart, downside embossed 5.

– *Ingredients*
Lodoz 2.5 mg/6.25 mg, film-coated tablet:
- Active ingredient:
2.5 mg bisoprolol fumarate & 6.25 mg hydrochlorothiazide
- Inactive ingredient:
Tablet core: Magnesium Stearate, Crospovidone, Maize Starch, Pregelatinized maize starch, Microcrystalline Cellulose, Calcium-hydrogen phosphate, anhydrous

Lodoz 5 mg/6.25 mg, film-coated tablet:
- Active ingredient:
5 mg bisoprolol fumarate & 6.25 mg hydrochlorothiazide
- Inactive ingredient:
Tablet core: Silica, colloidal anhydrous, Magnesium Stearate, Microcrystalline Cellulose, Maize Starch, Calcium-hydrogen phosphate, anhydrous

Each pack contains 3, 50, 60, 90 or 100 tablets film-coated tablets in blisters. Not all strengths and pack sizes are marketed.

– *MAL Number:*
Lodoz 2.5mg tablet:
MAL05051115ASZ
Lodoz 5 mg tablet:
MAL05051113AZ

Manufacturer
Merck Healthcare KGaA,
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Product Registration Holder
Merck Sdn Bhd (178145-V)
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