

Lercadip®

10 and 20 mg film-coated tablets
Lercanidipine hydrochloride

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.

In this leaflet:

1. What Lercadip is and what it is used for
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1. WHAT LERCADIP IS AND WHAT IT IS USED FOR

Lercadip belongs to a group of medicines called Calcium Channel Blockers (dihydropyridine derivatives). Lercadip is used to treat high blood pressure also known as hypertension in adults over the age of 18 years (it is not recommended for children under 18 years old).

2. BEFORE YOU TAKE LERCADIP

Do not take Lercadip and tell your doctor if:

- You are allergic (hypersensitive) to lercanidipine hydrochloride or to any other ingredients of Lercadip tablets
- You have had allergic reactions to drugs closely related to Lercadip tablets (such as amlodipine, nicardipine, felodipine, isradipine, nifedipine or lacidipine)
- If you are suffering from certain heart diseases:
 - Untreated heart failure
 - Obstruction to flow of blood from the heart
 - Unstable angina (angina at rest or progressively increasing)
 - Within one month of heart attack
- You have severe liver or kidney problems
- You are taking drugs that are inhibitors of CYP3A4 isoenzyme:
 - Antifungal medicines (such as ketoconazole or itraconazole).
 - Macrolide antibiotics (such as erythromycin or troleandomycin).
 - Antivirals (such as ritonavir).
- You are taking another drug called cyclosporin (used after transplants to prevent organ rejection)

- With grapefruit or grapefruit juice
- Do not use if you are pregnant or breast-feeding (see section Pregnancy and Breast-feeding for more information).

Take special care with Lercadip and tell your doctor if:

- You have certain other heart conditions which have not been treated by insertion of a pacemaker or have pre-existing angina
- You have problems with your liver or kidneys or you are on dialysis

Using 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
- You are taking beta-blockers e.g. metoprolol, diuretics (water tablets) or ACE-inhibitors (medicines to treat high blood pressure)
- You are taking cimetidine (more than 800 mg, a medicine for ulcers, indigestion, or heartburn)
- You are taking digoxin (a medicine to treat a heart problem)
- You are taking midazolam (a medicine that helps you sleep)
- You are taking rifampicin (a medicine to treat tuberculosis)
- You are taking astemizole or terfenadine (medicines for allergies)
- You are taking amiodarone or quinidine (medicines to treat a fast heart beat)
- You are taking phenytoin or carbamazepine (medicines for epilepsy). Your doctor will want to monitor your blood pressure more frequently than usual.
- Some medicines should **not** be taken at the same time as Lercadip. See section 2 'Do not take Lercadip and tell your doctor if:' for a list of these.

Taking Lercadip with food and drink

- Patients should not consume alcohol during treatment with Lercadip tablets since it may increase the effect of Lercadip tablets.
- Patients should not take grapefruit or grapefruit juice.

Pregnancy and breast-feeding

Do not use Lercadip if you are pregnant or breast-feeding, or you wish to become pregnant or if you are not using any contraceptive method.

If you are taking Lercadip and think that you may be pregnant, consult your doctor.

Driving and using machines

Caution should be exercised because of the possibility of dizziness, weakness and tiredness. Do not drive or use machines until you know how Lercadip affects you.

Information about some ingredients of Lercadip:

If you have been told by your doctor that you have an

intolerance to some sugars, e.g. intolerance to lactose, galactosaemia or glucose/galactose malabsorption syndrome, contact your doctor before taking this medicinal product, as the tablets contain lactose.

3. HOW TO TAKE LERCADIP

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

Adults: The usual dose is 10 mg film-coated tablet daily at the same time each day, preferably in the morning at least 15 minutes before breakfast, because a high fat meal significantly increases blood levels of the drug. Your doctor may advise you to increase the dose to one Lercadip 20 mg film-coated tablet daily, if needed. The tablets should preferably be swallowed whole with some water.

Elderly: No adjustment of the daily dose is required. However, special care should be exercised in starting treatment.

Patients with liver or kidney problems: Special care is needed in starting treatment in these patients and an increase in daily dose to 20 mg should be approached with caution.

Children: This medicine should not be used in children under 18 years of age.

If you have any further questions on the use of this product ask your doctor.

If you take more Lercadip than you should Do not exceed the prescribed dose.

If you take more than the prescribed dose or in the event of overdose, seek medical advice immediately and, if possible, take your tablets and/or the container with you.

Exceeding the correct dosage may cause blood pressure to become too low, and the heart to beat irregularly or faster. It may also lead to unconsciousness.

If you forget to take Lercadip

If you forget to take your tablet, simply miss that dose and then go on as before. Do not take a double dose.

If you stop taking Lercadip

If you stop taking Lercadip your blood pressure may increase again. Please consult your doctor before stopping the treatment.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

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

Some side effects can be serious:

If you experience any of these side effects tell your doc-

tor straight away.

- Rare (affecting less than 1 out of 1000 patients): angina pectoris (chest pain due to lack of blood to your heart)

- Very rare (affecting less than 1 out of 10,000 patients): chest pain, fall in blood pressure, fainting and allergic reactions (symptoms include itching, rash, hives)

If you suffer from pre existing angina pectoris, with the group of medicines to which Lercadip belongs, you may experience increased frequency, duration or severity of these attacks. Isolated cases of heart attack may be observed.

Other possible side effects:

- Uncommon (affecting less than 1 out of 100 patients): headache, dizziness, faster heart beats, palpitations (heart pounding or racing), sudden reddening of the face, neck or upper chest, ankle swelling.

- Rare (affecting less than 1 out of 1000 patients): sleepiness, feeling sick, vomiting, heartburn, stomach pain, diarrhoea, skin rash, muscle pain, passage of large amounts of urine, tiredness.

- Very rare (affecting less than 1 out of 10,000 patients): swelling of gums, changes in liver function (detected by blood tests), increase in the usual number of times one urinates.

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.

5. HOW TO STORE LERCADIP

Keep out of the reach and sight of children

Do not use Lercadip after the expiry date, which is stated on the carton and on blister. The expiry date refers to the last day of that month.

Do not store above 30°C.

Store in the original package in order to protect from light and moisture. The original package should be kept in a dry place.

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 Lercadip contains

The active substance is: lercanidipine hydrochloride 10 mg which is equivalent to 9.4 mg of lercanidipine or lercanidipine hydrochloride 20 mg which is equivalent to 18.8 mg of lercanidipine.

The other ingredients are:

Core tablet: lactose monohydrate, microcrystalline cellulose, sodium starch glycolate, povidone K30, magnesium stearate.

Film coating: hypromellose, talc, titanium dioxide (E171), macrogol 6000 and ferric oxide (E172).

What Lercadip looks like and contents of the pack

Lercadip 10 mg: yellow, circular, biconvex, film-coated tablet scored on one side, engraved "ALG L10" on the other. The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

Lercadip 20 mg: pink, circular, biconvex, film-coated tablet scored on one side, engraved "ALG L20" on the other.

Lercadip is available in blister packs of 7, 14, 28, 30, 35, 42, 50, 56, 98, 100 tablets. Not all pack sizes may be marketed.

For more information about this medicinal product, please contact:

Algorithm S.A.L
Tel: +961-9-222050

**To report any side effect:
Lebanon and all MENA countries**

Algorithm SAL
Fax: +961-9-222141
Email: pharmacovigilance@blgx.net
Website: www.algorithm-lb.com

Saudi Arabia

Also contact:
National Pharmacovigilance Center (NPC)
Fax: +966-1-210-7398
Email: npc.drug@sfd.gov.sa
Website: www.sfd.gov.sa/npc

Other GCC states

Also contact the relevant competent authority.

This is a Medicament

-Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.

-Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.

-The doctor and the pharmacist are the experts in medicines, their benefits and risks.

-Do not by yourself interrupt the period of treatment prescribed for you.

-Do not repeat the same prescription without consulting your doctor.

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