

PACKAGE LEAFLET: INFORMATION FOR THE USER

CORNELIN

10mg and 20mg film-coated tablets

LERCANIDIPINE HYDROCHLORIDE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 •

What is in this leaflet?

- 1 What Cornelin tablets are and what they are used for
- 2 What you need to know before you take
- 3 How to take
- 4 Possible side effects
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1. WHAT CORNELIN TABLETS ARE AND WHAT THEY ARE USED FOR

Lercanidipine belongs to a group of medicines called calcium channel blockers that block the entry of calcium into the muscle cells of the heart and the blood vessels that carry blood away from the heart (the arteries). It is the entry of calcium into these cells that causes the heart to contract and arteries to narrow. By blocking the entry of calcium, calcium channel blockers decrease contraction of the heart and dilate (widen) the arteries, and the blood pressure is reduced.

Lercanidipine has been prescribed to you to treat your high blood pressure, also known as hypertension.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE

Do not take Lercanidipine if you:

- are allergic to lercanidipine or any of the other ingredients of this medicine..
- have had allergic reactions to medicines that are closely related to Cornelin tablets (such as amlodipine, nifedipine, felodipine, isradipine, nifedipine or lercanidipine)
- are suffering from certain heart diseases:
 - uncontrolled cardiac failure
 - an obstruction to flow of blood from the heart
 - unstable angina (angina at rest or progressively increasing)
 - have had a heart attack less than one month ago

- have severe liver or kidney problems
- 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)
 - at the same time as another drug called ciclosporin or cyclosporin
 - with grapefruit or grapefruit juice
- are pregnant, or if you wish to become pregnant or if you are a woman in child-bearing age and do not use any contraceptive method
- if you are breast-feeding

Warnings and precautions

Talk to your doctor before taking Cornelin tablets if you:

- have a heart condition known as sick sinus syndrome, and do not have a pacemaker
- suffer from chest pain (angina pectoris), Lercanidipine may in very rare cases cause increased frequency of attacks that may last longer and become more severe. Heart attacks have been reported in isolated cases.
- have problems with your liver or kidney, or you are on dialysis

Other medicines and Lercanidipine

Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. Taking Lercanidipine with certain other medicines (see below), may alter the effect of these medicines or of Lercanidipine.

It is especially important for your doctor to know if you are already being treated with any of the following medicines:

- phenytoin or carbamazepine (medicines for epilepsy)
- rifampicin (a medicine to treat tuberculosis)
- midazolam (a medicine that helps you sleep)
- cimetidine, more than 800mg (a medicine for ulcers, indigestion, or heartburn)
- digoxin (a medicine to treat a heart problem)
- terfenadine or astemizole (medicines for allergies)
- amiodarone or quinidine (medicines to treat a fast heart beat)
- metoprolol (a medicine to treat high blood pressure)
- simvastatin (a medicine for high cholesterol value)

Lercanidipine with food, drink and alcohol

You must not eat grapefruit or drink grapefruit juice as this may increase the effect of Lercanidipine.

If you use alcohol together with Lercanidipine you may experience dizziness/fainting, tiredness or weakness. This is because the medicine may lower your blood pressure considerably together with alcohol.

Pregnancy and breast-feeding

Ask your doctor for advice before taking any medicine.

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

Do not use if you are pregnant, or if you wish to become pregnant or if you are a woman in childbearing age and do not use any contraceptive method.

Do not use if you are breast-feeding.

Driving and using machines

Lercanidipine has a negligible influence on the ability to drive or use machines. However, side effect such as dizziness, weakness, tiredness and rarely sleepiness may occur. You should be careful until you know how you react to Lercanidipine.

Cornelin tablet contains lactose monohydrate

Cornelin tablet contains lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3 HOW 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 Cornelin 10mg 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 your blood levels of the medicine.

Your doctor may decide to increase your dose to one Cornelin 20mg film-coated tablet daily, if needed.

The tablets should preferably be swallowed whole with 1/2 glass of water. The score line is only there to help you break the tablet if you have difficulty swallowing it whole.

Use in children and adolescents

Lercanidipine is not recommended for use in children and adolescents below 18 years.

If you take more Lercanidipine than you should

Immediately contact a doctor, the nearest hospital casualty department or the centre for poison information for advice.

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 Lercanidipine

If you forget to take your tablet, take it as soon as you remember, unless it is almost time for your next dose. Then go on as before. Do not take a double dose to make up for a forgotten dose.

If you stop taking Lercanidipine

If you stop taking Lercanidipine 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 medicine, ask your doctor or pharmacist.

4 POSSIBLE SIDE EFFECTS

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

The frequencies of side effect have been listed below according to the following definitions:

Very common: may affect more than 1 in 10 people

Common: may affect up to 1 in 10 people

Uncommon: may affect up to 1 in 100 people

Rare: may affect up to 1 in 1,000 people

Very rare: may affect up to 1 in 10,000 people

Not known: frequency cannot be estimated from the available data

Uncommon: Headache, dizziness, faster heartbeats, awareness of the beating of the heart, flushing (transient episodic redness of the face and neck), ankle swelling.

Rare: Sleepiness, weakness, tiredness, nausea, vomiting, diarrhoea, abdominal pain, indigestion, rash, muscle pain, passage of large amounts of urine, angina pectoris.

Very rare, not known: Decrease in blood pressure which may lead to fainting, allergic reaction, swelling of gums, increase in liver enzyme blood test values, fall in blood pressure which can cause dizziness, light-headedness or fainting, increase in the usual number of times one urinates, chest pain and heart attack.

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.

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

5 HOW TO STORE

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 label, carton or bottle after EXP. The expiry date refers to the last day of that month.

Storage conditions

Do not store above 25°C. Store in the original package to protect from moisture.

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.

This leaflet was last revised in - October 2014