

Proposed Clean Patient Information Leaflet

SCHEDULING STATUS

S3

LERTENS 10 (Film coated tablets)

(Lercanidipine Hydrochloride)

Sodium content: 0,788 mg per tablet

Sugar free

LERTENS 20 (Film coated tablets)


(Lercanidipine Hydrochloride)

Sodium content: 1,227 mg per tablet

Sugar free

Read all of this leaflet carefully before you start taking LERTENS

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- **LERTENS** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

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What is in this leaflet

1. What **LERTENS** is and what it is used for
2. What you need to know before you take **LERTENS**
3. How to take **LERTENS**
4. Possible side effects
5. How to store **LERTENS**
6. Contents of the pack and other information


1. What LERTENS is and what it is used for

Lercanidipine belongs to a group of medicines called calcium channel blockers (dihydropyridine derivatives). **LERTENS** is used to treat high blood pressure also known as hypertension in adults over the age of 18 years.

2. What you need to know before you take LERTENS

Do not take LERTENS if:

- You are allergic (hypersensitive) to lercanidipine hydrochloride or to any other ingredients of **LERTENS** tablets;
- You have had allergic reactions to medicines closely related to **LERTENS** tablets (such as amlodipine, nifedipine, felodipine, isradipine, nifedipine or lacidipine).
- If you are suffering from certain heart diseases:
 - Untreated heart failure;
 - Obstruction to flow of blood from the heart;

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- Unstable angina (chest discomfort occurring at rest or progressively increasing);
- Within one month of heart attack.
- You have severe liver problems;
- If you have severe kidney problems or you are undergoing dialysis.
- You are taking medicines such as:
 - Antifungal medicines (such as ketoconazole or itraconazole);
 - Macrolide antibiotics (such as erythromycin, troleandomycin or clarithromycin);
- Antivirals (such as ritonavir);
- Antidepressant medicines (such as fluoxetine)
- You are taking another medicine called ciclosporin (used after transplants to prevent organ rejection).

Do not take LERTENS with grapefruit or grapefruit juice.


Do not use if you are pregnant or breastfeeding (see section Pregnancy and Breastfeeding for more information).

LERTENS is not recommended for children under 18 years old.

Warnings and precautions

Take special care with **LERTENS**:

- You have certain other heart conditions or you have a pacemaker or have pre-existing angina;

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- You have problems with your liver or kidneys or you are on dialysis;
- If you have a heart problem such as left ventricular dysfunction or ischaemic heart disease.
- If you think you are (or might become) pregnant or if you are breastfeeding your baby (see Pregnancy and breastfeeding).
- If you are using medicines called CYP3A4 inducers, like anticonvulsants (e.g. phenytoin, carbamazepine) or a medicine to treat tuberculosis called rifampicin.

Children and adolescents


Do not give **LERTENS** in children aged up to 18 years because the safety and efficacy of **LERTENS** in children aged up to 18 years have not been established.

Other medicines and LERTENS

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines).

Please tell your doctor or pharmacist if:

- You are taking medicines that are inhibitors of CYP3A4 isoenzyme (medicines that will increase the blood levels of lercanidipine):
 - Antifungal medicines (such as ketoconazole or itraconazole);
 - Macrolide antibiotics (such as erythromycin, troleandomycin or clarithromycin);
 - Antivirals (such as ritonavir);
 - Antidepressants (such as fluoxetine)
- You are taking ciclosporin (used after transplants to prevent organ rejection).

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- You should not take these medicines with **LERTENS**.
- 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 simvastatin (a medicine to lower cholesterol in your blood).
- 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, phenobarbitone or carbamazepine (medicines for epilepsy).
- You are taking other medicines to treat high blood pressure.
- You are taking warfarin (to thin your blood).

LERTENS with food, drink and alcohol

Do not consume alcohol during treatment with **LERTENS** since it may increase the effect of **LERTENS**.

LERTENS should not be taken with grapefruit juice.

Pregnancy, breast-feeding and fertility

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If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Do not take **LERTENS** if you are pregnant or breastfeeding, or you wish to become pregnant or if you are not using any contraceptive method.

Driving and using machines

It is not always possible to predict to what extent **LERTENS** may interfere you're your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which **LERTENS** affects you.

Caution should be exercised because **LERTENS** may cause dizziness, weakness and tiredness.

LERTENS contains sodium


This medicine contains less than 1 mmol of sodium (23 mg) per dose, which means it is essentially sodium-free.

3. How to take LERTENS

Do not share medicines prescribed for you with any other person.

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

Adults: The usual dose is one **LERTENS 10** tablet daily at the same time each day, preferably in the morning at least 15 minutes before breakfast, because a high fat meal significantly

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increases blood levels of the medicine. Your doctor may advise you to increase the dose to one **LERTENS 20** tablet daily, if needed. The tablets should preferably be swallowed whole with some water.

Your doctor will tell you how long your treatment with **LERTENS** will last. If you have the impression that the effect of **LERTENS** is too strong or too weak, tell your doctor or pharmacist.

If you take more LERTENS than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

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 LERTENS

Always take **LERTENS** as prescribed. However if you miss a dose skip that dose and take the next dose at the normal time.


Do not take a double dose to make up for forgotten individual doses.

If you stop taking LERTENS

If you stop taking **LERTENS** 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

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LERTENS can have side effects.

Not all side effects reported for **LERTENS** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **LERTENS**, please consult your doctor, pharmacist or other healthcare provider for advice.

If any of the following happens, stop taking **LERTENS** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body, rash, itching or hives on the skin (allergic reaction, angioedema).

These are very serious side effects. If you have them, you may have had a serious allergic reaction to **LERTENS**. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Angina pectoris (chest pain due to lack of blood to your heart);
- Sharp stabbing pains in the chest, fall in blood pressure, heart attack.


If you suffer from pre-existing angina pectoris, with the group of medicines to which **LERTENS** belongs, you may experience increased frequency, duration or severity of these attacks.

These are serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Headache;
- Dizziness;
- Faster heart beats;

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- Swelling of hands, ankles or feet;
- Sudden reddening of the face, neck or upper chest;
- Unusual weakness.

Less frequent side effects:

- Sleepiness;
- Fainting;
- Feeling sick;
- Indigestion;
- Vomiting;
- Stomach pain, muscle pain;
- Diarrhoea;
- Skin rash;
- Itching;
- Hives (itchy rash);
- Passing more urine than normal;
- Tiredness.

Frequency not known:

- Mental depression;
- Eye pain;
- Changes in liver function (detected by blood tests);
- Swelling of gums;

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If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurses.

You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website or directly to the Holder of certificate of registration via email: pharmacovigilance.africasme@sunpharma.com or tel: +27(0) 12 643 2000.

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

5. How to store LERTENS

KEEP ALL MEDICINES OUT OF THE REACH AND SIGHT OF CHILDREN.

Store at or below 25 °C. Protect from light.


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

Keep the blisters in the outer carton in order to protect from light.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

Return all unused medicine to your pharmacist.

These measures will help protect the environment.

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6. Contents of the pack and other information

What LERTENS contains

The active substance is lercanidipine hydrochloride.

Each film coated tablet contains 10 mg/20 mg of lercanidipine hydrochloride

The other ingredients are: Cellulose microcrystalline, colloidal silicon dioxide, ferric oxide red, ferric oxide yellow, hypromellose 6cps, macrogol 6000, maize starch, methanol, poloxamer 188, povidone K-30, sodium starch glycolate, sodium stearyl fumarate, titanium dioxide.

What LERTENS looks like and contents of the pack

LERTENS 10

Yellow coloured, round shaped biconvex, film coated tablets with break-line on one side and plain on the other side.

LERTENS 20

Pink coloured, round shaped biconvex, film coated tablets with break-line on one side and plain on the other side.

Holder of Certificate of Registration


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