PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S3

LERBLOK™ 10, film-coated tablets

LERBLOK™ 20, film-coated tablets

lercanidipine hydrochloride

Sugar free

Read all of this leaflet carefully before you start taking LERBLOK

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- LERBLOK 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.

What is in this leaflet:

1. What LERBLOK is and what it is used for

2. What you need to know before you take LERBLOK

3. How to take LERBLOK

4. Possible side effects

5. How to store LERBLOK

6. Contents of the pack and other information

1. What LERBLOK is and what it is used for

LERBLOK, lercanidipine hydrochloride, belongs to a group of medicines called calcium channel blockers (dihydropyridine derivatives).

Lercanidipine lowers blood pressure by relaxing your blood vessels.

LERBLOK is used to treat mild to moderate high blood pressure (hypertension) in adults.

2. What you need to know before you take LERBLOK

Do not take LERBLOK:

- If you are hypersensitive (allergic) to lercanidipine hydrochloride or to any other ingredients of LERBLOK (listed in section 6).
- If you are suffering from certain heart diseases:
  - obstruction to flow of blood from the heart
  - untreated heart failure
  - unstable angina (chest discomfort occurring at rest or progressively increasing)
  - within one month of heart attack
- If you have severe liver problems
- If you have severe kidney problems
- If you are taking the following medicines:
  - antifungal medicines (such as ketoconazole, itraconazole)
  - fluoxetine (an antidepressant)
  - antibiotics (such as erythromycin)
  - ciclosporin (a medicine used for preventing the rejection of organ transplants)
  - antiviral medicines (such as ritonavir).

See *Other medicines and LERBLOK*.

- If you are pregnant, or breastfeeding (see *Pregnancy, breastfeeding and fertility*).
- If you are a woman of childbearing potential, unless you are using effective contraception.

Do not take LERBLOK with grapefruit or grapefruit juice.

Warnings and precautions

Take special care with LERBLOK:

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

Children and adolescents

The safety and efficacy of LERBLOK in children aged up to 18 years have not been established.

Other medicines and LERBLOK

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

Tell your doctor if you are taking any of the following:

- ketoconazole, itraconazole (antifungal medicines)
- erythromycin, troleandomycin (antibiotics)
- ritonavir (antiviral medicines)

- ciclosporin (a medicine used for preventing the rejection of organ transplants)
- phenytoin, phenobarbital or carbamazepine (medicines for epilepsy)
- rifampicin (a medicine to treat tuberculosis)
- terfenadine (medicine for allergies)
- amiodarone or quinidine (medicines to treat a fast heartbeat)
- diazepam (medicine for anxiety disorders), midazolam (medicine for sleep problems)
- digoxin (a medicine to treat a heart problem)
- fluoxetine (a medicine to treat depression)
- cimetidine (a medicine that reduces stomach acid production)
- simvastatin (a medicine for high cholesterol value)
- other medicines to lower the blood pressure, such as propranolol and metoprolol
- corticosteroids (cortisones) (medicines for inflammation).

LERBLOK with food, drink and alcohol

LERBLOK must not be taken with grapefruit or grapefruit juice (they can increase its hypotensive effect). See *Do not take LERBLOK*.

Alcohol can increase the effect of LERBLOK. Do not consume alcohol during treatment with LERBLOK.

Pregnancy, breastfeeding and fertility

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 healthcare provider for advice before taking LERBLOK.

Information on safety in pregnancy is not available. You should therefore not take LERBLOK if you are pregnant, or if you may become pregnant (see *Do not take LERBLOK*).

- If you are of childbearing age, you should ask your doctor for advice on effective contraception if you take LERBLOK.

Lercanidipine may pass into breast milk. You should therefore not take LERBLOK if you are breastfeeding your baby.

Driving and using machines

LERBLOK may make you feel dizzy, weak, tired or sleepy (see *POSSIBLE SIDE EFFECTS*). Do not drive or handle tools or machines if you have these side effects.

3. How to take LERBLOK

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

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

The usual starting dose is one 10 mg tablet per day.

Swallow the tablet whole with a glass of water, at least 15 minutes before a meal.

The score line is only to facilitate breaking if required for ease of swallowing, and not to divide the tablet into equal doses.

Your doctor will tell you what dose is suitable for you and may want to gradually increase your dosage.

If you are elderly, no adjustment of the daily dose is required. Your doctor will check your response on the treatment.

If you have liver or kidney problems, your doctor may have special dosing instructions for you.

Your doctor will tell you how long your treatment with LERBLOK will last. Do not stop treatment early, because your blood pressure may increase again.

If you have the impression that LERBLOK is too strong or too weak, you should talk to your doctor or pharmacist.

If you take more LERBLOK 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.

Take this leaflet and any remaining tablets with you, so that the doctor knows what you have taken.

Signs of overdosage differ; you may feel dizzy from blood pressure dropping too low and have a fast heartbeat.

If you forget to take LERBLOK

Try to take LERBLOK at the same time each day. If you forget to take a tablet, take the missed dose as soon as you remember. However, if it is almost time for your next dose, skip the missed dose and take only your next regularly scheduled dose.

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

If you stop taking LERBLOK

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

4. Possible side effects

LERBLOK can have side effects.

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

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

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash, red itchy skin, hives.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to LERBLOK. 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 the following:

- Heart attack (chest pain or discomfort that does not go away can be a sign of a heart attack).
- Angina (chest pain, shortness of breath, nausea, pain in the back, shoulders and jaw).

- Changes in the way your heart beats, for example, if you notice it beating faster.

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

Other possible side effects:

Tell your doctor if you notice any of the following:

Frequent side effects:

- Headache
- Dizziness
- Quick heartbeat
- Palpitations (fast-beating, fluttering or pounding heart)
- Flushing, swelling in your lower legs or hands
- Weakness and lack of energy (asthenia)

Less frequent side effects:

- Sleepiness
- Depression
- Fatigue
- Fainting
- Low blood pressure (you may feel dizzy or lightheaded)
- Indigestion, discomfort or pain in abdomen
- Nausea
- Diarrhoea
- Abdominal pain
- Vomiting

- Muscle pain
- Large volumes of urine or frequent, abnormal urination.
- Fatigue

Frequency unknown

- Eye pain.
- Swollen gums
- Laboratory tests may reveal increased liver enzymes.

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, pharmacist or nurse. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of LERBLOK.

5. How to store LERBLOK

Store all medicines out of reach of children.

Store at or below 25 °C, in the original packaging. Keep blisters in the carton to protect from light, until required for use.

Do not store in a bathroom.

Do not use after the expiry date printed on the carton and on the blister.

Return all unused or expired medicine to your pharmacist for safe disposal.

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

6. Contents of the pack and other information

What LERBLOK contains

- The active substance is lercanidipine hydrochloride.

Each film-coated tablet contains 10 mg lercanidipine hydrochloride equivalent to 9,4 mg lercanidipine, or 20 mg lercanidipine hydrochloride equivalent to 18,8 mg lercanidipine.

- The other ingredients are:

10 mg film-coated tablets: Maize starch, sodium starch glycolate (Type A), colloidal anhydrous silica, cellulose microcrystalline (pH 113), poloxamer 188, sodium stearyl fumarate, macrogol 6000, hypromellose 6 cps, ferric oxide yellow (E172) and titanium dioxide (E171).

20 mg film-coated tablets: Cellulose microcrystalline (pH 112), maize starch, sodium starch glycolate (Type A), colloidal anhydrous silica, microcrystalline cellulose (pH 113), povidone (K-30), sodium stearyl fumarate, hypromellose 6 cps, macrogol 6000, ferric oxide red (E172) and titanium dioxide (E171).

What LERBLOK looks like and contents of the pack

Film-coated tablets.

LERBLOK 10 are yellow, round, biconvex, film-coated tablets with a breakline on one side and plain on the other side.

LERBLOK 20 are pink, round, biconvex, film-coated tablets with a breakline on one side and plain on the other side.

LERBLOK is available in blister packs using a white opaque PVC/PVdC film sealed with plain silver aluminium foil with heat seal lacquer coating. The blister strips are packed in cartons.

Pack sizes: 2 x 14, 3 x 10, 6 x 10 & 10 x 10 tablets.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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This leaflet was last revised in

21 September 2021

Registration numbers

LERBLOK 10: 52 / 7.1 / 0384

LERBLOK 20: 52 / 7.1 / 0385

Access to the corresponding Professional Information

For a copy of the Professional Information (PI), please contact

abex.regulatory@abexpharm.com .

Resource code: LER/L/A