PROPOSED PATIENT INFORMATION LEAFLET FOR LERZAN

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

LERZAN 10 and LERZAN 20 Film coated tablets

Lercanidipine Hydrochloride

LERZAN is sugar free

Read all of this leaflet carefully before you start taking LERZAN.

- 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.
- LERZAN 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 LERZAN is and what it is used for

2. What you need to know before you take LERZAN

3. How to take LERZAN

4. Possible side effects

5. How to store LERZAN

6. Contents of the pack and other information

1. What LERZAN is and what it is used for

LERZAN, lercanidipine hydrochloride, belongs to a group of medicines called Calcium Channel Blockers (dihydropyridine derivatives) that lower blood pressure.

PROPOSED PATIENT INFORMATION LEAFLET FOR LERZAN

LERZAN 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 LERZAN

Do not take LERZAN:

- If you are allergic (hypersensitive) to lercanidipine or any of the other ingredients of LERZAN (listed in section 6).
- If you are a woman of childbearing potential, unless you are using effective contraception.
- 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 or you are undergoing dialysis.
- If you are under the age of 18 years.
- If you are pregnant or breastfeeding your baby (see **Pregnancy and breastfeeding**).
- With grapefruit or grapefruit juice.
- If 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)

- If you are taking another medicine called ciclosporin (used after transplants to prevent organ rejection).

Warnings and Precautions

Talk to your doctor before taking LERZAN:

- If you have any heart problems, or if you have a pacemaker.
- If you have liver or kidneys problems, or you are on dialysis.

Children and adolescents

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

Other medicines and LERZAN

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

This is because when LERZAN is taken with other medicines the effect of LERZAN or of the other medicine may be changed or certain side effects may occur more frequently.

The following medicines should **not** be taken together with LERZAN (also see **Do not take LERZAN**):

- antifungal medicines (such as ketoconazole or itraconazole)
- macrolide antibiotics (such as erythromycin, troleandomycin or clarithromycin)
- antivirals (such as ritonavir).
- antidepressant medicines (such as fluoxetine)
- ciclosporin (used after transplants to prevent organ rejection)

Tell your doctor or pharmacist if you are taking any of the following medicines

- phenytoin, phenobarbitone or carbamazepine (medicines for epilepsy)
- rifampicin (a medicine to treat tuberculosis)
- astemizole or terfenadine (medicines for allergies)
- amiodarone, quinidine or sotalol (medicines to treat a fast heart beat)
- midazolam (a medicine that helps you sleep)
- beta-blockers e.g. propranolol and metoprolol (medicines to treat high blood pressure, heart failure and abnormal heart rhythms)
- digoxin (a medicine to treat a heart problem)
- cimetidine (more than 800 mg, a medicine for ulcers, indigestion, or heartburn)
- simvastatin (a medicine to lower cholesterol in your blood)
- other medicines to treat high blood pressure

LERZAN with food, drink and alcohol

- Do not take LERZAN together with grapefruit or grapefruit juice.
- Avoid alcohol, while you are taking LERZAN.

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 health care provider for advice before taking this medicine.

Do not take LERZAN if you are pregnant or breastfeeding your baby.

LERZAN should not be taken during pregnancy or by woman of child-bearing potential unless effective contraception is used.

Driving and using machines

LERZAN can cause dizziness, weakness, tiredness or drowsiness, and may impair

your ability to drive or use machines. Take special care before performing tasks requiring your attention, until you know how LERZAN will affect you.

3. How to take LERZAN

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

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

Adults

The usual recommended dose is one LERZAN 10 mg tablet daily at the same time each day, preferably in the morning at least 15 minutes before breakfast

Your doctor may increase your dose to one LERZAN 20 mg tablet daily, if needed.

The tablets should preferably be swallowed whole with some water.

Your doctor will prescribe the right dose for you, and tell you how long your treatment with LERZAN will last.

If you have the impression that the effect of LERZAN is too strong or too weak, tell your doctor or pharmacist.

If you take more LERZAN than you should

Do not take more than the prescribed dose. Taking more than the correct dose can cause an excessive drop in blood pressure and your heart can beat irregularly or faster.

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

If you forget to take LERZAN

Always take LERZAN as prescribed. If you have missed a dose by only a few hours, take

the missed dose as soon as you remember. If it is almost time for your next dose, skip the missed dose and take LERZAN at the next regularly scheduled time. Do not take a double dose to make up for forgotten individual doses.

If you stop taking LERZAN

If you stop taking LERZAN, your blood pressure may increase again.

Do not stop taking LERZAN unless your doctor tells you to.

4. Possible side effects

LERZAN can have side effects.

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

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

- Swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- Rash or itching
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to LERZAN. 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:

- Chest pain (angina) or uncomfortable, tight feeling in your chest, which may be signs of a problem with your heart

- Changes in the way your heart beats (beating faster, slower or irregular)

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Headache
- Sudden reddening of your face, neck or upper chest (flushing), accumulation of fluid causing swelling, usually in the lower limbs.

Less frequent side effects:

- Dizziness, sleepiness, fainting, feeling depressed
- Eye pain
- Sharp stabbing pains in your chest
- Low blood pressure
- Abdominal pain, diarrhoea, indigestion, nausea (feeling sick), vomiting (being sick), swelling of your gums
- Changes in liver function (detected by blood tests)
- Skin rash, itching, hives (urticaria)
- Muscle pain
- Passage of large amounts of urine, increased urinary frequency
- Feeling weak or tired

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.

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 LERZAN.

5. How to store LERZAN

Store all medicines out of reach of children.

Store at or below 25 ºC.

Store in the original package in order to protect from light.

Do not take after the expiry date stated on the package.

Return all unused medicine to your pharmacist.

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

6. Contents of the pack and other information

What LERZAN contains

The active substance is lercanidipine hydrochloride.

LERZAN 10: Each film coated tablet contains 10 mg lercanidipine hydrochloride (equivalent to 9.4 mg lercanidipine).

LERZAN 20: Each film coated tablet contains 20 mg lercanidipine hydrochloride (equivalent to 18.8 mg lercanidipine).

The other ingredients are cellulose microcrystalline, colloidal anhydrous silica, macrogol 6000, maize starch, sodium starch glycolate and sodium stearyl fumarate. LERZAN 10 also contains poloxamer 188 and LERZAN 20 contains povidone (K-30).

The tablet coating contains hypromellose, macrogol 6000 and titanium dioxide.

LERZAN 10 also contains ferric oxide yellow and LERZAN 20 contains ferric oxide red.

PROPOSED PATIENT INFORMATION LEAFLET FOR LERZAN

What LERZAN looks like and contents of the pack

LERZAN 10 are yellow coloured, round shaped biconvex, film coated tablets with a break-line on one side and plain on the other side.

LERZAN 20 are pink coloured, round shaped biconvex, film coated tablets with a break-line on one side and plain on the other side.

White opaque PVC/PVdC blisters film sealed with plain aluminium foil. The blisters are are packed in cartons.

Pack size: 30 or 60 film coated tablets.

Holder of certificate of registration

Activo Health (Pty) Ltd.

Block B

Arena Office Park

272 West Avenue

Centurion

0157

South Africa

This leaflet was last revised in

07 February 2025

Registration numbers

LERZAN 10: 50/7.1/0663

LERZAN 20: 50/7.1/0664