Approved 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.

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, 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 (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 cyclosporin (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;
- You have problems with your liver or kidneys or you are on dialysis;

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 cyclosporin (used after transplants to prevent organ rejection).
- 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 tubercolosis).
- 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.

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

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.

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 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

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;
- 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;

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.
This includes any possible side effects not listed in this leaflet.
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 **LERTENS**.

5. How to store LERTENS
KEEP ALL MEDICINES OUT OF THE REACH AND SIGHT OF CHILDREN.
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 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.

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 lercanidpine 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
Ranbaxy Pharmaceuticals (Pty) Ltd
14 Lautre Road, Stormill, Ext.1,
Roodepoort, 1724
South Africa

This leaflet was last revised in:

Registration number(s):
Lertens 10 : 50/7.1/0638
Lertens 20:50/7.1/0636

Approved Patient information leaflet

SKEDULERINGSTATUS
S3
LERTENS 10 (Filmbedekte tablette)
(Lerkanidipienhidrochloried)
Natriuminhoud: 0,788 mg per tablet
Suikervry
LERTENS 20 (Filmbedekte tablette)
(Lerkanidipienhidrochloried)
Natriuminhoud: 1,227 mg per tablet
Suikervry

Lees hierdie hele inligtingsblad noukeurig deur voordat jy begin om LERTENS te neem
- Hou hierdie inligtingsblad. Dit mag vir jou nodig wees om dit weer te lees.
- Vra asseblief jou dokter, apteker, verpleegkundige of ander gesondheidsorgdeskundige as jy verdere vrae het.
- **LERTENS** is vir jou persoonlik voorgeskryf en jy moenie jou medisyne met ander persone deel nie. Dit kan skadelik vir hulle wees, selfs as hulle dieselfde simptome as jy het.

Wat is in hierdie inligtingstuk
1. Wat **LERTENS** is en waarvor dit gebruik word
2. Wat jy moet weet voordat jy **LERTENS** neem
3. Hoe om **LERTENS** te neem
4. Moontlike newe-effekte
5. Hoe om **LERTENS** te bewaar
6. Inhoud van die verpakking en ander inligting

1. Wat LERTENS is en waarvoor dit gebruik word
Lerkanidipien behoort aan ‘n groep medisyne wat kalsiumkanaal-remmers genoem word (dihidropiridien-derivate). **LERTENS** word gebruik om hoë bloeddruk, ook bekend as hipertensie, te behandel by volwassenes ouer as 18 jaar.

2. Wat jy moet weet voordat jy LERTENS neem

Moenie LERTENS neem nie as:
- Jy allergies (hipersensitief) is vir lerkanidipienhidrochloried of vir enige van die ander bestanddele van **LERTENS-**tablette;
- Jy allergiese reaksies gehad het vir medisyne wat nou verwant is aan **LERTENS-**tablette (soos amlodipien, nikardipien, felodipien, isradipien, nifedipien of lakidipien).
- As jy aan sekere hartsiektes ly:
  - Onbehandelde hartversaking;
  - Belemmering vir die vloei van bloed vanuit die hart;
  - Onstabiele angina (borskasongemak wat rustend voorkom of progressief erger word);
  - Binne een week na ‘n hartaanval.
- Jy ernstige lewerprobleme het;
- As jy ernstige nierprobleme het of as jy dialise ondergaan.
- Jy medisyne neem, soos:
  - Swamdodende middels (soos ketokonasool of itrakonasool);
  - Makrolied-antibiotika (soos eritromisien, troleandomisien of klaritromisien);
- Antivirale middels (soos ritonavir);
- Antidepressante (soos fluoksetien)

- Jy ander medisyne neem wat siklosporien genoem word (gebruik ná oorplantings om orgaanverwerping te voorkom).

Moenie LERTENS saam met pomelo's of pomelosap neem nie.
Moenie gebruik as jy swanger is of borsvoed nie (sien afdeling Swangerskap en Borsvoeding vir meer inligting).
LERTENS word nie aanbeveel vir kinders jonger as 18 jaar nie.
Waarskuwings en voorsorgmaatreëls
Tref spesiale voorsorg met **LERTENS** as:
- Jy sekere harttoestande of pasaangeër of voorafbestaande angina het;
- Jy probleme met jou lewer of niere het of as jy dialise ondergaan.

Kinders en adolessente
Moenie **LERTENS** aan kinders jonger as 18 jaar toegedien word nie omdat die veiligheid en doeltreffendheid van **LERTENS** nie vasgestel is by kinders jonger as 18 jaar nie.

Ander medisyne en LERTENS
Lig jou gesondheidsorgverskaffer altyd in as jy enige ander medisyne gebruik. (Dit sluit komplementêre of tradisionele medisyne in).
Lig jou dokter of apteker asseblief in as:
- Jy medisyne gebruik wat remmers van CYP3A4-isoënsiem is (medisyne wat die bloedvlakke van lerkanidipien kan verhoog):
  - Swamdodende middels (soos ketokonasool of itrakonasool);
  - Makrolied-antibiotika (soos eritromisien, troleandomisien of klaritromisien);
  - Antivirale middels (soos ritonavir);
  - Antidepressante (sood fluoksetien)
- Jy siklosporien neem (gebruik ná oorplantings om orgaanverwerping te voorkom).

Jy moenie hierdie medisyne saam met **LERTENS** neem nie**.**
- Jy beta-blokkers bv. metoprolol, diuretika (watertablette) gebruik of
- AOE-remmers (medisyne om hoë bloeddruk te behandel).
- Jy simetidien neem (meer as 800 mg, 'n middel vir maagsere, slegte spysvertering of sooibrand).
- Jy digoksien neem ('n middel wat gebruik word om hartprobleme te behandel).
- Jy midazolam neem ('n middel wat jou help om te slaap).
- Jy simvastatien neem ('n middel wat cholesterol in jou bloed verlaag).
- Jy rifampisien neem ('n middel om tuberkulose te behandel).
- Jy astemisool of terfenadien neem (medisyne vir allergieë).
- Jy amiodaroon of kinidien neem (middel om 'n vinnige hartklop te behandel).
- Jy fenitoïen, fenobarbitoon of karbamasepien neem (medisyne vir epilepsie).
- Jy ander medisyne neem om hoë bloeddruk te behandel.

LERTENS saam met voedsel, drinkgoed en alkohol
Moenie alkohol gebruik tydens behandeling met **LERTENS** nie, aangesien dit die effek van **LERTENS** kan verhoog.
LERTENS moet nie saam met pomelosap geneem word nie.

Swangerskap, borsvoeding en vrugbaarheid

As jy swanger is of borsvoed, dink dat jy swanger is of van plan is om 'n baba te kry, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat jy hierdie medisyne gebruik.

Moenie **LERTENS** neem as jy swanger is of borsvoed nie, of as jy beplan om swanger te raak nie of as jy nie enige voorbehoedmiddels gebruik nie.

Bestuur en gebruik van masjinerie
Dit is nie altyd moontlik om te voorspel tot watter mate **LERTENS** met jou daaglikse aktiwiteite kan inmeng nie**.** Jy moet seker maak dat jy nie betrokke raak in die bogenoemde aktiwiteite nie totdat jy bewus is van tot watter mate **LERTENS** jou affekteer.
Versigtigheid moet toegepas word omdat **LERTENS** duiseligheid, swakheid en moegheid kan veroorsaak.

3. Hoe om LERTENS te neem

Moenie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.
Neem **LERTENS** altyd presies soos wat jou dokter of apteker dit voorgeskryf het. Kontroleer met jou dokter of apteker as jy nie seker is nie.

Volwassenes: Die gewone dosis is een **LERTENS 10** tablet daagliks op dieselfde tyd elke dag, verkieslik in die oggend ten minste 15-minute voor ontbyt, omdat 'n hoë vet maaltyd bloedvlakke van die medisyne aansienlik verhoog. Jou dokter kan aanraai dat die dosis verhoog word na een **LERTENS 20** tablet daagliks, indien nodig. Die tablette moet verkieslik heel met water ingesluk word. Jou dokter sal jou inlig oor hoe lank jou behandeling met **LERTENS** sal duur. As jy onder die indruk is dat die effek van **LERTENS** te sterk of te swak vir jou is, moet jy jou dokter of apteker inlig.

As jy meer LERTENS geneem het as wat jy behoort te neem
Raadpleeg jou dokter of apteker in die geval van oordosering. As nie een van hulle beskikbaar is nie, kontak die naaste hospital of gifbeheersentrum.
Oorskryding van die regte dosis kan veroorsaak dat die bloeddruk te laag kan daal en die hart onreëlmatig of vinniger klop. Dit kan ook tot bewusteloosheid lei.

As jy vergeet het om LERTENS te neem
Neem **LERTENS** altyd presies soos voorgeskryf. As jy egter vergeet het om 'n dosis te neem, slaan die dosis oor en neem die volgende dosis op die normale tyd.
Moenie 'n dubbele dosis neem om te vergoed vir die individuele dosis wat jy vergeet het nie.

As jy ophou om LERTENS te neem
As jy ophou om **LERTENS** te neem, kan jou bloeddruk weer verhoog. Raadpleeg asseblief jou dokter voordat jy die behandeling staak.
Vra jou dokter of apteker as jy enige verdere vrae het oor die gebruik van hierdie produk.

4. Moontlike newe-effekte

LERTENS kan newe-effekte hê. Nie alle newe-effekte wat vir **LERTENS** aangemeld is, is in hierdie inligtingstuk ingesluit nie. Raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgdeskundige vir advies as jou algemene gesondheid sou versleg of as jy enige ongewenste effekte ervaar terwyl jy **LERTENS** neem**.**
Indien enige van die volgende gebeur, staak die gebruik van **LERTENS** en lig jou dokter onmiddellik in of gaan na die noodgevalle afdeling by jou naaste hospitaal:

- Kortasemigheid, hyging of moeilike asemhaling, swelling van die gesig, lippe, tong of ander dele van die liggaam, uitslag, gejeuk of korwe op die vel (allergiese reaksie, angio-edeem).

Hierdie is baie ernstige newe-effekte. As jy dit het, kon jy 'n ernstige allergiese reaksie teenoor **LERTENS** gehad het**.** Jy mag dringende mediese aandag of hospitalisasie benodig.
Lig jou dokter onmiddellik in of gaan na die noodgevalle afdeling by jou naaste hospitaal as jy enige van die volgende opmerk:

- Angina pectoris (borskaspyn as gevolg van 'n tekort van bloedvloei in jou hart);
- Skerp steekpyne in die borskas, daling in die bloeddruk, hartaanval.

Met die groep medisyne waaraan **LERTENS** behoort, kan jy verhoogde voorkoms, duur of ernstigheid van hierdie aanvalle ervaar as jy aan voorafbestaande angina pectoris ly.
Hierdie is ernstige newe-effekte. Jy mag dringend mediese aandag benodig.
Lig jou dokter in as enige van die volgende gebeur:

<u>Dikwelse newe-effekte:</u>

- Hoofpyn;
- Duiseligheid;
- Vinniger hartklop;
- Swelling van hande, enkels of voete;
- Skielike rooiheid van die gesig, nek of boonste gedeelte van die borskas;
- Ongewone swakheid.

<u>Minder dikwelse newe-effekte:</u>

- Slaperigheid;
- Floute;
- Siek gevoel;
- Slegte spysvertering;
- Braking;
- Maagpyn, spierpyn;
- Diarree;
- Veluitslag;
- Gejeuk;
- Netelroos (jeukende uitslag);
- Passeer meer urine as normaalweg;
- Moegheid.

<u>Voorkoms onbekend:</u>

- Geestelike depressie;
- Oogpyn;
- Veranderinge in lewerfunksie (waargeneem deur bloedtoetse);
- Swelling van die tandvleise;

Lig asseblief jou dokter of apteker in as jy enige newe-effekte opmerk wat nie in hierdie inligtingstuk opgeneem is nie.

Aanmelding van newe-effekte
Praat met jou dokter, apteker of verpleegkundige as jy newe-effekte ervaar.
Dit sluit enige moontlike newe-effekte in wat nie in hierdie inligtingstuk opgeneem is nie.
Jy kan ook newe-effekte by SAHPRA aanmeld *via* die "**6.04 Adverse Drug Reaction Reporting Form**", wat aanlyn beskikbaar is onder SAHPRA se publikasies:
https://www.sahpra.org.za/Publications/Index/8.
Deur newe-effekte aan te meld, kan jy meer inligting oor die veiligheid van **LERTENS** verskaf.

5. Hoe om LERTENS te bewaar
HOU ALLE MEDISYNE BUITE DIE BEREIK EN SIG VAN KINDERS.
Moenie hierdie medisyne ná die vervaldatum, soos aangedui op die karton en stulpstrook, gebruik nie. Die vervaldatum verwys na die laaste dag van daardie maand.
Hou die stulpstroke in die buitenste karton om dit teen lig te beskerm.
Moenie enige medisyne *via* afvalwater of huishoudelike afval weggooi nie.
Vra jou apteker hoe jy van medisyne ontslae kan raak wat jy nie langer gebruik nie.
Hierdie maatreëls sal help om die omgewing te beskerm.

6. Inhoud van die verpakking en ander inligting

Wat LERTENS bevat
Die aktiewe bestanddel is lerkanidipienhidrochloried.
Elke filmbedekte tablet bevat 10 mg/20 mg lerkanidipienhidrochloried.
Die ander bestanddele is: Mikrokristallyne sellulose, kolloïdale silikondioksied, rooi ysteroksied, geel ysteroksied, hipromellose 6cps, makrogol 6000, mieliestysel, metanol, poloksamer 188, povidoon K-30, natrium-styselglikolaat, natrium-stearielfumaraat, titaandioksied.

Hoe LERTENS lyk en inhoud van die verpakking
LERTENS 10
Geelgekleurde, ronde, bikonvekse, filmbedekte tablette met ‘n breeklyn op die een kant en skoon op die ander kant.
LERTENS 20
Pienkgekleurde, ronde, bikonvekse, filmbedekte tablets tablette met ‘n breeklyn op die een kant en skoon op die ander kant.

Houer van die Registrasiesertifikaat
Ranbaxy Pharmaceuticals (Pty) Ltd
Lautreweg 14, Stormill, Uitbreiding1,
Roodepoort, 1724
Suid-Afrika

Hierdie inligtingstuk was laas hersien op:

Registrasienommers:
Lertens 10: 50/7.1/0638
Lertens 20: 50/7.1/0636