PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

LECARDOP 25/250 tablets

LECARDOP 25/100 tablets

Carbidopa and levodopa

Sugar free

Read all of this leaflet carefully before you start taking LECARDOP tablets.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- LECARDOP 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 LECARDOP is and what it is used for
2. What you need to know before you take LECARDOP
3. How to take LECARDOP
4. Possible side effects
5. How to store LECARDOP
6. Contents of the pack and other information

1. What LECARDOP is and what it is used for

LECARDOP contains two different medicines called levodopa and carbidopa. Levodopa turns into dopamine in your brain. Dopamine helps to improve the signs of your Parkinson's disease. Carbidopa belongs to a group of medicines called aromatic amino acid decarboxylase inhibitors. It helps levodopa work more effectively by slowing the speed at which levodopa is broken down in your body.

LECARDOP improves the signs of Parkinson's disease such as:

- Stiff muscles.
- Slowness of movement.
- Unsteadiness, shaking or trembling (tremor).
- Difficulties swallowing.
- Drooling or excessive salivation.

If not treated, Parkinson's disease can make it hard for you to continue your normal daily activities.

2. What you need to know before you take LECARDOP

Do not take LECARDOP if:

- You are allergic (hypersensitive) to carbidopa, levodopa or any of the other ingredients of LECARDOP (listed in section 6.1).
- You have ever had skin cancer or you have any unusual moles which have not been examined by your doctor.
- You are taking certain medicines called 'MAOIs' (monoamine oxidase inhibitors). You need to stop taking these medicines at least two weeks before you start LECARDOP (see "Other medicines and LECARDOP" below).
- You have a condition called 'narrow-angle glaucoma' that may cause a sudden build-up of pressure in your eye.
- You have a severe mental disorder.
- You are pregnant, might become pregnant, or are breastfeeding.

Warnings and precautions:

Tell your doctor or pharmacist if:

- You are taking levodopa (used to treat Parkinson's disease).
- You have a history of fits (convulsions).
- You have a history of an ulcer in your gut (called 'duodenal' or 'peptic' ulcer) or have vomited blood.
- You have had a heart attack or have abnormal heart beat (changes in the way your heart beats), circulation or breathing problems (such as asthma).
- You have had kidney, liver or hormonal problems.
- You are depressed or you suffer from other mental problems.
- You experience suicidal thoughts or tendencies. Please consult your doctor or health care provider immediately.
- You have a condition called 'chronic wide-angle glaucoma' that may cause a build-up of pressure in your eye. You must have regular checks to monitor the pressure in your eye.
- You sometimes have sudden sleep attacks or sometimes feel very sleepy.
- You are due to have general anaesthesia (if you are having surgery done).
- You cannot control your movements (involuntary movements).
- You experience an urge to gamble or spend money. Please consult your doctor or health care provider as soon as possible.
- You experience an increase in sexual desire. Please consult your doctor or health care provider as soon as possible.
- You cannot control your eating habits (such as compulsive eating or binge eating). Please consult your doctor or health care provider as soon as possible.
- You suffer from seizures (fits) or you have had a seizure previously.
- Patients who have Parkinson's disease are more prone to develop skin cancer. You must have regular skin examinations by your doctor to monitor your skin for the development of abnormal lesions/moles.

- You or your family/care giver notices you are developing addiction-like symptoms leading to craving for large doses of LECARDOP or other medicines used to treat Parkinson's disease.

Children and adolescents:

LECARDOP is not suitable for children under the age of 18 years.

Other medicines and LECARDOP:

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

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- Medicines for Parkinson's disease *containing* levodopa:

  If they are 'slow release', you will need to wait 24 hours after your last dose before starting LECARDOP. If they are 'normal release', you will need to wait 12 hours after your last dose before starting LECARDOP.

  Tell the doctor or pharmacist even if you have only taken them in the past.

  Medicines for Parkinson's disease which *do not contain* levodopa will usually be continued. However, your dose may be changed.
- Antihypertensive medicines, such as reserpine (used to treat high blood pressure).
- Antidepressant medicines, such as selegiline (used to treat depression).
- Iron or iron supplements (used to treat low iron levels in your body).
- Metoclopramide (used to treat nausea and vomiting).
- Medicines called 'MAOIs' (monoamine oxidase inhibitors) (see also "Do not take LECARDOP if").
- Anticholinergic medicines, such as orphenadrine (used to treat muscle spasms), trihexyphenidyl, benzatropine and procyclidine (used to treat Parkinson's disease). Your dose may need to be changed.
- Phenytoin (used to treat fits/convulsions).
- Papaverine (used to treat impotence in men).

- Haloperidol, phenothiazines, butyrophenones or risperidone (used to treat schizophrenia or mental problems).
- Isoniazid (used to treat tuberculosis (TB)).
- Tetrabenazine (used to decrease uncontrollable movements).
- High protein diet or protein supplements.

Laboratory tests while you are taking LECARDOP:

LECARDOP can affect some laboratory tests that your doctor may perform on blood or urine samples. Please remind your doctor if you are taking LECARDOP and are having any urine or blood tests.

LECARDOP with food and drink:

Avoid a diet containing too much protein (meat, eggs, milk and cheese), since LECARDOP may not work as well as it should. Always take LECARDOP on an empty stomach.

Pregnancy and breastfeeding:

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 before taking LECARDOP.

Do not take LECARDOP if you are pregnant, might become pregnant or are breastfeeding.

Levodopa, one of the substances in LECARDOP, is passed into human milk.

Driving and using machines:

LECARDOP can have side effects, such as drowsiness or dizziness, which may affect one's ability to drive a vehicle or use tools or machines (see section 4). Do not drive a vehicle or use tools or machines until you know how LECARDOP affects you.

LECARDOP can also make you sleepy or cause 'sudden sleep attacks'. If this happens to you, you must not drive a vehicle or use tools or machines. Your doctor will tell you when you can start driving again if these attacks stop.

3. How to take LECARDOP

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

Always take LECARDOP exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Your doctor will determine the correct dose for you and will adjust your dose according to the severity of your disease and your response to LECARDOP treatment. Inform your doctor of any changes in your condition as this may require an adjustment in your prescribed dose.

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

If you take more LECARDOP 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.

If you forget to take LECARDOP:

If you have missed your 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 LECARDOP at the next regularly scheduled time.

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

Effects when treatment with LECARDOP is stopped:

Do not stop taking LECARDOP or change your dose without talking to your doctor first. When you

stop taking LECARDOP the following may occur: stiff muscles, high temperature (fever) and mental changes.

4. Possible side effects

LECARDOP can have side effects.

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

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

- Swelling of your hands, feet, ankles, face, 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 allergic reaction to LECARDOP. 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:

The following side effects occur frequently:

- Yellowing of your skin and eyes, also called jaundice.
- Chest pain.
- Mental changes including delusions, hallucinations (seeing or hearing things that are not real), increased suspiciousness and depression with thoughts of harming yourself.
- Uneven (irregular) heartbeat or palpitations.
- Blood problems, the signs may include pale skin (pallor), tiredness, fever, sore throat or mild bruising and prolonged bleeding after injury.

- Fits (convulsions).
- Shortness of breath.
- Bladder infection (frequent urge to urinate, painful urination or burning sensation during urination).
- Frequent need to urinate.
- Damage to your nerves (weakness, numbness or pain in your hands or feet).
- Neuroleptic malignant syndrome (NMS) (high fever, tight/stiff muscles, altered mental status (feeling confused, agitated or disoriented), changes in the way your heart beats, changes in your pulse rate or blood pressure and increased sweating).
- infections in your urinary system

The following side effects occur less frequently:

- Bleeding from your gut which may be seen as blood in your faeces or darkened faeces (gastrointestinal bleeding).
- Irregular movement of your eye (prolonged, involuntary upward deviation of your eyes).
- Difficulty passing urine or incontinence (inability to control urine flow).
- Changed patches of pigmented skin, including irritated or irregular moles, or moles in which you have noticed changes (melanoma).
- Blistering skin rash.

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

Tell your doctor as soon as possible if you notice any of the following:

The following side effects occur frequently:

- Dizziness on standing-up quickly.
- Abnormal movements such as twitching or spasms (which may or may not be like your Parkinson's symptoms).
- Nausea.
- Anorexia (severe weight loss), high blood pressure.
- Inflammation of your veins.

- Being sick (vomiting), diarrhoea, constipation, indigestion, dry mouth.
- Discolouration of urine, sweat or saliva.
- "On-off" phenomenon, characteristic of some people with long-standing Parkinson's disease. This is when you can have unpredictable changes from being mobile - "on" - to a sudden inability to move - "off". "Off" to "on" can occur just as suddenly.
- Dizziness.
- Sleepiness (including excessive drowsiness or sudden sleep onset episodes).
- Dream abnormalities (including nightmares), difficulty sleeping.
- Confusion, feeling agitated.
- Increased sexual drive.
- Increased sweating, hair loss.
- Impulsivity (lack of self-control), an excessive desire to gamble.
- Back pain, shoulder pain, muscle cramps.
- Weakness.
- Infection of your upper respiratory tract (sore throat, blocked sinuses, coughing, runny nose).

The following side effects occur less frequently:

- Paraesthesia (pins and needles).
- Loss of control over the voluntary movements of everyday life.
- Numbness, increased tremor (involuntary movement), muscle twitching, irregular movement of jaw muscles resulting in difficulty opening the mouth (muscle spasm).
- Feeling anxious or high (euphoric), nervousness.
- Loss of memory or disorientation.
- Falling over or abnormal walking patterns.
- Headache.
- Drooping or involuntary closing of your eyelids, dilated pupils.
- Changes in vision (blurred vision or double vision).
- Excessive production of saliva, swelling of the salivary glands, difficulty swallowing, grinding of your teeth, bitter taste.

- Hiccups, abdominal pain and distress, wind, heartburn.
- Burning sensation of your tongue.
- Persistent and painful erection of the penis.
- Leg pain.
- Weight gain or weight loss, swelling of your limbs due to water retention.
- Flushing, hot flushes.
- Hoarseness, general feeling of being unwell.
- Tiredness.
- Increased energy or activity, unusual breathing patterns.
- Throat pain or coughing.
- Changes in your blood results when tests are done.
- Strong impulse to gamble.
- Increased sexual interest or urge.
- Uncontrollable excessive shopping or spending.
- Eating large amounts of food in a short time period

Frequency not known:

- Craving for large doses of LECARDOP in excess of that required to control motor symptoms, known as dopamine dysregulation syndrome. Some patients experience severe abnormal involuntary movements (dyskinesias), mood swings or other side effects after taking large doses of LECARDOP.

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 "**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 LECARDOP.

5. How to store LECARDOP

- Store at or below 25 °C.
- Store in the original package in order to protect from light.
- Store all medicines out of reach of children.
- Do not use LECARDOP after the expiry date which is stated on the blister and carton after 'EXP.' The expiry date refers to the last day of that month.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.
- Keep the bottle tightly closed.

6. Contents of the pack and other information

What LECARDOP contains:

The active substances in LECARDOP are carbidopa and levodopa.

Each tablet of LECARDOP 25/250 contains 25 mg carbidopa and 250 mg levodopa.

Each tablet of LECARDOP 25/100 contains 25 mg carbidopa and 100 mg levodopa.

The other ingredients are corn starch/maize starch, D&C Yellow no. 10 aluminium lake (LECARDOP 25/100), FD&C Blue no. 2 aluminium lake (LECARDOP 25/250), FD&C Yellow no. 6 aluminium lake (LECARDOP 25/100), magnesium stearate, microcrystalline cellulose, pregelatinised starch and sodium starch glycolate.

What LECARDOP looks like and contents of the pack:

LECARDOP 25/250: Mottled blue to light blue coloured oval shaped, biconvex, uncoated tablets debossed with "519" on one side and scored on the other side.

LECARDOP 25/100: Mottled (Orange coloured speckles) yellow to light yellow coloured oval shaped, biconvex, uncoated tablets debossed with "518" on one side and scored on the other side.

LECARDOP tablets are packed into HDPE, white, smooth, round bottles with a white ribbed child resistant cap, embossed with a pictorial design on top. The bottle is packed in a printed outer carton.

Pack size: 100 tablets.

Holder of certificate of registration and manufacturer:

Ranbaxy Pharmaceuticals (Pty) Ltd

14 Lautre Road

Stormill, Ext. 1, Roodepoort

Johannesburg 1724

011 495 0100

This leaflet was last revised:

06 February 2024

Registration numbers:

LECARDOP 25/250: 45/5.4.1/0764

LECARDOP 25/100: 45/5.4.1/0765

Date of registration:

25 November 2016