Date of submission: 19 August 2022
Approved: 31 October 2022

Patient Information Leaflet for LECARDOP 25/250 and 25/100

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

Date of submission: 19 August 2022
Approved: 31 October 2022

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, such as antisocial behaviour (behaviour that is considered to be disruptive to others in society).
- 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 texts 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).

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: 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:

31 October 2022

Registration numbers:

LECARDOP 25/250: 45/5.4.1/0764

Date of submission: 19 August 2022
Approved: 31 October 2022

LECARDOP 25/100: 45/5.4.1/0765

Date of registration:

25 November 2016

This submission: Clinical Safety Update and PI/PIL reformat
Date of submission: 20 May 2022

Pasiëntinligtingsblad vir LECARDOP 25/250 and 25/100

SKEDULERINGSTATUS

S4

LECARDOP 25/250 tablette

LECARDOP 25/100 tablette

Karbidopa and levodopa

Suikervry

Lees die hele inligtingsblad noukeurig deur voordat jy begin om LECARDOP tablette te neem.

- Hou hierdie inligtingsblad. Dit mag vir jou nodig wees om dit weer te lees.
- Indien jy enige verdere vrae het, vra asseblief jou dokter, apteker, verpleegster of ander gesondheidsorgvoorsiener.
- LECARDOP is vir jou persoonlik voorgeskryf en jy moenie jou medisyne met enige ander persone deel nie. Dit mag skadelik vir hulle wees, selfs as hulle dieselfde simptome as jy het.

Wat is in hierdie inligtingsblad:

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

1. Wat is LECARDOP en waarvoor word dit gebruik

LECARDOP bevat twee verskillende middels, naamlik levodopa en karbidopa. Levodopa verander na dopamien in jou brein. Dopamien help om die tekens van jou Parkinson se siekte te verbeter. Karbidopa behoort aan ‘n groep van medisyne wat aromatiese aminosuur-dekarboksilase-remmers genoem word. Dit help levodopa om meer doeltreffend te werk deur die tempo waardeur levodopa in jou liggaam afgebreek word, te vertraag.

LECARDOP verbeter die tekens van Parkinson se siekte soos:

- Spierstyfheid.
- Stadige beweging.
- Onvastigheid, skudding of bewing (rillings).
- Moeilike sluk.
- Kwyling van oormatige speeksel.

Parkinson se siekte kan dit vir jou moeilik maak om voort te gaan met jou daaglikse aktiwiteite as dit nie behandel word nie.

2. Wat jy moet weet voordat jy LECARDOP neem

Moenie LECARDOP neem nie as:

- Jy allergies (hipersensitief) is vir karbidopa, levodopa of enige van die ander bestanddele van LECARDOP (gelys in afdeling 6.1).
- Jy al ooit velkanker gehad het, of jy enige ongewone moesies wat nie deur jou dokter ondersoek is nie.

- Jy sekere medisyne neem wat 'MAOIs' (monoamienoksidase-remmers) genoem word. Jy moet ten minste twee weke voordat jy begin om LECARDOP te neem, ophou om hierdie medisyne te gebruik (sien "Ander medisyne en LECARDOP" hieronder).
- Jy 'n toestand het wat 'nou-hoek gloukoom' genoem word wat 'n skielike opbou van druk in jou oog kan veroorsaak.
- Jy 'n ernstige geestesversteuring het.
- Jy swanger is, swanger mag raak, of as jy borsvoed.

Waarskuwings en voorsorgmaatreëls:

Lig jou dokter of apteker in as:

- Jy levodopa neem (gebruik om Parkinson se siekte te behandel).
- Jy 'n geskiedenis van toevalle (stuiptrekkings) het.

  Jy 'n geskiedenis van 'n ulkus in jou ingewande (sogenaamde 'duodenale' of 'peptiese' ulkus) het of indien jy bloed gebraak het.
- Jy 'n hartaanval gehad het of abnormale hartklop (veranderings in die manier waarop jou hart klop), sirkulasie- of asemhalingsprobleme (soos asma) het.
- Jy nier, lewer of hormoonprobleme gehad het.
- Jy depressief is of aan ander geestesversteurings ly.
- Jy selfdoodgedagtes of -neigings ervaar. Raadpleeg asseblief onmiddellik jou dokter of gesondheidsorgvoorsiener.
- Jy 'n toestand het wat 'chroniese wye-hoek gloukoom' genoem word wat 'n opbou van druk in jou oog kan veroorsaak. Jy moet gereelde ondersoeke ondergaan om die druk in jou oog te moniteer.
- Jy soms uit die bloute aan die slaap raak en soms baie lomerig voel.
- Jy algemene narkose moet kry (as jy 'n operasie moet ondergaan).

- Jy nie jou bewegings kan beheer nie (onwillekeurige bewegings).
- Jy 'n drang ondervind om te dobbel of om geld uit te gee. Raadpleeg asseblief jou dokter of gesondheidsorgvoorsiener so gou as moontlik.
- Jy verhoogde seksuele begeerte ervaar. Raadpleeg asseblief jou dokter of gesondheidsorgvoorsiener so gou as moontlik.
- Jy nie jou eetgewoontes kan beheer nie (soos kompulsiewe etery of ooretery). Raadpleeg asseblief jou dokter of gesondheidsorgvoorsiener so gou as moontlik.
- Jy ly aan toevalle (stuiptrekkings) of as jy voorheen 'n toeval gehad het.
- Pasiënte met Parkinson se siekte is meer geneig om velkanker te ontwikkel. Jou dokter moet jou vel gereeld ondersoek om dit vir die ontwikkeling van abnormale letsels/moesies te moniteer.
- Jy of jou familie/versorger opmerk dat jy verslawingsagtige simptome ontwikkel wat lei tot die behoefte vir groter dosisse van LECARDOP of ander medisyne wat gebruik word om Parkinson se siekte te behandel.

Kinders en adolessente:

LECARDOP is nie geskik vir kinders onder die ouderdom van 18 jaar nie.

Ander medisyne en LECARDOP:

Lig jou gesondheidsorgvoorsiener altyd in as jy enige ander medisyne gebruik. (Dit sluit komplementêre of tradisionele medisyne in.)

Lig jou dokter of apteker veral in indien jy enige van die volgende medisyne gebruik:

- Medisyne vir Parkinson se siekte wat levodopa *bevat*:

Indien dit 'stadige vrystelling' is, moet jy 24 uur ná jou laaste dosis wag voordat jy begin om **LECARDOP** te neem. Indien dit 'normale vrystelling' is, moet jy 12 uur ná jou laaste dosis wag voordat jy begin om **LECARDOP** te neem.

Lig jou dokter of apteker in, selfs al het jy dit net in die verlede gebruik.

Medisyne vir Parkinson se siekte wat *nie* levodopa *bevat nie* sal gewoonlik voortgesit word. Jou dosis mag egter aangepas word.

- Antihipertensiewe medisyne, soos reserpien (gebruik om hoë bloeddruk te behandel).
- Antidepressante, soos selegilien (gebruik om depressie te behandel).
- Yster of ysteraanvullings (gebruik om lae ystervlakke in jou liggaam te behandel).
- Metoklopramied (gebruik om naarheid en braking te behandel).
- Medisyne wat 'MAOIs' (monoamienoksidase-remmers) genoem word (sien ook "Moenie LECARDOP neem nie as").
- Anticholinergiese medisyne, soos orfenadrien (gebruik om spierspasmas te behandel), triheksifenidiel, bensatropien en prosiklidien (gebruik om Parkinson se siekte te behandel). Dit mag nodig wees om jou dosis aan te pas.
- Fenitoïen (gebruik om toevalle/konvulsies te behandel).
- Papaverien (gebruik om impotensie in mans te behandel).
- Haloperidol, fenotiasiene, butirofenone of risperidoon (gebruik om skisofrenie of geesteversteurings te behandel).
- Isoniasied (gebruik om tuberkulose (TB) te behandel).
- Tetrabenasien (gebruik om ongekontrolleerse bewegings te verminder).
- Hoëproteïendieet of proteïenaanvullings.

Laboratoriumtoetse terwyl jy LECARDOP neem:

LECARDOP kan sommige laboratoriumtoetse affekteer wat jou dokter mag uitvoer op bloed- of urine monsters. Herinner asseblief jou dokter daaraan dat jy LECARDOP neem en wanneer jy enige urine of bloedtoetse moet kry.

LECARDOP saam met voedsel en drinkgoed:

Vermy ‘n dieet wat te veel proteïene (vleis, eiers, melk en kaas) bevat, aangesien LECARDOP nie so doeltreffend mag werk soos wat dit moet nie. Neem LECARDOP altyd op ‘n leë maag.

Swangerskap en borsvoeding:

As jy swanger is of borsvoed, dink dat jy swanger mag wees of as jy beplan om ‘n baba te kry, moet jy asseblief jou dokter, apteker of ander gesondheidsorgvoorsiener raadpleeg voordat jy LECARDOP neem.

Moenie LECARDOP neem as jy swanger is, swanger mag raak of as jy borsvoed nie. Levodopa, een van die bestanddele in LECARDOP, word in borsmelk uitgeskei.

Bestuur em gebruik van masjinerie:

LECARDOP kan newe-effekte, soos lomerigheid of duiseligheid, hê wat jou vermoë om ‘n voertuig te bestuur of gereedskap en masjinerie te gebruik, mag belemmer (sien afdeling 4). Moenie ‘n voertuig bestuur of gereedskap en masjinerie gebruik totdat jy weet hoe LECARDOP jou sal affekteer nie. LECARDOP kan jou ook slaperig maak of ‘skielike aanvalle van slaap’ veroorsaak. Indien dit met jou gebeur, moet jy nie ‘n voertuig bestuur of gereedskap en masjinerie gebruik nie. Jou dokter sal vir jou sê wanneer jy weer kan begin bestuur indien hierdie aanvalle ophou.

3. Hoe om LECARDOP te neem

Moenie medisyne wat vir jou voorgeskryf is, met enige ander persone deel nie.

Neem LECARDOP altyd presies soos wat jou dokter dit voorgeskryf het. Kontroleer met jou dokter of apteker indien jy onseker is.

Jou dokter sal bepaal wat die regte dosis vir jou is en sal die dosis aanpas na gelang van die ernstigheidsgraad van jou siekte en jou respons op die behandeling met LECARDOP. Lig jou dokter in rakende enige veranderings in jou toestand aangesien dit kan aandui dat jou voorgeskrewe dosis aangepas moet word.

Jou dokter sal jou inlig oor hoe lank jou behandeling met LECARDOP sal voortduur. As jy onder die indruk is dat die effek van LECARDOP te sterk of te swak is, moet jy jou dokter of apteker inlig.

As jy meer LECARDOP geneem het as wat jy behoort te neem:

In die geval van oordosering, raadpleeg jou dokter of apteker. Indien nie een van hulle beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.

As jy vergeet het om LECARDOP te neem:

Indien dit net ‘n paar uur later is nadat jy ‘n dosis oorgeslaan het, neem die dosis wat jy oorgeslaan het sodra jy onthou. Indien dit byna tyd is vir die volgende dosis, slaan die dosis oor wat jy vergeet het en neem LECARDOP soos gewoonlik op die volgende geskeduleerde tyd.

Moenie ‘n dubbele dosis neem om te vergoed vir die dosis wat jy vergeet het nie.

Effekte wanneer behandeling met LECARDOP gestaak word:

Moenie ophou om LECARDOP te neem of jou dosis verander sonder om eers met jou dokter te

praat nie. Wanneer jy ophou om LECARDOP te neem kan die volgende voorkom: stywe spiere, hoë temperatuur (koors) en veranderings in geestestoestand.

4. Moontlike newe-effekte

LECARDOP kan newe-effekte hê.

Nie al die newe-effekte wat vir LECARDOP aangemeld is, word in hierdie inligtingsblad ingesluit nie.

Indien jou algemene gesondheid verswak of as jy enige ongunstige effekte ervaar terwyl LECARDOP geneem word, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgvoorsiener vir advies.

Indien enige van die volgende gebeur, hou op om LECARDOP te neem en lig jou dokter onmiddellik in of gaan na die noodgevalle-afdeling by jou naaste hospitaal:

- Swelling van jou hande, voete, enkels, gesig, mond of keel, wat dit moeilik kan maak om te sluk of asem te haal.
- Uitslag of gejeuk.
- Floutes.

Hierdie is almal baie ernstige newe-effekte. Indien jy dit het, mag jy ‘n ernstige allergiese reaksie teen LECARDOP 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:

Die volgende newe-effekte kom dikwels voor:

- Vergeling van jou vel en oë, ook geelsug genoem.
- Borskaspyn.
- Geestesveranderings, insluitende waansin, hallusinasies (sien of hoor dinge wat nie bestaan

nie), verhoogde agterdogtigheid en terneergedrukdheid met gedagtes om jouself skade aan te doen.

- Onegalige (onreëlmatige) hartklop of palpitasies.
- Bloedprobleme, die tekens kan bleek vel (bleekheid), moegheid, koors, keelseer of geringe kneusing en verlengde bloeding na besering insluit.
- Toevalle (stuiptrekkings).
- Kortasemigheid.
- Blaasinfeksie (drang om dikwels te urineer, pynlike urinering of branderige gevoel tydens urinering).
- Behoefte om dikwels te urineer.
- Beskadiging van jou senuwees (swakheid, gevoelloosheid of pyn in jou hande of voete).
- Neuroleptiese maligne sindroom (NMS) (hoë koors, stywe spiere, gewysigde geestestoestand (voel verward, prikkelbaar of gedisoriënteerd), veranderings in die manier waarop jou hart klop, veranderings in jou polsspoed of bloeddruk en verhoogde sweetafskeiding).

Die volgende newe-effekte kom minder dikwels voor:

- Bloeding vanaf jou ingewande wat waargeneem kan word as bloed in jou feses of donker feses (gastroïntestinale bloeding).
- Onreëlmatige oogbeweging (verlengde, onwillekeurige opwaartse draaiing van jou oë).
- Sukkel om urine te passeer of inkontinensie (onvermoë om vloei van urine te beheer).
- Gewysigde kolle van gepigmenteerde vel, insluitende geïrriteerde of onreëlmatige moesies, of moesies waar veranderings opgemerk is (melanoom).
- Blasieagtige veluitslag.

Hierdie is almal ernstige newe-effekte. Jy mag dringende mediese aandag benodig.

Lig jou dokter so gou as moontlik in as jy enige van die volgende opmerk:

Die volgende newe-effekte kom dikwels voor:

- Duiseligheid as jy vinnig opstaan.
- Abnormale bewegings soos spiertrekkings of spasmas (wat soos jou simptome van Parkinson se siekte kan wees, of nie).
- Naarheid.
- Anoreksie (erge gewigsverlies), hoë bloeddruk.
- Inflammasie van jou are.
- Braking, diarree, hardlywigheid, slegte spysvertering, droë mond.
- Verkleuring van urine, sweet of speeksel.
- “Aan-af” verskynsel, kenmerkend van sommige persone met langdurige Parkinson se siekte. Dit is wanneer jy onvoorspelbare veranderings kan hê van beweeglikheid – “aan” – na ‘n skielike onvermoë om te beweeg – “af”. “Af” na “aan” kan net so skielik gebeur.
- Duiseligheid.
- Slaperigheid (insluitende uitermatige lomerigheid of episodes waar jy skielik aan die slaap raak).
- Abnormale drome (insluitende nagmerries), sukkel om te slaap.
- Verwarring, voel rusteloos.
- Verhoogde geslagsdrang.
- Verhoogde sweetafskeiding, haarverlies.
- Impulsiwiteit (gebrek aan selfbeheersing), ‘n uitermatige begeerte om te dobbel.
- Rugpyn, skouerpyn, spierkrampe.
- Swakheid.
- Infeksie van jou boonste lugweg (keelseer, verstopte sinusse, hoes, loopneus).

Die volgende newe-effekte kom minder dikwels voor:

- Parestesie (naalde-en-spelde).

- Verlies van beheer oor die willekeurige bewegings van die allerdaagse lewe.
- Gevoelloosheid, verhoogde bewing (onwillekeurige beweging), spiertrekkings, onreëlmatige beweging van kakebeenspiere wat veroorsaak dat dit moeilik is om jou mond oop te maak (spierspasma).
- Voel angstig of hoog (eufories), senuweeagtigheid.
- Geheueverlies of disoriëntasie.
- Val vooroor of abnormale stappatrone.
- Hoofpyn.
- Ooglede hang of maak onwillekeurig toe, verwyde pupille.
- Veranderings in visie (wasige sig of dubbelvisie).
- Oormatige speekselproduksie, swelling van die speekselkliere, probleme om te sluk, knersing op jou tande, bitter smaak.
- Hik, buikpyn en -nood, winderigheid, sooibrand.
- Branderige gevoel op jou tong.
- Volgehoue en pynlike ereksie van die penis.
- Pyn in jou bene.
- Gewigstoename of gewigsverlies, swelling van jou hande as gevolg van vogretensie.
- Blosing, warmgloede.
- Heesheid, algemene gevoel van ongesteldheid.
- Moegheid.
- Verhoogde energie of aktiwiteit, ongewone asemhalingspatrone.
- Seer keel of hoes.
- Veranderings in jou bloeduitslae as toetse uitgevoer word.
- Sterk drang om te dobbel.
- Verhoogde seksuele belangstelling of drang.

- Onbeheersde uitermatige aankope of besteding.
- Eet groot hoeveelhede voedsel in ‘n kort tydperk.

Voorkoms onbekend:

- Behoefte vir groot dosisse van LECARDOP, ver bokant dit wat nodig is om motoriese simptome te beheer, bekend as dopamiendisreguleringsindroom. Sommige pasiënte ervaar ernstige abnormale onwillekeurige bewegings (diskinesie), gemoedsversteurings of ander newe-effekte nadat groot dosisse van LECARDOP geneem is.

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

Aanmelding van newe-effekte:

Praat met jou dokter of apteker as jy newe-effekte ervaar. Jy kan ook newe-effekte by SAHPRA aanmeld *via* die “**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 help om meer inligting oor die veiligheid van LECARDOP te verskaf.

5. Hoe om LECARDOP te bewaar

- Bewaar by of onder 25 °C.
- Bewaar in die oorspronklike verpakking om teen lig te beskerm.
- Bewaar alle medisyne buite die bereik van kinders.
- Moenie LECARDOP na die vervaldatum soos op die stulpstrook en karton aangedui, gebruik nie. Die vervaldatum verwys na die laaste dag van daardie maand.

- Medisyne moenie in afvalwater of huishoudelike afval weggegooi word nie. Vra jou apteker hoe om medisyne weg te gooi wat nie meer benodig word nie. Hierdie maatreëls sal bydra om die omgewing te beskerm.
- Hou die bottel styf toe.

6. Inhoud van die verpakking en ander inligting

Wat LECARDOP bevat:

Die aktiewe bestanddele in LECARDOP is karbidopa en levodopa.

Elke LECARDOP 25/250 tablet bevat 25 mg karbidopa en 250 mg levodopa.

Elke LECARDOP 25/100 tablet bevat 25 mg karbidopa en 100 mg levodopa.

Die ander bestanddele is mieliestysel, D&C Geel nr. 10 aluminiumlak (LECARDOP 25/100), FD&C Blou nr. 2 aluminiumlak (LECARDOP 25/250), FD&C Geel nr. 6 aluminiumlak (LECARDOP 25/100), magnesiumstearaat, mikrokristallyne sellulose, vooraf-gegelatineerde stysel en natriumstyselglikolaat.

Hoe LECARDOP lyk en inhoud van die verpakking:

LECARDOP 25/250: Gespikkelde blou tot ligblougekleurde, ovaalvormige, bikonvekse, onbedekte tablette, met “519” aan die een kant ingepers en met ‘n keep aan die ander kant.

LECARDOP 25/100: Geel tot liggeelgekleurde, ovaalvormige, bikonvekse, onbedekte tablette, met “518” aan die een kant ingepers en met ‘n keep aan die ander kant.

LECARDOP tablette word verpak in HDPE, wit, gladde, ronde bottels met ‘n wit geriffelde kinderbestande prop, met ‘n ontwerp aan die bokant. Die bottel word in ‘n gedrukte buitenste karton verpak.

Verpakking: 100 tablette.

Houer van die registrasiesertifikaat:

Ranbaxy Pharmaceuticals (Pty) Ltd

Lautreweg 14

Stormill, Uitbreiding 1, Roodepoort

Johannesburg 1724

011 495 0100

Hierdie inligtingsblad was laaste hersien op:

4 August 2022

Registrasienommers:

LECARDOP 25/250: 45/5.4.1/0764

LECARDOP 25/100: 45/5.4.1/0765

Datum van registrasie:

25 November 2016