1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

CARBILEV 25/100 tablets

Carbidopa 25 mg and levodopa 100 mg.

CARBILEV 25/250 tablets

Carbidopa 25 mg and levodopa 250 mg.

Sugar free

Read all of this leaflet carefully before you start taking CARBILEV

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

1. WHAT CARBILEV is and what it is used for

CARBILEV belongs to a group of medicines called medicines affecting autonomic function.

CARBILEV contains two different medicines called: levodopa and carbidopa.

- levodopa turns into a material called ‘dopamine’ in your brain. The 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.

CARBILEV improves the signs of Parkinson’s disease. Parkinson's disease is a long-term illness where:

- you become slow and unsteady.
- your muscles feel stiff.
- you may develop shaking or trembling (called ‘tremor’).

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 CARBILEV

Do not take CARBILEV

- if you are hypersensitive (allergic) to carbidopa or levodopa or any of the other ingredients of CARBILEV (see What CARBILEV contains).
- if you are taking certain medicines called monoamine oxidase (MAO) inhibitors used for depression. You need to stop using these medicines at least two weeks before you start taking CARBILEV (see Taking other medicines with CARBILEV).
- if you are pregnant, might become pregnant, or are breastfeeding.
- if you are a women of childbearing age.
- if you have ever had skin cancer or you have any unusual moles which have not been examined by your doctor.
- you have a severe mental disorder.

- if you have a condition called ‘closed-angle glaucoma’ that may cause a sudden build up of pressure in the eye.
- in children under the age of 18 years.

Warnings and precautions

Special care should be taken with CARBILEV:

- if you have lung conditions such as breathing problems.
- if you have heart conditions such as heart attack, heart beat problems or circulation.
- if you have open sores in the lining of your stomach or the upper part of the small intestine known as peptic ulcers.
- if you have involuntary movements that you cannot control (dyskinesia).
- if you sometimes have sudden sleep attacks or sometimes feel very sleepy.
- if you have a history of fits (convulsions).
- if you have had depression or other mental problems.
- if you have a condition called ‘open-angle glaucoma’ that may cause a sudden build up of pressure in the eye.
- if you have kidney problems.
- if you unable to start urination, or if you are able to start, you can't fully empty your bladder.
- if the results from your blood test are not normal. You doctor will tell you if your blood test are not normal.
- if you have high levels of sugar in the blood known as diabetes mellitus.
- if you think about suicide or wanting to take your own life (suicidal tencencies).

If you are not sure if any of the above apply to you, talk to your doctor before taking CARBILEV.

Tell your doctor if you notices you are developing addiction-like symptoms leading to craving for large doses of CARBILEV and other medicines used to treat Parkinson’s disease.

Tell your doctor if you notice that you are developing urges or cravings to behave in ways that are unusual for you or you cannot resist the impulse, drive or temptation to carry out certain activities that could harm yourself or others. These behaviours are called impulse control disorders and can include addictive gambling, excessive eating or spending, an abnormally high sex drive or an increase in sexual thoughts or feelings. Your doctor may need to review your treatment.

Children and adolescents

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

Other medicines and CARBILEV

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

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

- *Anaesthetics*: medicines used to prevent pain during surgery.
- *Anticonvulsants*: medicines used to treat fits (seizures).
- *Haloperidol and phenothiazines*: medicines used to treat mental problems.
- *Anticholinergic:* medicines such as orphenadrine, trihexyphenidyl, benzatropine and procyclidine. Your dose may need to be changed.
- *Antihypertensives*: medicines used to treat high blood pressure, such as lisinopril.
- *Monoamine oxidase (MAO) inhibitors*: medicines used to treat depression (see Do not take CARBILEV).
- *Selegiline*: medicine used to reduce symptoms in early-stage Parkinson's disease.
- *Cocaine*: a medicine used to prevent pain but mostly used illegally in the form of a white powder that is breathed in through the nose.
- Medicines to treat low iron. Your dose may need to be changed.

- Medicines for mental problems including depression.

CARBILEV with food and drink

Take CARBILEV with or after meals. Try to avoid taking your tablets with a heavy meal. If your diet contains too much protein (meat, eggs, milk, cheese) CARBILEV may not work as well as it should.

Pregnancy, breastfeeding and fertility

You should not take CARBILEV if you are pregnant or breastfeeding your baby (see Do not take CARBILEV).

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 this medicine.

Driving and using machines

CARBILEV has a major influence on the ability to drive and use machines

It is not always possible to predict to what extent CARBILEV may interfere with the daily activities of a patient. You should ensure that you do not engage in the above activities until you are aware of the measure to which CARBILEV affects you (see section 4).

3. How to take CARBILEV

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

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

Your dose will be slowly increased by your doctor until the correct dose suitable for you has been achieved and you will be monitored to see if you have nausea or abnormal involuntary movements or if these symptoms gets worse.

If you have not had levodopa before

The usual starting dose:

- For CARBILEV 25/100: Take one tablet three times a day.
- For CARBILEV 25/250: Take half a tablet once or twice a day.

The maintenance dose is:

- CARBILEV 25/250: Take one tablet three times a day.

If you have had levodopa before

- Your doctor will ask you to stop taking your medicine for Parkinson's disease at least eight hours before you start taking CARBILEV.
- Your dose will depend on what you were taking before.

Your doctor will tell you how long your treatment with CARBILEV will last.

Your dose will be slowly decreased when your doctor tells you to stop taking CARBILEV.

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

If you take more CARBILEV 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 CARBILEV

Do not take a double dose to make up for forgotten individual doses. If you have missed a dose of CARBILEV, take the dose that you have missed as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose. If you have forgotten to take several doses, contact your doctor without delay.

If you stop taking CARBILEV

Do not stop taking CARBILEV or change your dose without talking to your doctor first. When you stop taking CARBILEV the following can occur: stiff muscles, high temperature (fever) and mental changes.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

CARBILEV can have side effects.

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

If any of the following happens, stop taking CARBILEV 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 or itching.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to CARBILEV. 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,
- uneven (irregular) heart beat or palpitations,
- dizziness on standing-up quickly,
- bleeding from your gut which may be seen as blood in your faeces or darkened faeces (gastrointestinal bleeding),
- blood problems, the signs may include pale skin (pallor), tiredness, fever, sore throat or mild bruising and prolonged bleeding after injury,
- stiff muscles, high fever,
- mental changes including delusions, hallucinations and depression,
- fits (convulsions).

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:

- abnormal movements such as twitching or spasms (which may or may not be like your Parkinson's symptoms),
- nausea.

Side effects with an unknown frequency

- obsessive desire to lose weight by refusing to eat (anorexia), high blood pressure,
- dopamine dysregulation syndrome (DDS). It typically occurs in people with Parkinson's disease (PD) who have taken dopamine agonist medications for an extended period of time,
- inflammation of the veins, being sick (vomiting) diarrhoea, discoloration 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), pins and needles,
- dream abnormalities, confusion, feeling agitated, shortness of breath, hair loss,
- craving for large doses of CARBILEV 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 CARBILEV,
- inability to resist the impulse to perform an action that could be harmful, which may include:
    - strong impulse to gamble excessively despite serious personal or family consequences,
    - altered or increased sexual interest and behaviour of significant concern to you or to others, for example, an increased sexual drive,
    - uncontrollable excessive shopping or spending,
    - binge eating (eating large amounts of food in a short time period) or compulsive eating (eating more food than normal and more than is needed to satisfy your hunger),
- loss of control over the voluntary movements of everyday life,
- numbness, increased hand tremor, muscle twitching, muscle cramp, irregular movement of jaw muscles resulting in difficulty opening the mouth,
- difficulty sleeping, feeling anxious or high, falling over and abnormal walking patterns,
- headache,
- drooping eyelid and dilated pupil,
- changes in vision, irregular movement of the eye,
- indigestion, dry mouth, bitter taste,

- swelling of the salivary glands, difficulty swallowing, grinding of the teeth,
- hiccups, abdominal pain and distress, constipation, wind
- burning sensation of the tongue,
- 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),
- weight gain or loss, swelling in the limbs,
- flushing, hot flushes, increased sweating,
- feeling weak, faint or tired,
- hoarseness, general feeling of being unwell,
- increased energy or activity, unusual breathing pattern.

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: https://www.sahpra.org.za/health-products-vigilance/

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088

By reporting side effects, you can help provide more information on the safety of CARBILEV.

5. How to store CARBILEV

Store at or below 25 °C in an airtight container, and protect from light.

Keep in original packaging until required for use.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

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

6. Contents of the pack and other information

What CARBILEV contains

CARBILEV 25/100

The active substance is 25 mg of carbidopa and 100 mg of levodopa.

The other ingredients are croscarmellose sodium, dye lennon lake yellow no. 520 (C.I No. 47005), magnesium stearate, microcrystalline cellulose, povidone K25, purified talc.

Sugar free

CARBILEV 25/250

The active substance is 25 mg of carbidopa and 250 mg oflevodopa.

The other ingredients are croscarmellose sodium, dye lennon blue no. 198, dye lennon lake blue No. 197, magnesium stearate, microcrystalline cellulose, povidone K25, purified talc.

Sugar free

What CARBILEV looks like and contents of the pack

CARBILEV 25/100 tablet is a round, flat, yellow tablet with bevelled edges, bisected on one side and plain on the other side.

CARBILEV 25/250 tablet is a light blue, mottled, round, biconvex tablet, bisected on one side and plain on the other side.

CARBILEV 25/100: 100 tablets are packed in white polypropylene securitainers with a package leaflet and a white rayon insert, and sealed with a white low density polyethylene snap-on cap, with a tamper-proof seal.

100 tablets are packed in a clear PVC film and aluminium foil blister packs, together with a package leaflet, into pre-printed cardboard unit cartons.

100 tablets are packed into amber round polypropylene, hingelid vials, together with a foam insert and package leaflet.

CARBILEV 25/250: 100 tablets are packed in white polypropylene securitainers with a package leaflet and white rayon insert, and sealed with a white low density polyethylene cap.

100 tablets are packed in a clear PVC film and aluminium foil blister packs, together with a package leaflet, into pre-printed cardboard unit cartons.

100 tablets are packed into amber round polypropylene, hingelid vials, together with a foam insert and package leaflet.

Not all packs and pack sizes are necessarily marketed.

Holder of Certificate of Registration

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

Tel: 0800 122 912

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Registration number

CARBILEV 25/100: 30/5.4.1/0271

CARBILEV 25/250: 30/5.4.1/0269

Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information Leaflets:

https://www.sahpra.org.za/pi-pil-repository/

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088

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