

Applicant: Teva Pharmaceuticals (Pty) Ltd	Product: TEVA CARBI-LEVO 25/100 & 25/250 Dosage Form: Tablets
Registration No:	TEVA CARBI-LEVO 25/100: 32/5.4.1/0081 TEVA CARBI-LEVO 25/250: 32/5.4.1/0024

PATIENT INFORMATION LEAFLET

<p>PATIENT INFORMATION LEAFLET:</p> <p>SCHEDULING STATUS:</p> <p>S4</p>
<p>TEVA CARBI-LEVO 25/100, 25 mg carbidopa and 100 mg levodopa per tablet.</p> <p>TEVA CARBI-LEVO 25/250, 25 mg carbidopa and 250 mg levodopa per tablet.</p> <p>Sugar free.</p>
<p>Read all of this leaflet carefully before you start taking TEVA CARBI-LEVO.</p> <ul style="list-style-type: none"> • Keep this leaflet. You may need to read it again. • If you have further questions, please ask your doctor or your pharmacist. • TEVA CARBI-LEVO 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.
<p>WHAT IS IN THIS LEAFLET:</p> <ol style="list-style-type: none"> 1. WHAT TEVA CARBI-LEVO IS AND WHAT IT IS USED FOR 2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE TEVA CARBI-LEVO 3. HOW TO TAKE TEVA CARBI-LEVO 4. POSSIBLE SIDE EFFECTS 5. HOW TO STORE TEVA CARBI-LEVO 6. CONTENTS OF THE PACK AND OTHER INFORMATION
<p>1. WHAT TEVA CARBI-LEVO IS AND WHAT IT IS USED FOR:</p> <p>TEVA CARBI-LEVO is used to treat Parkinson's disease which is caused by a lack of a chemical, called dopamine, in the nervous system. The tablets will help to restore the level of dopamine and help to reduce the signs and symptoms of the disease. Ask your doctor or pharmacist if you need additional information.</p>

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2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE TEVA CARBI-LEVO:

Do not take TEVA CARBI-LEVO:

- if you are hypersensitive (allergic) to carbidopa or levodopa or any of the ingredients of TEVA CARBI-LEVO
- if you are pregnant, intending to become pregnant or breastfeeding
- if you are taking any medicines known as 'monoamine oxidase inhibitors' (which are used to treat depression) such as phenelzine, tranylcypromine or moclobemide
- if you have narrow-angle glaucoma (that may cause a sudden build-up of pressure in the eye)
- if you ever suffered from skin cancer or think that you may have skin cancer
- if you have heart disease
- if you have any severe mental disorders.

Warnings and precautions:

Take special care with TEVA CARBI-LEVO:

- TEVA CARBI-LEVO should not be used for the treatment of medicine induced effects such as tremor, slurred speech, anxiety or distress.
- Inform your doctor if you have sudden sleep attacks or sometimes feel very sleepy.
- Inform your doctor if you are taking levodopa (a medicine used in the treatment of Parkinson's disease) or if you have experienced involuntary movements with levodopa treatment.
- If you suffer from open-angle glaucoma; severe heart or lung disease; asthma; kidney, liver or endocrine (gland) disease; or a history of stomach or intestinal ulceration, vomiting blood.
- If you have a history of heart disease.
- If you have a history of seizures (fits).
- If you suffer from diabetes, your blood sugar needs to be monitored and your diabetic medicine dose might be adjusted.
- If you suffer from psychiatric disturbances or psychosis (mental disorders).
- If you experience a form of low blood pressure which causes dizziness on standing-up quickly.
- Tell your doctor if you or your family/care giver notices you are developing addiction-like symptoms leading to cravings for large doses of TEVA CARBI-LEVO and other medicines used to treat Parkinson's disease.

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- Tell your doctor if you or your family/care giver notices 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 TEVA CARBI-LEVO treatment.

Your liver, heart and kidney functions should be tested periodically.

You should not stop taking TEVA CARBI-LEVO without consulting your medical practitioner.

Other medicines and TEVA CARBI-LEVO:

Always tell your healthcare provider if you are taking any other medicine. If you are pregnant or breastfeeding your baby please consult your healthcare provider for advice before taking TEVA CARBI-LEVO.

(This includes complementary or traditional medicines.)

Monoamine oxidase inhibitors used in the treatment of depression (e.g. moclobemide) should be discontinued at least 2 weeks prior to initiating therapy with TEVA CARBI-LEVO.

Tell your doctor if you are taking:

- medicines used to treat high blood pressure e.g. reserpine
- tricyclic antidepressant medicine (e.g. amitriptyline, clomipramine, imipramine)
- iron supplements
- antipsychotic medicine called phenothiazines (chlorpromazine, promazine) and butyrophenones (e.g. haloperidol, droperidol)
- isoniazid a medicine used to treat TB (tuberculosis)
- seizure (fits) treatment such as phenytoin and papaverine
- anticholinergic medicines (such as orphenadrine, trihexyphenidyl, benztropine and procyclidine), since your dose may need to be changed.

TEVA CARBI-LEVO can affect some blood tests performed by laboratories; inform your medical

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practitioner that you are taking TEVA CARBI-LEVO if you are to undergo blood tests.

Taking TEVA CARBI-LEVO with food and drink:

Inform your doctor if you are on high protein diet. If your diet contains too much protein (meat, eggs, milk, cheese) TEVA CARBI-LEVO may not work as well as it should.

Pregnancy and breastfeeding:

The safety of TEVA CARBI-LEVO in pregnant or breastfeeding women has not been established.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking TEVA CARBI-LEVO.

Driving and using machinery:

TEVA CARBI-LEVO may cause dizziness or blurred vision, therefore you should not engage in activities such as driving or operating machinery until you know how TEVA CARBI-LEVO affects you.

TEVA CARBI-LEVO can also make you sleepy or cause sudden sleep onset episodes. If this happens you must not drive or operate machinery. Your doctor will advise you when you can start driving again if these sleep episodes stop.

3. HOW TO TAKE TEVA CARBI-LEVO:

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

Always take TEVA CARBI-LEVO exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The tablets should be swallowed with a drink of water.

The usual dosage instructions are given below:

The number of tablets which you should take each day will depend on your personal needs. Your doctor will tell you how many tablets to take each day. During the first few weeks your doctor may change your dose of TEVA CARBI-LEVO until it is exactly right. It is important to follow your doctor's instructions carefully. If you are not sure of anything, always ask your doctor.

Depending on your needs, the dosage may be as low as one tablet a day or every other day, or as high

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as eight tablets of TEVA CARBI-LEVO 25/250 a day.

If you are taking levodopa with another medicine, this treatment will be discontinued at least 12 hours before starting treatment with TEVA CARBI-LEVO.

You should continue to take TEVA CARBI-LEVO for as long as your doctor tells you to.

If you have the impression that the effect of TEVA CARBI-LEVO is too strong or too weak, tell your doctor or pharmacist.

If you take more TEVA CARBI-LEVO 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 a dose of TEVA CARBI-LEVO:

If you forget to take a tablet, take one as soon as you remember, unless it is nearly time to take the next one. Never take two doses together. Take the remaining doses at the correct time.

If you stop taking TEVA CARBI-LEVO:

Do not stop taking TEVA CARBI-LEVO or change your dose without checking with your doctor. When you stop taking TEVA CARBI-LEVO the following symptoms can occur: muscle stiffness, high temperature (fever) and mental changes.

4. POSSIBLE SIDE EFFECTS:

TEVA CARBI-LEVO can have side effects.

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

If any of the following happens, stop taking TEVA CARBI-LEVO 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

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swallowing or breathing

- rash or itching.

These are all very serious side effects. If you have them, you may have had a serious reaction to TEVA CARBI-LEVO. 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, irregular heartbeat or palpitations
- dizziness on standing up quickly
- bleeding from your gut which may be seen as blood in your faeces or darkened faeces (gastro-intestinal 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)
- abnormal movements such as twitching or spasms
- abnormal involuntary tight closure of the eyelids
- changed patches of pigmented skin, including irritated or irregular moles, or moles in which you have noticed changes (melanoma).

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

Tell your doctor if you notice any of the following which may occur frequently:

- urinary tract infections (bladder infections)
- loss of appetite
- confusion, nightmares, abnormal thinking, hallucinations, depression with or without suicidal behaviour, difficulty sleeping, changes in your mood or thoughts, tiredness
- dizziness, headache, feeling of pins and needles, loss of control over voluntary movements
- fainting
- shortness of breath

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- nausea (feeling sick), vomiting, stomach pain, constipation, loose stools, dry mouth, heartburn, teeth grinding
- muscle cramps
- weakness, feeling ill.

Tell your doctor if you notice any of the following which may occur less frequently:

- weight loss or weight gain
- agitation, anxiety, fear, disorientation, aggression, paranoia, delirium, confusion, increased sex drive, lethargy, compulsive gambling, compulsive spending/shopping, excessive eating
- falling, abnormal walking patterns, sleepiness (including excessive drowsiness or sudden sleep onset episodes), numbness, increased hand tremor, muscle twitching, irregular movement of jaw muscles resulting in difficulty opening the mouth
- blurred vision, irregular movement of the eye
- hot flushes, high blood pressure (with symptoms such as headaches and dizziness)
- irregular breathing pattern, hoarseness
- bitter taste, hiccups, burning sensation of the tongue, dark saliva, difficulty swallowing, flatulence, increased saliva
- increased sweating, itching, hair loss, dark sweat
- difficulty passing urine or incontinence (inability to control urine flow), discoloured urine
- persistent abnormal erection of the penis.

Tell your doctor if you notice any of the following which may also occur:

- cravings for large doses of TEVA CARBI-LEVO 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 TEVA CARBI-LEVO.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects:

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If you get any 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 TEVA CARBI-LEVO.

5. HOW TO STORE TEVA CARBI-LEVO:

Do not use after the expiry date shown on the pack.

Store at or below 25 °C and keep the tablets in the package or container supplied. Do not transfer them to another container.

Return all unused medicines to your pharmacist for safe disposal.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Do not store in a bathroom.

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

6. CONTENTS OF THE PACK AND OTHER INFORMATION:

What TEVA CARBI-LEVO contains:

The active substance is carbidopa and levodopa.

TEVA CARBI-LEVO 25/100: Each tablet contains carbidopa monohydrate equivalent to carbidopa anhydrous 25 mg and levodopa 100 mg.

TEVA CARBI-LEVO 25/250: Each tablet contains carbidopa monohydrate equivalent to carbidopa anhydrous 25 mg and levodopa 250 mg.

The other ingredients are maize starch, pregelatinised maize, microcrystalline cellulose, magnesium stearate, aluminium lake (E132) in TEVA CARBI-LEVO 25/250 and aluminium lake yellow (E104) in TEVA CARBI-LEVO 25/100.

Sugar free.

What TEVA CARBI-LEVO looks like and contents of the pack:

TEVA CARBI-LEVO 25/100 Tablets:

Mottled yellow, round, flat, bevelled tablet, scored on both sides.

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<p>TEVA CARBI-LEVO 25/250 Tablets:</p> <p>Mottled blue, round, flat, bevelled tablet, plain on one side, scored on the other side.</p> <p>Packaging material:</p> <p>TEVA CARBI-LEVO 25/100 Tablets: Blister strips of 10 tablets each, with 100 tablets per carton.</p> <p>TEVA CARBI-LEVO 25/250 Tablets: Blister strips of 10 tablets each, with 100 tablets per carton.</p>
<p>Holder of Certificate of Registration:</p> <p>Teva Pharmaceuticals (Pty) Ltd, Maxwell Office Park, Magwa Crescent West, Waterfall City, Midrand, Gauteng, 2090, South Africa Tel: (011) 055 0200</p>
<p>This leaflet was last revised in:</p> <p>11 April 2024</p>
<p>Registration numbers:</p> <p>TEVA CARBI-LEVO 25/100: 32/5.4.1/0081 TEVA CARBI-LEVO 25/250: 32/5.4.1/0024</p>