

INFORMATION FOR THE PATIENT

APO-LEVOCARB CR

Levodopa / Carbidopa Controlled-Release Tablets

The Product Monograph is available on request to the physician and pharmacist only. Read the following information carefully. If you need any explanations, or further information, ask your physician or pharmacist.

What is APO-LEVOCARB CR?

APO-LEVOCARB CR 200 mg/50 mg (levodopa/carbidopa) is an oval, peach, biconvex tablet scored and engraved "200" over "50" on one side and "APO" on the other which contains 200 mg of levodopa and 50 mg of anhydrous carbidopa as the active ingredients.

In addition, APO-LEVOCARB CR contains the following non-medicinal ingredients: Hydroxypropyl Methylcellulose USP, Yellow Ferric Oxide NF, Red Ferric Oxide NF, Purified Water USP and Magnesium Stearate NF.

APO-LEVOCARB CR is a combination of levodopa, the metabolic precursor of dopamine, and carbidopa, an aromatic amino acid decarboxylase inhibitor, in a controlled-release tablet. It treats the symptoms of Parkinson's disease.

Why has my doctor prescribed APO-LEVOCARB CR?

Your physician has prescribed APO-LEVOCARB CR to treat the symptoms of Parkinson's disease.

Parkinson's disease is a chronic disorder characterized by slow and unsteady movement, muscular stiffness, and tremor. If untreated, Parkinson's disease can cause difficulty in performing normal daily activities.

How does APO-LEVOCARB CR treat Parkinson's disease?

APO-LEVOCARB CR tablets are formulated to slowly release the two active ingredients, levodopa and carbidopa.

It is believed that the symptoms of Parkinson's disease are caused by a lack of dopamine, a naturally occurring chemical produced by certain brain cells. Dopamine has the role of relaying messages in certain regions of the brain that control muscle movement. Difficulty in movement results when too little dopamine is produced.

Levodopa acts to replenish dopamine in the brain, while carbidopa ensures that enough levodopa gets to the brain where it is needed. In many patients, this reduces the symptoms of Parkinson's disease. The controlled release formula keeps the amount of levodopa in your body as even as possible.

What should I know before taking APO-LEVOCARB CR

• Who should not take APO-LEVOCARB CR?

Do not take APO-LEVOCARB CR:

- if you are allergic to any of its ingredients (see What is APO-LEVOCARB CR? Section).
- if you have any suspicious skin lesions (moles) which have not been examined by your doctor or if you have ever had skin cancer
- if you are being treated for depression with certain MAO inhibitor drugs
- if you have narrow-angle glaucoma.

• What should I tell my physician before taking APO-LEVOCARB CR?

Tell your physician about any medical conditions you have or have had including: allergies; depression or mental disturbances; lung, kidney, liver, heart or hormonal problems; peptic ulcer disease; convulsions; or glaucoma.

Let your doctor know if you have previously been treated with levodopa.

Use in children

APO-LEVOCARB CR should not be given to children.

Use in pregnancy and breast-feeding

It is not recommended to use APO-LEVOCARB CR while you are pregnant or breast-feeding.

It is not known what effect APO-LEVOCARB CR may have on human pregnancy. Levodopa, one of the components of APO-LEVOCARB CR is passed into human milk. If you are pregnant, may become pregnant, or intend to breast-feed, tell your physician, who will help you weigh the benefits of the drug for you against possible risks to your baby.

Can I take APO-LEVOCARB CR with other medicines?

Although APO-LEVOCARB CR can generally be given with other medicines, there are exceptions. Your physician may warn against use with certain medications used to treat psychiatric conditions or mental depression, tuberculosis, high blood pressure, muscle spasms or convulsions.

Your physician or pharmacist has a more complete list of medicines to avoid while taking APO-LEVOCARB CR. Tell your physician about all medicines you are taking or plan to take, including those obtained without a prescription.

Foods which may lower the effectiveness of APO-LEVOCARB CR

A change in diet to foods that are high in protein may delay the absorption of levodopa and may reduce the amount taken up in the circulation.

Excessive acidity delays stomach emptying, thus delaying the absorption of levodopa.

Iron salts (such as in multi-vitamin tablets) may also reduce the amount of levodopa available to the body.

The above factors may reduce the clinical effectiveness of the levodopa or levodopa/carbidopa therapy.

Can I drive or operate machinery while using APO-LEVOCARB CR?

Individual responses to medication may vary. Certain side effects that have been reported with APO-LEVOCARB CR may affect some patients' ability to drive or operate machinery (See What undesirable effects may APO-LEVOCARB CR have?).

APO-LEVOCARB CR can cause somnolence (excessive drowsiness) and sudden sleep onset episodes. Therefore you must refrain from driving or engaging in activities where impaired alertness may put yourself or others at risk of injury or death (e.g. operating machines) until such episodes and somnolence have resolved.

How should I take APO-LEVOCARB CR?

The dosage of APO-LEVOCARB CR is variable and your physician will adjust it according to the severity of your disease and your response to treatment.

APO-LEVOCARB CR is a sustained-release formulation of levodopa/carbidopa which releases these ingredients over a 4- to 6- hour period.

The effect of the first morning dose of APO-LEVOCARB CR may be delayed for up to 1 hour compared with the response usually obtained from the first morning dose of APO-LEVOCARB (levodopa/carbidopa). Consult your physician if such delayed responses pose a problem in treatment.

If so prescribed, the APO-LEVOCARB CR 200 mg/50 mg tablets may be broken in half. The whole or half tablet should be swallowed without chewing or crushing in order to maintain the slow-release properties of APO-LEVOCARB CR.

For best results take APO-LEVOCARB CR every day. It is important to carefully follow your physician's advice on how much APO-LEVOCARB CR to take and how often to take it. Promptly inform your physician of any change in your condition such as nausea or abnormal movements, as this may require an adjustment in your prescription.

Do not change the dose regimen prescribed by your physician and do not add any additional antiparkinson medications, including other levodopa/carbidopa preparations, without first consulting your physician.

Do not stop taking this medicine abruptly or lower the dosage without checking with your physician.

What should I do if I miss a dose?

Try to take APO-LEVOCARB CR as prescribed. However, if you have missed a dose, take it as soon as you remember. If it is almost time to take your next tablet, do not take the missed tablet, but resume your normal schedule.

What should I do in case of an overdose?

In case of an overdose, contact your physician immediately so that medical attention may be given promptly.

What undesirable effects may APO-LEVOCARB CR have?

APO-LEVOCARB CR is generally well tolerated. Like any other medicine, however, APO-LEVOCARB CR may have unintended or undesirable effects, so called side-effects.

The most frequent side effects are: abnormal movements (which may or may not resemble your Parkinson's symptoms), nausea, hallucinations, confusion, dizziness, and dry mouth.

Other possible side effects include: abnormal dreams or difficulty sleeping, sleepiness, sudden sleep onset episodes, mental changes, depression, weakness, vomiting, and loss of appetite, increased sexual drive, flushing, hair loss, fainting. Occasionally, dark color (red, brown or black) may appear in your saliva, urine, sweat after you take APO-LEVOCARB CR.

Hypersensitivity reactions may occur such as hives, itching, rash, and swelling of the face, lips, tongue, and/or throat, which may cause difficulty in breathing or swallowing: contact your physician immediately if these symptoms occur.

Some people may have other reactions. If you notice **any unusual effect**, check with your physician or pharmacist.

Remember - This medicine is prescribed for the particular condition that you have. **Do not give this medicine to other people, nor use it for any other condition.**

Do not use outdated medicine.

Store your tablets in a tightly closed container at room temperature (15° - 30°C). Protect from sunlight.

Keep all medicines out of the reach of children.