Carlevent
levodopa/carbidopa/entacapone

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet
This leaflet answers some common questions about this medicine. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking this medicine against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.
You may need to read it again.

What this medicine is used for
This medicine is used to treat Parkinson's disease. Parkinson's disease is a disorder of the nervous system. It is caused by a lack of dopamine, a natural substance that is produced in the brain.

Dopamine relays messages in the part of the brain that controls muscle movement. When too little dopamine is produced, problems with movement result. This medicine helps to relieve symptoms such as shaking of the limbs, stiffness and slowness of movement, which make it difficult to perform normal daily activities. Other medicines can also be added to help treat this condition.

This medicine contains three active ingredients: levodopa, carbidopa and entacapone. Levodopa is a chemical closely related to dopamine, which allows the body to make its own dopamine. This medicine works by increasing the level of dopamine in the brain. Carbidopa makes sure that enough levodopa gets to the brain where it is needed, and entacapone makes the effect of levodopa last longer.

This medicine helps to relieve symptoms such as shaking of the limbs, stiffness and slowness of movement, which make it difficult to perform normal daily activities. Other medicines can also be added to help treat this condition.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.
Your doctor may have prescribed it for another reason.
This medicine is/is not addictive. It is available only with a doctor's prescription.
There is not enough information to recommend the use of this medicine for children under the age of 18 years.

Before you take medicine
When you must not take it
Do not take this medicine if you have an allergy to:

- any medicine containing levodopa, carbidopa, entacapone.
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

• shortness of breath
• wheezing or difficulty breathing
• swelling of the face, lips, tongue or other parts of the body
• rash, itching or hives on the skin
• a type of glaucoma called wide-angle
• glaucoma
• stomach ulcers
• Problems with your gall bladder
• Inflammatory bowel disease

Your doctor can discuss with you the risks and benefits involved.
If you have not told your doctor about any of the above, tell them before you start taking this medicine.

Taking other medicines
Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.
Your doctor and pharmacist may have more information on medicines to be careful with or avoid while taking this medicine.

How to take this medicine
Follow all directions given to you by your doctor or pharmacist carefully.
They may differ from the information contained in this leaflet.
If you do not understand the directions, ask your doctor or pharmacist for help.

How much to take
The dose varies from patient to patient.
People with moderate to severe Parkinson's disease usually take from 3 to 7 tablets of CARLEVENT each day.
For CARLEVENT 50/12.5/200 mg, 75/18.75/200 mg, 100/25/200 mg, 125/31.25/200 mg and 150/37.5/200 mg, the maximum dose is 10 tablets each day.
For CARLEVENT 200/50 mg: The maximum dose is 7 tablets each day. Take only one CARLEVENT tablet at each dose.
Do not take 2 or more CARLEVENT tablets at a time.
Do not break the tablets into halves.

Follow all directions given to you by your doctor and pharmacist carefully.

How to take it
Swallow the tablets with a full glass of water.
If your stomach is upset after taking the tablet, take it with a meal or after a snack.
It does not matter if you take this medicine with or without food but avoid a high protein meal.
If you are taking any medicines containing iron, take them at least 2 or 3 hours before or after a dose of this medicine.

If you take the two medicines at the same time, your body may absorb less iron than usual.

If you forget to take it
If it is almost time for your next dose (say, within an hour of the next dose), skip the dose you missed and take your next dose when you are meant to.
If you forget to take a tablet of CARLEVENT, you should take it as soon as you notice that you have forgotten to take your medication.
Do not take a double dose to make up for the dose you missed.
If you are not sure what to do, ask your doctor or pharmacist.

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When to take it
Take your medicine at about the same time each day. Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

It does not matter if you take this medicine before or after food.

Food can interfere with the absorption of this medicine.

How long to take it
Continue taking your medicine for as long as your doctor tells you.

You may need to take this medicine for a long time to control your symptoms. If you stop taking it, the dose of your other medicines for Parkinson’s disease may have to be increased to prevent your symptoms from getting worse.

Keep taking this medicine for as long as your doctor recommends.

If you forget to take it
If it is almost time to take your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose that you missed. This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)
Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are using this medicine

Things you must do

If you experience times where this medicine does not appear to be working as well as it did previously, tell your doctor.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking this medicine.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the pharmacists who treat you that you are taking this medicine.

If you are about to be started on any new medicine, remind your doctor, pharmacist or dietician to check your diet.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking this medicine.

Like all other medicines, this medicine may have unwanted side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

• nausea (feeling sick) or vomiting
• diarrhoea
• pain in the stomach
• constipation
• dry mouth
• dizziness or light-headedness
• unsteadiness when walking, or a lack of coordination in your movements or speech
• spinning sensation (vertigo)
• tiredness or sleepiness
• shakiness
• aches and pains
• muscle cramps
• headache
• increased sweating
• difficulty sleeping or unusual dreams
• feeling depressed or agitated
• a reddish-brown colour to the urine (this is harmless)
• weight gain or loss (these are less common side effects)
• behavioural changes such as urge to gamble or increased sexual desire urges
• blurred vision
• seeing double.

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

• rash, itching or hives on the skin

• unusual and uncontrolled movements of the body such as twisting, jerking or writhing movements
• symptoms of neuroleptic malignant syndrome, such as a sudden increase in body temperature, sweating, fast heart beat, muscle stiffness and fluctuating blood pressure
• extreme sleepiness or sudden onset of sleep in the middle of daytime activities
• worsening of your symptoms of Parkinson’s disease
• compulsive behaviour such as gambling or unusual increases in sexuality, shopping, eating, medicine use or repetitive purposeless activities
• confusion or hallucinations (seeing, hearing or feeling things that are not there)
• difficulty breathing, congestion in the chest, chest pain
• signs of possible anaemia (low amount of iron in your blood)
• such as tiredness, headaches, shortness of breath when exercising, dizziness and looking pale
• signs of possible liver problems such as loss of appetite, feeling generally unwell, fever, itching, yellow colour to the skin and eyes
• temporary paralysis or weakness
• gastrointestinal bleeding (coughing up blood or blood in the stools)
• diarrhoea, usually with blood and mucus, stomach pain, fever.

The above list includes serious side effects that may require medical attention. Serious side effects are rare.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

• symptoms of an allergic reaction including cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin

Other side effects not listed above may also occur in some people.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Storage and Disposal

Storage

Keep your tablets in the original container until it is time to take them.

If you take the tablets out of the container they may not keep well.

Keep your medicine in a cool dry place where the temperature stays below 25°C.

Do not store this medicine or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

CARLEVENT comes in 6 strengths of tablets:

Carlevent
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• CARLEVENT 50/12.5/200 mg – oval biconvex red tablet marked “50” on one side and “LEC” on the other side.
• CARLEVENT 75/18.75/200 mg – oval biconvex red tablet marked “75” on one side and “LEC” on the other side.
• CARLEVENT 100/25/200 mg – oval biconvex red tablet marked “100” on one side and “LEC” on the other side.
• CARLEVENT 125/31.25/200 mg – oval biconvex red tablet marked “125” on one side and “LEC” on the other side.
• CARLEVENT 150/37.5/200 mg – oval biconvex red tablet marked “150” on one side and “LEC” on the other side.
• CARLEVENT 200/50/200 mg – oval biconvex red tablet marked “200” on one side and “LEC” on the other side.

Each pack contains 100 tablets.

**Ingredients**

This medicine contains:
- levodopa
- carbidopa anhydrous
- entacapone

Each CARLEVENT 50/12.5/200 tablet contains:
- 50 mg of levodopa
- 12.5 mg of carbidopa anhydrous
- 200 mg of entacapone

Each CARLEVENT 75/18.75/200 tablet contains:
- 75 mg of levodopa
- 18.75 mg of carbidopa anhydrous
- 200 mg of entacapone

Each CARLEVENT 100/25/200 tablet contains:
- 100 mg of levodopa
- 12.5 mg of carbidopa anhydrous
- 200 mg of entacapone

Each CARLEVENT 125/31.25/200 tablet contains:
- 125 mg of levodopa
- 31.25 mg of carbidopa anhydrous
- 200 mg of entacapone

Each CARLEVENT 150/37.5/200 tablet contains:
- 150 mg of levodopa
- 37.5 mg of carbidopa anhydrous
- 200 mg of entacapone

Each CARLEVENT 200/50/200 tablet contains:
- 200 mg of levodopa
- 50 mg of carbidopa anhydrous
- 200 mg of entacapone

This medicine also contains the following:
- carmellose sodium
- hydroxypropylcellulose
- trehalose dihydrate
- powdered cellulose
- anhydrous sodium sulphate
- microcrystalline cellulose
- magnesium stearate
- Opadry II complete film coating system 85G35208 RED

This medicine does not contain gluten, lactose, tartrazine or any other azo dyes.

**Supplier**

This medicine is supplied in Australia by:
Medis Pharma Pty Ltd
5 Essex Street
The Rocks, NSW, 2000
Australian registration numbers: