

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

Do not take this medicine if you are taking a medicine called a monoamine oxidase inhibitor (MAOI) such as phenelzine and tranylcypromine.

Taking this medicine together with some, but not all, MAOI medicines may cause a serious reaction with a sudden increase in body temperature, extremely high blood pressure and severe convulsions. Your doctor will know whether or not the MAOI medicine you are taking can be safely taken with this medicine.

Do not take this medicine if you are pregnant. There is not enough information to recommend its use during pregnancy.

Do not breastfeed if you are taking this medicine.

It is not known if the active ingredient in this medicine passes into breast milk and could affect your baby.

Do not take this medicine if you have any of the following health problems /medical conditions:

- a problem with your liver
- a tumour of the adrenal gland (called pheochromocytoma), which could cause your blood pressure to rise to a dangerous level
- you have ever had a serious condition called neuroleptic malignant syndrome (NMS), with symptoms such as a sudden increase in body temperature, sweating, fast heartbeat, muscle stiffness and fluctuating blood pressure
- you have ever had a condition called rhabdomyolysis, with symptoms of severe muscle weakness that was not due to an injury.
- unusual skin lumps or moles which have not been examined by your doctor, or if you have ever had skin cancer or melanoma.
- have a type of glaucoma called narrow-angle glaucoma
- trehalase insufficiency.

Do not give this medicine to a child under the age of 18 years.

Safety and effectiveness in children younger than 18 years have not been established.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.

Tell your doctor if you have or have had any of the following medical conditions:

- depression, mental disturbances, or you recognise anti-social behaviour
- heart disease, including irregular heartbeat, also known as arrhythmia
- kidney problems
- lung problems including asthma
- hormonal problems
- convulsions or fits

- 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 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 200/50/200 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.

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 surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

If you become pregnant or start to breastfeed while taking this medicine, tell your doctor immediately.

You should not take this medicine while you are pregnant.

Keep all your doctor's appointments so that your progress can be checked.

Things you must not do

Do not stop taking this medicine or lower the dose, without checking with your doctor.

Your doctor may want you to gradually reduce the amount of this medicine you are taking before

stopping completely in order to prevent side effects.

Do not take this medicine to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or change the dosage without checking with your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how this medicine affects you.

This medicine may cause (dizziness, light-headedness, tiredness, drowsiness, etc.) in some people. Very rarely it can cause extreme sleepiness and sudden onset of sleep in the middle of daytime activities, sometimes without warning. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Be careful getting up from a sitting or lying position. Dizziness, light-headedness or fainting may occur, especially when you get up quickly. Getting up slowly may help.

Be careful not to eat a diet high in protein. The amount of levodopa absorbed by the body may be impaired if you eat a diet high in protein. Ask 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 heartbeat, 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 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
- CARLEVENT 50/12.5/200 - AUST R 195198
- CARLEVENT 75/18.75/200 - AUST R 195194
- CARLEVENT 100/25/200 - AUST R 195747
- CARLEVENT 125/31.25/200 - AUST R 195748
- CARLEVENT 150/37.5/200 - AUST R 195749
- CARLEVENT 200/50/200 - AUST R 195192

This leaflet was prepared in September 2020.

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: