

CARLEVENT

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using CARLEVENT?

CARLEVENT contains the active ingredient levodopa, carbidopa monohydrate and entacapone. CARLEVENT is used to treat the symptoms of Parkinson's disease.

For more information, see Section [1. Why am I using CARLEVENT?](#) in the full CMI.

2. What should I know before I use CARLEVENT?

Do not use if you have ever had an allergic reaction to CARLEVENT or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use CARLEVENT?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with CARLEVENT and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use CARLEVENT?

- People with moderate to severe Parkinson's disease usually take from 3 to 7 tablets of CARLEVENT each day.
- Take only one CARLEVENT tablet at each dose.
- Do not take 2 or more CARLEVENT tablets at any one time. Do not break the tablets into halves.

More instructions can be found in Section [4. How do I use CARLEVENT?](#) in the full CMI.

5. What should I know while using CARLEVENT?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using CARLEVENT.• If you become pregnant, tell your doctor immediately. You should not take this medicine while you are pregnant.• Visit your doctor regularly so they can check on your progress.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine or reduce the dose suddenly without talking to your doctor.
Driving or using machines	<ul style="list-style-type: none">• Be careful driving, operating machinery or doing jobs that require you to be alert while you are taking CARLEVENT until you know how it affects you.
Looking after your medicine	<ul style="list-style-type: none">• Store below 25°C.

For more information, see Section [5. What should I know while using \[insert medicine\]?](#) in the full CMI.

6. Are there any side effects?

Common side effects: nausea (feeling sick), vomiting, diarrhoea, pain in the stomach, constipation, dry mouth, dizziness, light-headedness, extreme sleepiness and sudden onset of sleep and unusual and uncontrollable twitching, jerking or writhing movements, muscle and/or joint pain.

Severe side effects: compulsive behaviours, confusion, chest pain/tightness, shortness of breath or difficulty breathing and fast or irregular heartbeats.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

CARLEVENT

Active ingredient(s): *Levodopa/Carbidopa monohydrate/Entacapone*

Consumer Medicine Information (CMI)

This leaflet provides important information about using CARLEVENT. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using CARLEVENT.**

Where to find information in this leaflet:

- [1. Why am I using CARLEVENT?](#)
- [2. What should I know before I use CARLEVENT?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use CARLEVENT?](#)
- [5. What should I know while using CARLEVENT?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using CARLEVENT?

CARLEVENT contains the active ingredient **levodopa, carbidopa monohydrate and entacapone**.

CARLEVENT is an anti-Parkinson medicine containing dopaminergic agents that work together to increase the level of dopamine in the brain.

CARLEVENT is used to treat the symptoms of Parkinson's disease, such as shaking of the limbs, stiffness and slowness of movement, which make it difficult to perform normal daily activities.

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.

Other medicines can also help to treat this condition.

2. What should I know before I use CARLEVENT?

Warnings

Do not use CARLEVENT if:

- you are allergic to levodopa, carbidopa monohydrate or entacapone, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- you are taking a medicine called a monoamine oxidase inhibitor (MAOI) such as phenelzine and tranylcypromine.
- you are pregnant
- you are breastfeeding
- you have a problem with your liver

- you have 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 heart beat, muscle stiffness and fluctuating blood pressure
- you have ever had a condition called non-traumatic rhabdomyolysis, with symptoms of severe muscle weakness that was not due to an injury.
- you have unusual skin lumps or moles which have not been examined by your doctor, or if you have ever had skin cancer or melanoma.
- you have a type of glaucoma called narrow-angle glaucoma.
- it is after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.
- trehalase insufficiency

If you are not sure whether any of the above conditions apply to you, your doctor can advise you.

Check with your doctor if you:

- have depression, mental disturbances, or you recognize anti-social behaviour
- have heart disease, including irregular heartbeat, also known as arrhythmia
- have kidney problems
- have lung problems including asthma
- have hormonal problems
- have convulsions or fits
- have a type of glaucoma called wide angle glaucoma
- have stomach ulcers
- have problems with your gall bladder
- have inflammatory bowel disease
- have allergies to any other medicines, foods, dyes or preservatives

Your doctor may need to adjust the dose of CARLEVENT in some of these cases.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Do not take CARLEVENT if you are pregnant.

Check with your doctor if you are pregnant or intend to become pregnant. There is not enough information to recommend using CARLEVENT during pregnancy.

Do not take CARLEVENT if you are breastfeeding.

It is not known if the active ingredient in CARLEVENT passes into breast milk and could affect your baby. Talk to your doctor if you are breastfeeding or intend to breastfeed.

Use in children under 18 years

CARLEVENT should not be used in children under the age of 18 years. The safety of CARLEVENT and how well it works has not been studied in children younger than 18 years of age.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

You may need to take a different amount of your medicines or to take different medicines while you are taking CARLEVENT. Your doctor and pharmacist have more information.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect CARLEVENT.

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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect CARLEVENT.

4. How do I use CARLEVENT?

How much to take

- 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 [

When to take CARLEVENT

- 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 to take CARLEVENT

- Take the tablet with a full glass of water.
- Do not break the tablets into halves.
- 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 CARLEVENT 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 CARLEVENT. If you take the two medicines at the same time, your body may absorb less iron than usual.

If you forget to use CARLEVENT

CARLEVENT should be used regularly at the same time each day. If you miss your dose at the usual time, you should take it as soon as you notice that you have forgotten to take your medication.

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.

Do not take a double dose to make up for the dose you missed.

If you use too much CARLEVENT

If you think that you have used too much CARLEVENT, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using CARLEVENT?

Things you should 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 should 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 [if relevant].

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.

Looking after your medicine

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

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on windowsills.

Keep it where young children cannot reach it. A locked cupboard at least one-and-a-half meters above the ground is a good place to store medicines.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<p>Stomach, bowel or urinary related</p> <ul style="list-style-type: none"> • nausea (feeling sick) or vomiting • indigestion • diarrhoea • pain in the stomach • constipation • a reddish-brown colour to the urine (this is harmless) • dry mouth <p>Motion or movement related</p> <ul style="list-style-type: none"> • dizziness or light-headedness • spinning sensation (vertigo) • aches and pains, muscle cramps and pain or joint pain • unusual and uncontrolled movements of the body such as twisting, jerking or writhing movements • shakiness <p>Mental states or behavior related</p> <ul style="list-style-type: none"> • difficulty sleeping or unusual dreams • feeling depressed or agitated • unsteadiness when walking, or a lack of coordination in your movements or speech • extreme sleepiness or sudden onset of sleep in the middle of daytime activities <p>Eye related</p> <ul style="list-style-type: none"> • blurred vision • seeing double <p>Others</p> <ul style="list-style-type: none"> • headache • increased sweating • weight gain or loss 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>Allergy related</p> <ul style="list-style-type: none"> • cough, shortness of breath, wheezing or difficulty 	<p>Call your doctor straight away or go straight</p>

breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin

Mental states or behavior related

- worsening of your symptoms of Parkinson's disease
- confusion or hallucinations (seeing, hearing or feeling things that are not there)
- compulsive behaviour such as gambling or unusual increases in sexuality, shopping, eating, medicine use or repetitive purposeless activities

Heart or blood pressure related

- difficulty breathing, congestion in the chest, chest pain

Signs of possible anemia (low amount of iron in your blood)

- tiredness, headaches, shortness of breath when exercising, dizziness and looking pale

Signs of possible liver problems

- loss of appetite, feeling generally unwell, fever, itching, yellow colour to the skin and eyes

Stomach, bowel or urinary related

- gastrointestinal bleeding (coughing up blood or blood in the stools)
- diarrhoea, usually with blood and mucus

Others

- symptoms of neuroleptic malignant syndrome, such as a sudden increase in body temperature, sweating, fast heartbeat, muscle stiffness and fluctuating blood pressure
- temporary paralysis or weakness of muscles
- fever

**to the
Emergency
Department at
your nearest
hospital if you
notice any of
these serious
side effects.**

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the

Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What CARLEVENT contains

Active ingredient	Each tablet contains: <ul style="list-style-type: none">• 50, 75, 100, 125, 150 or 200 mg of levodopa and,• 12.5, 18.75, 25, 31.25, 37.5 or 50 mg of carbidopa and, 200 mg of entacapone
Other ingredients	<ul style="list-style-type: none">• carmellose sodium• hydroxypropylcellulose• trehalose dihydrate• powdered cellulose• anhydrous sodium sulphate• microcrystalline cellulose• magnesium stearate• Opadry II complete film coating system 85G35208 RED
Potential allergens	NA

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

Do not take this medicine if you are allergic to any of these ingredients.

What CARLEVENT looks like

CARLEVENT comes in 6 strengths of tablets:

CARLEVENT 50/12.5/200 – oval biconvex red tablet marked “50” on one side and “LEC” on the other side (AUST R 195198).

CARLEVENT 75/18.75/200 – oval biconvex red tablet marked “75” on one side and “LEC” on the other side (AUST R 195194).

CARLEVENT 100/25/200 – oval biconvex red tablet marked “100” on one side and “LEC” on the other side (AUST R 195747)

CARLEVENT 125/31.25/200 – oval biconvex red tablet marked “125” on one side. (AUST R 195748).

CARLEVENT 150/37.5/200 – oval biconvex red tablet marked “150” on one side and “LEC” on the other side (AUST R 195749).

CARLEVENT 200/50/200 – oval biconvex red tablet marked “200” on one side and “LEC” on the other side (AUST R 195192).

Each pack contains 100 tablets..

Who distributes CARVELENT

Arrotex Pharmaceuticals Pty Ltd
15 – 17 Chapel Street
Cremorne VIC 3121
Australia
Web: www.arrotex.com.au

This leaflet was prepared in February 2026