

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 L.C.E. SANDOZ?

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

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

2. What should I know before I use L.C.E. SANDOZ?

Do not use L.C.E. SANDOZ if you have ever had an allergic reaction to levodopa, carbidopa or entacapone 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 L.C.E. SANDOZ?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with L.C.E. SANDOZ 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 L.C.E. SANDOZ?

- People with moderate to severe Parkinson's disease usually take from 3 to 7 tablets of L.C.E. SANDOZ each day.
- **Take only one L.C.E. SANDOZ tablet at each dose.**
- Do not take 2 or more L.C.E. SANDOZ tablets at any one time. Do not break the tablets into halves. More instructions can be found in Section [4. How do I use L.C.E. SANDOZ?](#) in the full CMI.

5. What should I know while using L.C.E. SANDOZ?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using L.C.E. SANDOZ.• 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 reducing 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 L.C.E. SANDOZ until you know how it affects you.
Looking after your medicine	<ul style="list-style-type: none">• Store below 30°C.

For more information, see Section [5. What should I know while using L.C.E. SANDOZ?](#) in the full CMI.

6. Are there any side effects?

Common side effects: nausea (feeling sick), vomiting, diarrhoea, pain in the stomach, constipation, 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.

L.C.E. SANDOZ®

Active ingredient(s): Levodopa/carbidopa monohydrate/entacapone

Consumer Medicine Information (CMI)

This leaflet provides important information about using L.C.E. SANDOZ. **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 L.C.E. SANDOZ.**

Where to find information in this leaflet:

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

1. Why am I using L.C.E. SANDOZ?

L.C.E. SANDOZ contains the active ingredient levodopa, carbidopa monohydrate and entacapone.

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

L.C.E. SANDOZ 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 L.C.E. SANDOZ?

Warnings

Do not use L.C.E. SANDOZ 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.
- you have an intolerance to sucrose
- it is after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

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

Ask your doctor or pharmacist if you are not sure if you have been taking one of these medicines.

Check with your doctor if you:

- have depression, mental disturbances, or you recognise anti-social behaviour
- have heart disease, including irregular heart beat, 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 L.C.E. SANDOZ 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 L.C.E. SANDOZ if you are pregnant. Tell your doctor immediately if you become pregnant. There is not enough information to recommend using L.C.E. SANDOZ during pregnancy.

Do not take L.C.E. SANDOZ if you are breastfeeding.

It is not known if the active ingredient in L.C.E. SANDOZ 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

L.C.E. SANDOZ should not be used in children under the age of 18 years. The safety of L.C.E. SANDOZ 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.

Some medicines may interfere with L.C.E. SANDOZ and affect how it works. These include:

- monoamine oxidase inhibitor (MAOI) such as phenelzine and tranylcypromine. Taking L.C.E. SANDOZ 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 L.C.E. SANDOZ.
- dopamine D2 receptor antagonists such as phenothiazines, butyrophenones, risperidone and isoniazid
- some antibiotics such as erythromycin, rifampicin, ampicillin and chloramphenicol
- apomorphine, a medicine used in Parkinson's Disease.
- adrenaline, a medicine used in some local anaesthetics and in emergency treatment of allergic reactions
- cholestyramine, a medicine used to reduce high levels of cholesterol in the blood
- papaverine, a medicine used to expand blood vessels to treat men with erectile dysfunction
- probenecid, a medicine used to prevent gout
- some medicines used to treat high blood pressure
- other medicines for Parkinson's disease
- some medicines for depression
- some medicines for psychiatric disorders
- methyl dopa, a medicine for high blood pressure
- isoniazid, a medicine used to treat tuberculosis
- some medicines for nausea and vomiting
- phenytoin, a medicine used to treat convulsions
- medicines containing iron, such as iron tablets or multiple vitamins
- warfarin, a medicine used to prevent blood clots.

You may need to take a different amount of your medicines or to take different medicines while you are taking L.C.E. SANDOZ. 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 L.C.E. SANDOZ.

4. How do I use L.C.E. SANDOZ?

How much to take

- People with moderate to severe Parkinson's disease usually take from 3 to 7 tablets of L.C.E. SANDOZ each day.
- For L.C.E. SANDOZ 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 L.C.E. SANDOZ 200/50/200 mg, the maximum dose is 7 tablets each day.
- **Take only one L.C.E. SANDOZ tablet at each dose.**
- Do not take 2 or more L.C.E. SANDOZ tablets at a time.

How to take L.C.E. SANDOZ

- 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 L.C.E. SANDOZ 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 L.C.E. SANDOZ. If you take the two medicines at the same time, your body may absorb less iron than usual.

How long to take L.C.E. SANDOZ

- Do not stop taking this medicine without first checking with your doctor. You may need to take L.C.E. SANDOZ 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.

If you forget to use L.C.E. SANDOZ

L.C.E. SANDOZ 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 forgotten individual doses. This may increase the chance of you getting unwanted side effects.

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

If you use too much L.C.E. SANDOZ

If you think that you or anyone else have used too much L.C.E. SANDOZ, 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 L.C.E. SANDOZ?

Things you should do

- If you experience times where L.C.E. SANDOZ does not appear to be working as well as it did previously, tell your doctor.
- If you become pregnant, tell your doctor immediately. You should not take this medicine while you are pregnant.
- Before having any surgery or other hospital treatment, tell the anaesthetist or the doctor that you are taking L.C.E. SANDOZ. It may cause unwanted side effects if you take it at the same time as some medicines that are used in hospital.
- If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking L.C.E. SANDOZ.
- Be sure to keep all of your doctor's appointments so that your progress can be checked. Your doctor may also want to take some tests from time to time to help prevent unwanted side effects.
- Tell your doctor if you or your family/carer notices you are developing addiction-like symptoms leading to craving for large doses of L.C.E. SANDOZ and other medicines used to treat Parkinson's disease (known as dopamine dysregulation syndrome).
- Tell your doctor if you or your family/caregiver 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 a preoccupation with an increase in sexual thoughts or feelings. Your doctor may need to review your treatments.

Remind any other doctor, dentist or pharmacist who treats you that you are taking L.C.E. SANDOZ.

Things you should not do

- Do not give this medicine to anyone else, even if their condition seems similar to yours.
- Do not use it to treat any other complaints unless your doctor tells you to.
- Do not reduce the dose or stop treatment abruptly without consulting your doctor. It may be necessary to reduce the dose of L.C.E. SANDOZ gradually in order to prevent side effects.

Things to be careful of

- **If this medicine makes you feel light-headed, dizzy or faint, be careful when getting up from a sitting or**

lying position. These symptoms may be a sign of low blood pressure. You can usually prevent them by getting up slowly and flexing leg muscles and toes to get the blood flowing. When getting out of bed, dangle your legs over the side for a minute or two before standing up.

- **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.

Driving or using machines

Be careful before you drive, use any machines or tools or doing jobs that require you to be alert until you know how L.C.E. SANDOZ affects you.

This medicine may increase the dizziness, light-headedness or sleepiness that sometimes happens when you take levodopa. 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 or do anything else that could be dangerous.

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 below 30°C; for example, do not store it:

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

Keep it where young children cannot reach it. A locked cupboard at least one-and-a-half metres 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
Stomach, bowel or urinary related <ul style="list-style-type: none"> • nausea (feeling sick) or vomiting • indigestion • diarrhoea 	Speak to your doctor if you have any of these less

<ul style="list-style-type: none"> • pain in the stomach • constipation • strong urge to urinate that cannot be delayed, which is followed by a sharp pain or burning sensation in the urethra when the urine is released (urinary tract infection) • 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 behaviour 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 (these are less common side effects) 	<p>serious side effects and they worry you.</p> <p>They are generally mild and do not cause patients to stop taking L.C.E. SANDOZ.</p>
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<p>to control motor symptoms, known as dopamine dysregulation syndrome. Some patients experience severe uncontrolled movements (dyskinesias), mood swings, or other side effects after taking large doses of L.C.E. SANDOZ.</p> <ul style="list-style-type: none"> • inability to resist the impulse to perform an action that could be harmful, which may include: <ul style="list-style-type: none"> ○ strong impulse to gamble excessively despite serious or personal family consequences ○ altered or increased sexual interest and behaviour of significant concern to your or to others, for example, an increased sexual drive, ○ uncontrolled excessive shopping or spending, ○ binge eating (eating large amounts of food in a short time period) or compulsive eating (eating more food than normal and more than is needed to satisfy your hunger) ○ medicine use or repetitive purposeless activities. <p>Heart or blood pressure related</p> <ul style="list-style-type: none"> • difficulty breathing, congestion in the chest, chest pain <p>Signs of possible anemia (low amount of iron in your blood)</p> <ul style="list-style-type: none"> • tiredness, headaches, shortness of breath when exercising, dizziness and looking pale <p>Signs of possible liver problems</p> <ul style="list-style-type: none"> • loss of appetite, feeling generally unwell, fever, itching, yellow colour to the skin and eyes <p>Stomach, bowel or urinary related</p> <ul style="list-style-type: none"> • gastrointestinal bleeding (coughing up blood or blood in the stools) • diarrhoea, usually with blood and mucus <p>Others</p> <ul style="list-style-type: none"> • symptoms of neuroleptic malignant syndrome, such as a sudden increase in body temperature, sweating, fast heart beat, muscle stiffness and fluctuating blood pressure • temporary paralysis or weakness of muscles 	<p>experience any of these behaviours.</p> <p>Your doctor will discuss ways of managing or reducing the symptoms.</p>
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Serious side effects

Serious side effects	What to do
<p>Allergy related</p> <ul style="list-style-type: none"> • rash, itching or hives on the skin <p>Mental states or behaviour related</p> <ul style="list-style-type: none"> • worsening of your symptoms of Parkinson's disease • confusion or hallucinations (seeing, hearing or feeling things that are not there) • craving for large doses of L.C.E. SANDOZ in excess of that required 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects or</p>

• fever	
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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 L.C.E. SANDOZ contains

Active ingredient (main 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 (inactive ingredients)	<ul style="list-style-type: none"> • croscarmellose sodium • magnesium stearate • maize starch • mannitol • povidone • glycerol • hypromellose • polysorbate 80 • iron oxide red • sucrose • titanium dioxide • iron oxide yellow (not present in the 75/18.75/200 mg, 125/31.25/200 mg, 200/50/200 mg tablets).
Potential allergens	<ul style="list-style-type: none"> • sucrose • mannitol

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

What L.C.E. SANDOZ looks like

L.C.E. SANDOZ 50/12.5/200 – round-shaped tablets marked with 'LCE 50' on one side. (Aust R 192173).

L.C.E. SANDOZ 75/18.75/200 – oval-shaped tablets marked with 'LCE 75' on one side. (AUST R 192172).

L.C.E. SANDOZ 100/25/200 – oval-shaped tablets marked with 'LCE 100' on one side. (AUST R 192174).

L.C.E. SANDOZ 125/31.25/200 – oval-shaped tablets marked with 'LCE 125' on one side. (AUST R 192175).

L.C.E. SANDOZ 150/37.5/200 – ellipse-shaped tablets marked with 'LCE 150' on one side. (AUST R 192176).

L.C.E. SANDOZ 200/50/200 – oval-shaped tablets marked with 'LCE 200' on one side. (AUST R 192177).

L.C.E. SANDOZ 50/12.5/200 mg, 100/25/200 mg and 150/37.5/200 mg are brownish- or greyish-red; 200/50/200 mg is a dark brownish-red; and 75/18.75/200 mg and 125/31.25/200 mg are light brownish red film-coated tablets.

All strengths of the tablets are registered in HDPE bottles with a polypropylene child resistant closure of 10, 30, 100 and 250 (not 75/18.75/200, 125/31.25/200 and 200/50/200) tablets.

**Not all presentations may be marketed.*

Who distributes L.C.E. SANDOZ

Sandoz Pty Ltd
100 Pacific Highway
North Sydney, NSW 2060
Australia
Tel 1800 726 369

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