

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 LECIGON?

LECIGON contains the active ingredients levodopa, carbidopa monohydrate and entacapone. LECIGON is used to treat advanced Parkinson's disease.

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

2. What should I know before I use LECIGON?

Do not use if you have ever had an allergic reaction to LECIGON 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 LECIGON?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with LECIGON 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 LECIGON?

- LECIGON is given directly into the tummy using a pump and tube. The tube is inserted during a surgical operation.
- The dose of LECIGON is calculated by your doctor based on your individual needs and how you respond to the medicine.

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

5. What should I know while using LECIGON?

Things you should do	<ul style="list-style-type: none">• Tell your doctor if you have any problem with the pump or tube, including the skin where the tube is located.• Tell your doctor if your Parkinson's symptoms get worse.• Tell your doctor if you become pregnant.• Remind any doctor, dentist or pharmacist you visit that you are using LECIGON.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine suddenly.
Driving or using machines	<ul style="list-style-type: none">• Use caution when driving or operating machines
Looking after your medicine	<ul style="list-style-type: none">• Store LECIGON in the refrigerator. Do not allow it to freeze.• The cartridge should be used immediately once the sealed pouch has been opened. The purple cap should be disposed of immediately once removed from the cartridge.• Any unused medicine should be discarded 24 hours after taking it out of the refrigerator. Use each cartridge once only.

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

6. Are there any side effects?

Some of the most common side effects of LECIGON are nausea, diarrhoea, stomach pains, constipation, weight loss, abnormal urine colour, dizziness or light-headedness, extreme sleepiness and sudden onset of sleep and unusual and uncontrollable twitching, jerking or writhing movements. Serious side effects may include feeling suicidal, compulsive behaviours, muscle and/or joint pain, 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.

LECIGON™

Active ingredient(s): *levodopa/carbidopa monohydrate/entacapone*

Consumer Medicine Information (CMI)

This leaflet provides important information about using LECIGON. **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 LECIGON.**

Where to find information in this leaflet:

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

1. Why am I using LECIGON?

LECIGON contains three active ingredients: **levodopa, carbidopa monohydrate and entacapone**. LECIGON is an anti-Parkinson medicine. 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. The combination of active ingredients works together to increase the levels of dopamine in the brain

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

2. What should I know before I use LECIGON?

Warnings

Do not use LECIGON 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 have liver problems
- you have severe heart failure or an irregular heartbeat
- you have recently had a stroke
- you have an eye problem called narrow-angle glaucoma
- you have any condition that affects the adrenal glands, the glands responsible for releasing hormones that control heart rate, metabolism, and blood pressure, such as a tumour on the gland called pheochromocytoma, or a condition called Cushing's syndrome
- you have an over-active thyroid

- you have ever had a reaction to some medicines with a sudden increase in body temperature, extremely high blood pressure and severe convulsion (called neuroleptic malignant syndrome)
- you have ever had temporary paralysis or weakness of muscles (called rhabdomyolysis)
- 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 are taking medicines for depression called selective MAO-A inhibitors (like moclobemide) or non-selective MAO inhibitors (like phenelzine or tranylcypromine).

Check with your doctor if:

You have or have had, any other medical conditions including:

- depression, mental disturbances or you recognise anti-social behaviour
- heart disease, including irregular heartbeats
- kidney or liver problems
- lung problems including asthma
- hormonal problems
- convulsions or fits
- a type of glaucoma called wide-angle glaucoma
- stomach ulcers
- abdominal (tummy) surgery
- inflammatory bowel disease
- take any medicines for any other condition.

This medicine contains 166 mg sodium (main component of cooking/table salt) in each cartridge. This is equivalent to 8.3% of the recommended maximum daily dietary intake of sodium.

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 use LECIGON if you are pregnant or planning to become pregnant. There is not enough information to recommend using LECIGON during pregnancy.

Do not take LECIGON if you are breastfeeding or plan to breastfeed. There is not enough information to recommend using LECIGON during breastfeeding.

Use in children

LECIGON should not be used in children under the age of 18 years. The safety of LECIGON 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.

LECIGON and monoamine oxidase inhibitors (MAOIs) must not be taken together. Check with your doctor before you use LECIGON if you are taking or have recently taken (in the last 2 weeks), any medicine to treat depression. There are certain types of antidepressants that cannot be taken with LECIGON. These can include some monoamine oxidase inhibitors. Examples include phenylzine, tranylcypromine and moclobemide.

Some medicines may interfere with LECIGON and affect how it works. These include:

- other medicines used in Parkinson's disease
- medicines that stimulate the sympathetic nervous system e.g. adrenaline (a medicine used in some local anaesthetics and in emergency treatment of allergic reactions)
- medicines for urinary incontinence (like oxybutynin), asthma and chronic obstructive pulmonary disease, COPD (like ipratropium and tiotropium). These medicines are known as anticholinergics.
- 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 mental conditions (e.g. psychosis) and mood disorders
- medicines for anxiety (e.g. medicines known as benzodiazepines)
- 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.

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

4. How do I use LECIGON?

How much to use

- Follow the instructions provided by your doctor and use LECIGON until your doctor tells you to stop.
- The doctor will calculate the dose for you individually based on previous medication. It may be necessary to adjust the dose during the first few weeks of treatment.

How to use LECIGON

- LECIGON is a gel that travels through a portable pump (Crono LECIG) and tube directly into the upper part of your intestine. The tube is inserted during a surgical operation.
- The gel is contained in a cartridge connected to the pump. The pump gives you a small dose throughout the day. This means that the level of the medicine in your blood stays the same. It also means that some side effects, like those affecting movement, are lower compared to medicines taken by mouth.
- Before the tube is inserted into your small intestine, the doctor may choose to check whether treatment with LECIGON works for you. This is done by giving the medicine through a tube that passes up through the nose and into your stomach.
- **The pump is supplied with a manual containing instructions on how the pump should be used.**
- The cartridge should be used immediately once the sealed pouch has been opened. The purple cap should be disposed of immediately once removed from the cartridge.

When to use LECIGON

- A larger dose of LECIGON (called a bolus dose) is usually given in the morning when treatment is started so the blood reaches the right levels of medicine quickly. After this, a continuous maintenance dose is given during time you are awake (usually about 16 hours). If necessary, your doctor can decide to give LECIGON up to 24 hours a day.
- Depending on how you respond your doctor may tell you to take extra doses or you may need to adjust the continuous maintenance dose during the day.
- The total daily dose may not exceed 100 mL of the gel (which corresponds to 2000 mg levodopa, 500 mg carbidopa and 2000 mg entacapone).

If you forget to use LECIGON

LECIGON should be used every day.

If you miss your dose, start the pump with your usual dose as soon as you remember.

Do not increase the dose to make up for compensate for the forgotten dose.

If you use too much LECIGON

If you think that you have used too much LECIGON, 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 LECIGON?

Things you should do

- Tell your doctor if you have any problems with the pump or tube, including if you are finding it difficult to manage it.
- Tell your doctor if you have any pain near the point where the tube is located, and you feel nauseous.
- If your symptoms appear to worsen or it is harder to move than usual, tell your doctor.
- Visit your doctor regularly so they can check on your progress. Your doctor may also carry out tests to check your blood, liver, heart and kidney functions.
- If you plan to have surgery, including dental surgery, tell your doctor or dentist that you are using LECIGON.
- Remind any doctor, dentist or pharmacist you visit that you are using LECIGON.
- Tell your doctor if you become pregnant while using LECIGON
- Get regular skin cancer checks.

Things you should not do

- **Do not stop using this medicine suddenly.** Suddenly lowering your dose or stopping treatment with LECIGON too quickly could lead to serious conditions called neuroleptic malignant syndrome and rhabdomyolysis.

Dietary considerations

- **Be careful not to eat a high protein diet.** If you are unsure, ask your doctor, pharmacist or dietician to check your diet.

Behavioural Changes

Tell your doctor if you or your family/care giver notices you are developing:

- addiction-like symptoms leading to craving for larger doses of LECIGON and other medicines used to treat Parkinson's disease (known as dopamine dysregulation syndrome)
- urges or craving 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.

Driving or using machines

LECIGON can have a major influence on the ability to drive and use machines. Do not drive or use machines until you are sure how LECIGON affects you.

- LECIGON may make you feel very sleepy, or you may sometimes find yourself suddenly falling asleep (sleep attacks).

- LECIGON may cause your blood pressure to drop especially when you stand up from sitting or lying down, and make you feel dizzy.

Wait until you feel fully awake again or you no longer feel light-headed or dizzy before driving, using tools or machines, or performing any activities where lack of concentration may put you or others at risk.

Looking after your medicine

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

- Store LECIGON in the refrigerator (Between 2°C and 8°C). Do not allow the medicine to freeze. Protect from light.
- Keep cartridge in sealed pouch until immediately before use. Dispose of purple cap immediately after opening to avoid choking hazard.
- Once opened, use the cartridge immediately. LECIGON can be used for up to 24 hours after being removed from the refrigerator. Discard any unused medicine after 24 hours.
- The dosing pump with installed cartridge can be worn close to the body for up to 16 hours. During overnight treatment, the pump should not be worn next to the body but can, for example, be kept on the bedside table.
- The cartridges are intended for single use only. Do not reuse an opened cartridge.

Keep it where young children cannot reach it.

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• stomach pains, cramping• diarrhoea• constipation• a reddish-brown colour to the urine• weight loss, reduced appetite Mouth, throat, or lung related: <ul style="list-style-type: none">• pain in mouth or throat• breathing difficulties	Speak to your doctor if you have any of these less serious side effects and they worry you.

<p>Motion or movement related:</p> <ul style="list-style-type: none"> dizziness or light-headedness unusual and uncontrollable twitching, jerking movements or a worsening of your Parkinson's symptoms. muscle and/or joint pain <p>Eye related:</p> <ul style="list-style-type: none"> difficulty in opening the eyes <p>Skin related:</p> <ul style="list-style-type: none"> unusual marks or moles on your skin that appear or get worse discolouration of the skin, hair, nails or sweat sweating more than usual redness, itchy rash 	
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<p>Mental states or behaviour related:</p> <ul style="list-style-type: none"> feeling depressed with suicidal thoughts urge to gamble or increased sexual desires, uncontrollable shopping, binge eating, medicine use or repetitive purposeless activities confusion, paranoia or hallucinations (seeing, hearing or feeling things that are not there) inability to concentrate or solve problems extreme sleepiness and sudden onset of sleep 	
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Serious side effects

Serious side effects	What to do
<p>Allergic reaction:</p> <ul style="list-style-type: none"> swelling of the face, lips, tongue or throat which may cause difficulty in swallowing or breathing rash (hives). <p>Neuroleptic Malignant Syndrome:</p> <ul style="list-style-type: none"> fast heartbeat, sweating, fever fast breathing muscle stiffness, cramps confusion, losing consciousness. <p>Rhabdomyolysis:</p> <ul style="list-style-type: none"> unexplained muscle weakness, muscle cramps or muscle pain <p>Heart or blood pressure related:</p> <ul style="list-style-type: none"> chest pain/tightness, shortness of breath or difficulty breathing fast or irregular heartbeats <p>Reduced white blood cell count (known as agranulocytosis):</p> <ul style="list-style-type: none"> fever with severely impaired general condition or with local infection (e.g. sore throat or difficulty urinating) <p>Problems from the surgery or with the tube:</p> <ul style="list-style-type: none"> stomach pain, nausea or vomiting redness, pain or irritation at the location of the tube the tube has moved or appears to be blocked <p>Infections:</p> <ul style="list-style-type: none"> frequent infections, with symptoms such as fever, lack of energy, skin sores, problems with teeth and gums, burning when passing urine. 	<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.</p>

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 LECIGON contains

Active ingredients	<ul style="list-style-type: none"> Levodopa Carbidopa monohydrate Entacapone
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> carmellose sodium sodium hydroxide (for pH adjustment) hydrochloric acid (for pH adjustment) purified water

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

What LECIGON looks like

- LECIGON is a yellow or yellowish-red opaque viscous gel.
- LECIGON gel is provided in a plastic cartridge containing 47 mL of gel. Each mL of gel contains 20 mg

levodopa, 5 mg carbidopa monohydrate and 20 mg entacapone.

- One carton of LECIGON contains 7 cartridges. Each cartridge is provided in a sealed pouch.

(Aust R 377437).

Who distributes LECIGON

STADA Pharmaceuticals Australia Pty Ltd
Suite 2.04, 26 Rodborough Road
Frenchs Forest NSW 2086

This leaflet was prepared in April 2024.