This material is non-promotional and is essential to ensure
the safe and effective use of LECIGON® (levodopa/carbidopa/entacapone intestinal gel)

LECIGON®
(Levodopa/carbidopa/entacapone gel)

Important risk minimisation information for patients – do not discard

Patient Pocket Guide

This pocket guide provides a practical overview of the LECIGON® therapy and potential complications related to the medication and its delivery system.

For further information, please read the Crono® LECIG pump manual for each device and the LECIGON® patient information leaflet. If you have any further questions, speak to your doctor, pharmacist or nurse.

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Introduction to LECIGON®

What LECIGON® Is Used For

LECIGON® is used to treat Parkinson's disease. The symptoms of Parkinson's disease include tremor, feeling rigid, slow movements and balance problems. The pump continuously delivers levodopa/carbidopa /entacapone throughout the day.

What LECIGON® Cartridge Contains

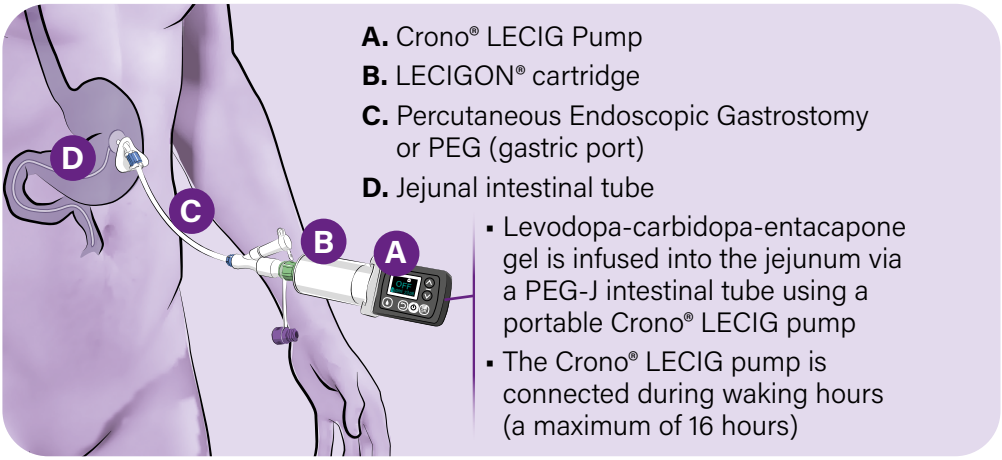
- Levodopa 20 mg/mL
- Carbidopa 5 mg/mL
- Entacapone 20mg/ml

The Crono® LECIG pump

The LECIGON® treatment (**Figure 1**) consists of a pump, intestinal tube and cartridge (which contains the medication levodopa/carbidopa /entacapone). You will need to have a procedure to make a small hole (called a "stoma") in your stomach wall to place a gastro jejunostomy tube (called a PEG-J tube) in an area of your small intestine called the jejunum.

The LECIGON® medicine is a gel contained in a plastic cartridge. The cartridge is connected to a pump. The pump is connected to the PEG-J tube which is placed into your gut (small intestine). The pump continuously gives you a small dose throughout the day. Your doctor or nurse will talk to you about the stoma procedure.

Figure 1



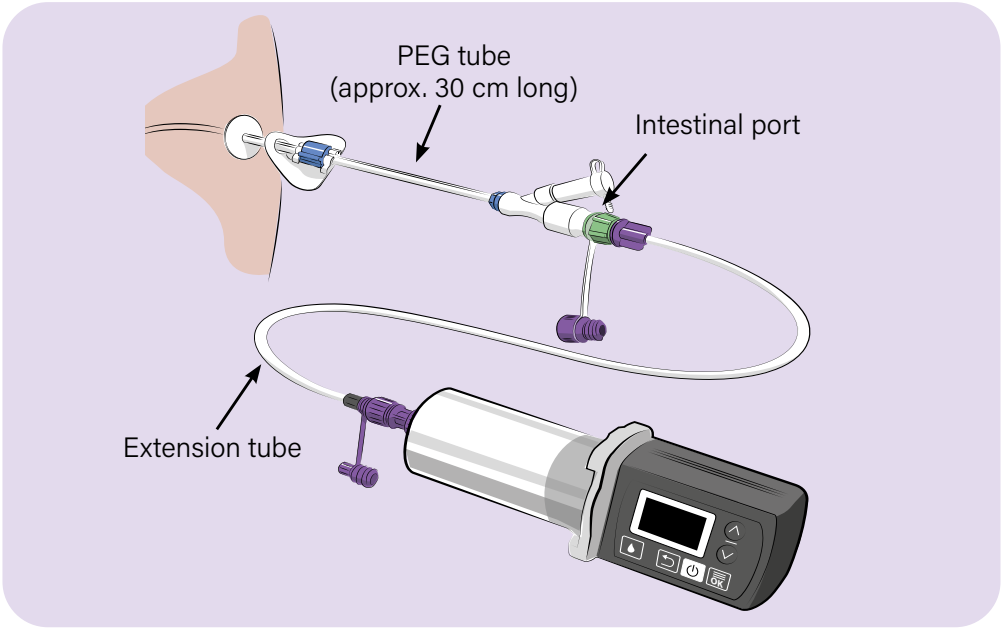
Daytime Treatment

The following is a short guide for patients who use one cartridge per day (up to 16 hours). For further instructions please read the Crono® LECIG pump manual for each device and the LECIGON® patient information leaflet.

LECIGON® daily procedure: Morning – Getting Started

Connecting the cartridge and pump to the PEG-J tube with the optional extension tube

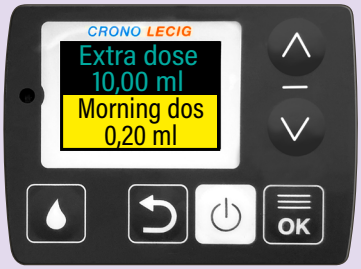
1. Connect the extension tube to the LECIGON® cartridge and turn clockwise to attach the extension tube.
2. Use the bolus dose to fill the extension tube before connecting the cartridge to the intestinal port.
3. Undo the purple cap of the PEG-J tube and connect to the intestinal port of the PEG-J.
4. Do this by holding the PEG-J Y-connector with one hand securely whilst gently rotating clockwise the cartridge tube onto the PEG-J with the other hand.
5. **Make sure to twist the cartridge tube and NOT the PEG-J tube.**



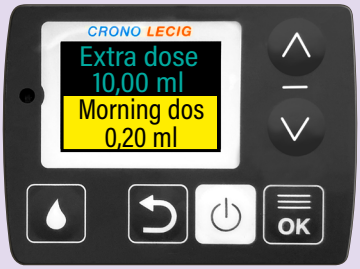
LECIGON® daily procedure: Morning – Starting the pump and administering the morning dose

1. Press any button on the Crono® LECIG Pump to turn on the display.

2. To switch on the pump, press and hold the **ON/OFF** button until **ON** shows on the display.



3. Press and hold the **DROPLET** button.



4. Use the up and down **ARROW** buttons to select 'morning dose' on the menu. Press and hold the **DROPLET** button to start the selected dose. The Crono® LECIG Pump will now deliver the morning dose.

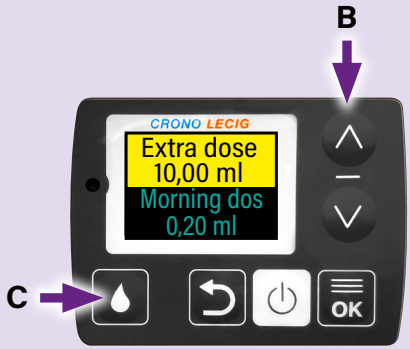
LECIGON® Daily Procedure: continuous dose

Once the Crono® LECIG Pump has finished delivering the morning dose it will automatically switch to delivering the continuous dose and continue to run for the rest of the day.

LECIGON® Daily Procedure: extra bolus doses

When symptoms of Parkinson's appear, an extra dose by can be administered.

A. Press any button to turn on the display, then press and hold the **DROPLET** button.



B. Use the up and down **ARROW** buttons to select 'Extra dose' on the menu.

C. Press and hold the **DROPLET** button. The Crono® LECIG Pump will now deliver the extra dose.

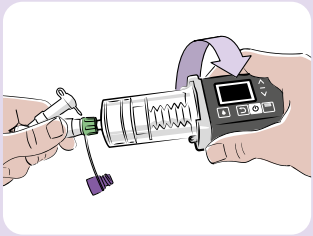
LECIGON® daily procedure: Evening

Discontinuing the Infusion and Flushing the Intestinal Tube

LECIGON® is usually stopped before going to bed. The tube is rinsed with 20 ml drinking water to prevent the medication from coagulating in the tube causing an obstruction.

1. Press any button on the Crono® LECIG Pump to turn on the display.

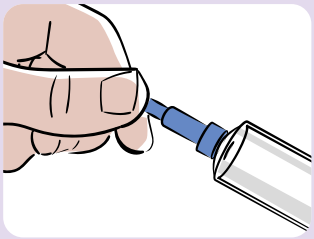
2. To stop the infusion, press and hold the **ON/OFF** button.
The pump will display the prompt 'STOP?' Press **OK** to stop the infusion. 'STOP' appears on the display, and the infusion is stopped.



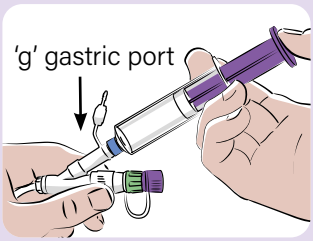
3. Disconnect the LECIGON® cartridge tube from the intestinal port of the PEG-J. Make sure to twist the cartridge tube, NOT the PEG-J tube.

Close port with the purple cap.

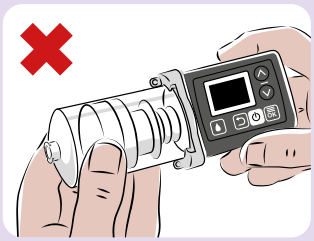
4. Open the intestinal port and press down on the syringe to flush the tube. Once flushed, remove the syringe and close the intestinal port (i).



5. Attach adapter to the syringe.



6. Open the gastric port, and press down on the syringe to flush the tube. Once flushed, remove the syringe and close the gastric port (g).

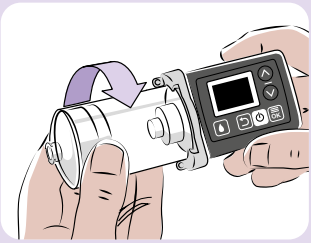


7. **DO NOT** REMOVE CARTRIDGE WHEN PISTON IS EXTENDED.

LECIGON® daily procedure: Evening *cont...*

8. Press any button on the Crono® LECIG Pump to switch on the display.

Press and hold the **OK** button and use the down button to select **END**. After 10 seconds the pusher starts to retract. This could take up to 6 minutes.



9. Once the piston is fully retracted, the LECIGON® cartridge can be removed by twisting the cartridge.

10. Empty cartridges and used batteries should be disposed of according to local regulations.

Stoma Care

Before the stoma procedure, tell your healthcare provider if you have ever had abdominal or pelvic surgery or problems with your stomach. Talk to your healthcare provider about what you need to do to care for your stoma. After the procedure, you and your healthcare provider will need to regularly check the stoma for any signs of infection.

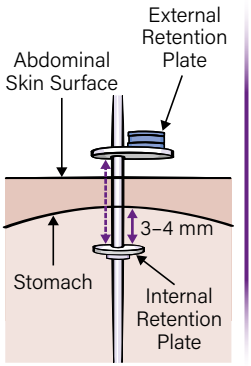
Tube Mobilisation to Prevent Buried Bumper Syndrome

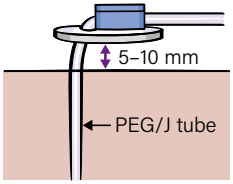
After initial wound healing (24–72 hours, after initial PEG-J insertion), the following procedure should be performed every 2–3 days to prevent buried bumper syndrome.

Remove the dressing and release the external retention plate to allow free movement of the PEG-J tube

- Avoid in/out movement of the PEG tube within 72 hours post-placement.
- The PEG tube should remain under moderate tension for 24–72 hours to promote good adherence of the stomach wall to the inner abdominal wall.
- Carefully push the tube 3–4 cm into the stomach and gently pull back until you feel resistance of the internal retention plate into the stoma and move the tube in a bi-directional motion (in and out) every time the dressing is changed.

Do not twist or rotate the PEG tube. It is important for the tube to move freely in the stoma to prevent the inner retention plate becoming embedded: 'buried bumper syndrome'





Replace the retention plate allowing free movement of 5–10 mm; apply a sterile Y compress under the tube

A plaster fixation is recommended for agitated patients

Important Information

LECIGON®, 20 mg/mL + 5 mg/mL + 20 mg/ml intestinal gel, levodopa, carbidopa monohydrate and entacapone

Read all of this information carefully before you start using this medicine.

If you have any further questions, ask your doctor, pharmacist or nurse. Additional information is also provided in the patient information leaflet.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this patient information leaflet or pocket guide.

Important Information *cont...*

If your PEG-J tube becomes kinked, knotted, or blocked this may cause you to have worsening of your Parkinson's symptoms or recurring movement problems (motor fluctuations). Call your doctor or nurse if your Parkinson's symptoms get worse or you have slow movement while you are treated with LECIGON®

Driving and Using Machines

Do not drive or use any tools or 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 (sudden sleep episodes)
- LECIGON® may lower your blood pressure, which can make you feel light-headed or dizzy, particularly on standing

Do not drive or use any tools or machines until you feel fully awake again or you no longer feel light headed or dizzy

If you have had more LECIGON® than you should

Talk to your doctor or go directly to a hospital. Take the medicine pack with you. The following effects may happen:

- Problems opening your eyes (blepharospasm)
- Muscle spasms you cannot control in your eyes, head, neck and body (dystonia)
- Movement you make without wanting to (dyskinesia)
- Unusual fast, slow or uneven heart beats (arrhythmia)

If You Forget to Use LECIGON®

Start your pump, with your normal dose, as soon as possible. Do not increase your dose to make up for a forgotten dose.

If You Stop or Lower Your Dose of LECIGON®

It is important that you do not stop having LECIGON® or lower your dose until told to do so by your doctor. Suddenly stopping or lowering your LECIGON® dose may result in a serious problem called **Neuroleptic Malignant Syndrome**.

The signs may include:

- Fast heartbeat, changing blood pressure and sweating followed by fever
- Faster breathing, muscle stiffness, lower consciousness and coma
- Higher levels of a protein in your blood (an enzyme called creatine phosphokinase). This is measured by your doctor.

This problem is more likely to happen if you are also taking a medicine called an **antipsychotic**.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

Possible Side Effects

The following very common complications have been reported for the tube delivery system:

- Leaks at the connections and leakage of gastric fluid
- Blockade of flow of LECIGON® due to occlusion, kinking and knotting of the tubing
- Dislocation of the tube (e.g. to the stomach, resulting in decreased treatment response)
- Local infection around the site of tube entering the stomach area (stoma), inflammation of the abdominal cavity (peritonitis), and perforation of adjacent organs, bleeding and abdominal pain, especially during tube placement

If you are experiencing serious side effects, or if you notice any side effects not listed here, please tell your doctor or pharmacist as soon as possible.

Side Effects From the Pump or Tube

The following side effects have been reported for the pump and tube, and tube delivery system. Tell your doctor or nurse if you notice any of these.

- If you become less able to handle the pump and tube, your Parkinson's disease symptoms get worse or it is harder to move (bradykinesia) – the pump and tube may not be working properly
- If you have pain in your stomach area, feel sick (nausea) and are sick (vomit) tell your doctor straight away – you might have a problem with your pump or tube

Possible Side Effects *cont...*

Very Common: May Affect More Than 1 in 10 People

- Abdominal pain
- Infection of the wound after surgery
- Thick scarring at the site of the incision
- Problems with tube insertion, such as pain or swelling in the mouth or throat, difficulty swallowing, stomach discomfort, pain or swelling, injury to the throat, mouth or stomach, internal bleeding, vomiting, bloated stomach, anxiety
- Problems at the site of the incision, redness, sore, stoma leakage, pain or irritation

Common: May Affect up to 1 in 10 People

- Abdominal discomfort, upper abdominal pain
- Infection at the surgery site or in the intestine, infection after surgery when the tube was positioned in the intestine
- Inflammation of the peritoneum (peritonitis)
- The tube changes position from the intestine to e.g. the stomach or is blocked, which can lead to decreased response to treatment
- Problems in the gastrointestinal tract due to the stoma (where the tube enters the abdomen), pain at the incision, stop of bowel movements after surgery, and problems, discomfort or bleeding as the result of the treatment procedure

Uncommon: May Affect up to 1 in 100 People

- Inflammation of the large intestine or pancreas
- Inflammation of the pancreas (pancreatitis)
- The tube penetrates the large intestine wall
- Blockage in the intestines, bleeding or ulcer in the small intestine
- Part of the intestine folds into the section next to it (intussusception)
- Blockage of the tube due to undigested food that has gotten stuck around the tube
- Abscess after insertion of the tube in the intestine

Other risks

- Reduced blood flow in the small intestine
- The tube penetrates the stomach wall or small intestine
- Infection in the blood (sepsis)

Please read the patient information leaflet for complete information including the side effects of LECIGON®

How to Store LECIGON®

- Keep the cartridges with gel out of the reach and sight of children.
- Do not use LECIGON® after the expiry date which is stated on the carton label after EXP.
- Store in a refrigerator (2°C to 8°C).
- Keep the cartridges in the outer carton in order to protect from light.
- A cartridge of the gel may be used for up to 24 hours once it is out of the refrigerator.
- The drug cartridges are for single use only and should not be used for longer than 24 hours even if some gel remains.
- Do not re-use an opened cartridge.
- The gel might become slightly yellow – this does not affect the medicine.

How to Dispose of LECIGON®

Do not throw away any medicine via wastewater or household waste.
Your at home nurse team will dispose of waste product. Ask your pharmacist how to throw away medicine you no longer use.

About the Pump

Caution: Fluid and water can damage the pump. Before showering and bathing always disconnect the pump.

Travelling

- Ensure that the stoma wound has healed properly before travelling. If you have any questions consult your doctor, pharmacist or nurse or the LECIGON® Support Helpline on **+44 808 196 1460**
- Plan your trip well in advance. Ensure that you have adequate cool packaging for the journey, and that you have refrigeration for the LECIGON® cartridges at your destination.
- The LECIGON® system contains metal parts that may affect magnetic fields such as those in MRI scanners and metal detectors.

Take the following:

1. LECIGON® prescription (copy)
2. Sufficient LECIGON® medication
3. Patient's Pump Manual
4. Rescue tablet medication
5. Reserve pump (if travelling abroad)
6. EnFit syringe, 20 mL
7. EnFit syringe, 10 mL for clearing occlusions (optional)
8. Reserve batteries (3V Lithium)
9. Wound dressing material
10. Patient Pocket Guide

Pump Trouble Shooting

Code	Acoustic signal/LED	Cause	Corrective Action
Error	Short acoustic signal	Operation cannot be executed	–
Er.2	Continuous acoustic signal/ LED flashing	Safety system fault (pump locked)	Press OK
Er.3	Intermittent acoustic signal repeated every 10 seconds	Motor fault	Press OK
Er.4	Intermittent acoustic signal repeated every 10 seconds	Pusher retraction blocked	Remove the obstacle impeding retraction of the pusher
Er.5	Intermittent acoustic signal repeated every 10 seconds	Advancement system blocked	Press OK
Er.6	Intermittent acoustic signal repeated every 10 seconds	Motor fault	Initialise the pump (see "Initialising the pump" on page 75 of the manual)
Er.7	Intermittent acoustic signal repeated every 10 seconds/ LED off or flashing	Microcontroller circuit fault	Press OK
Er.8	Intermittent acoustic signal repeated every 10 seconds	Pump settings incongruous (factory settings restored)	Initialise and re-programme the pump (see "Initialising the pump" on page 75 of the manual and "Setting the pump" on page 57 of the manual)
Er.9	Intermittent acoustic signal repeated every 10 seconds	Motor safety circuit fault	Initialise the pump (see "Initialising the pump" on page 75 of the manual)
Er.11	Intermittent acoustic signal repeated every 10 seconds	Advancement system fault (pump locked)	Initialise the pump (see "Initialising the pump" on page 75 of the manual)
BATT	Intermittent acoustic signal	Battery discharged	Change the battery (see "Changing the battery" on page 76 of the manual)
OCCL	Intermittent acoustic signal repeated every 10 seconds	Occlusion along the infusion line (pump blocked)	Remove the cause of the occlusion (see "Resolving occlusions" on page 81 of the manual)

Further Information: Some Technical Pump Data

The device may be damaged upon contact with any liquid, therefore remove it before taking a bath or shower etc. Should the pump accidentally come into contact with any liquid (drug solution, sweat, bed wetting) the pump needs to be returned to Britannia Customer Services Department, 200 Longwater Avenue, Green Park, Reading, Berkshire RG2 6GP

The pump must be kept away from:

- heating sources (radiators, burners, stoves)
- direct sunlight
- high electromagnetic fields (magnets, loud-speakers, mobile phones or other devices that emit radio waves)
- ionogenic radiations (devices for radiotherapy or diagnostic radiology)
- ultrasound devices
- magnetic resonance devices

Do not sterilize the pump.

Do not place the pump in a fridge.

If you have any questions or queries, please do not hesitate to contact the LECIGON® Support Helpline on: **+44 808 196 1460**.

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

Please report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme. You can report via:

- the Yellow Card website www.mhra.gov.uk/yellowcard
- the free Yellow Card app available in Apple App Store or Google Play Store
- some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals.

Alternatively you can report a suspected side effect to the Yellow Card scheme by calling **0808 731 6789** for free, Monday to Friday between 9am and 5pm. You can leave a message outside these hours.

When reporting please provide as much information as possible. By reporting side effects, you can help provide more information on the safety of this medicine.

For additional hard copies of this Patient Pocket Guide, please contact:
Britannia Medical Information: Tel **0808 196 8585**
Email: **medinfo@britannia-pharm.com**
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