

LECIG

20 mg/ml levodopa, 5 mg/ml carbidopa, 20 mg/ml entacapone

User guide – PEG-J tube

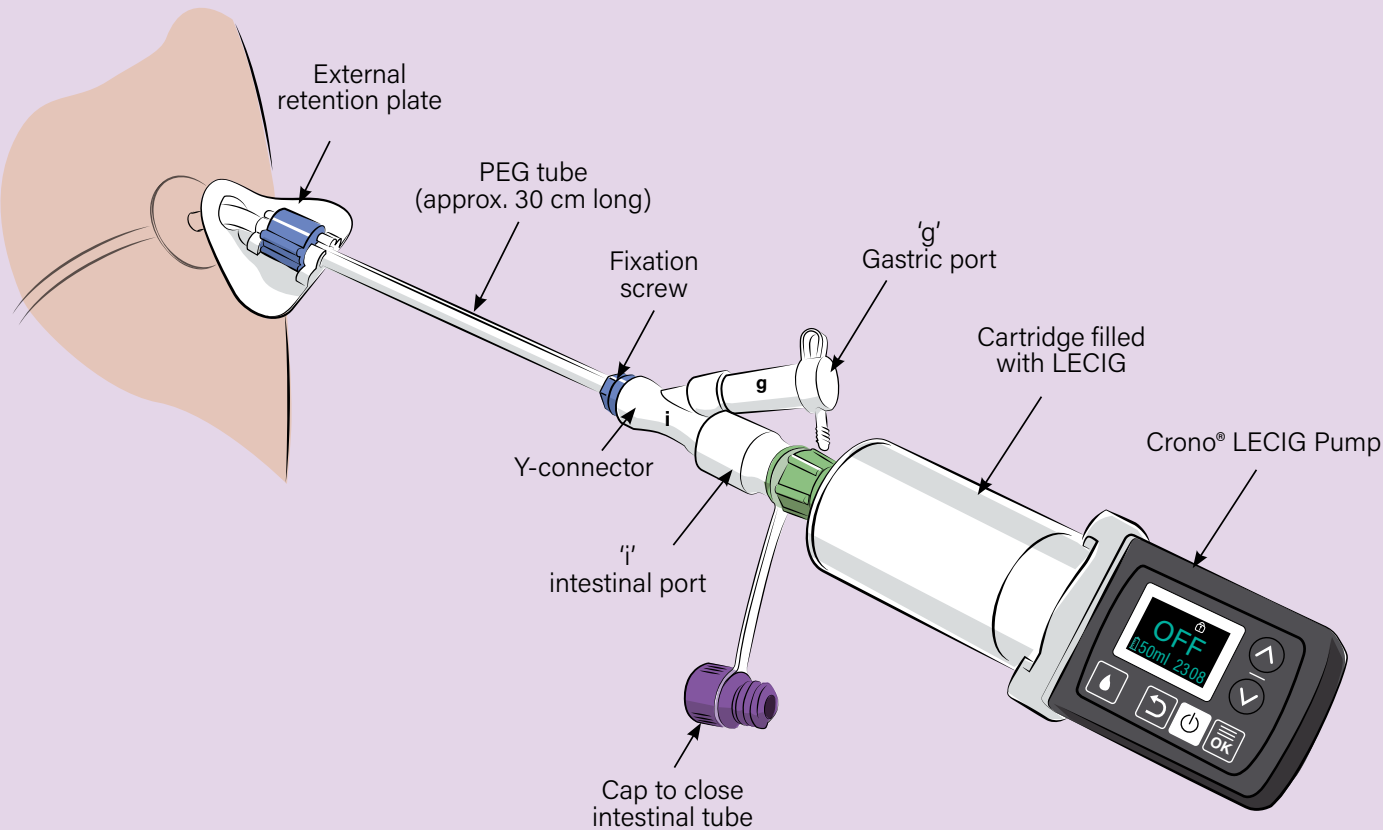


You have been provided with this booklet by your doctor or nurse because you've been prescribed LECIG. For full details, please refer to the Pump User Manual and LECIG Package Leaflet.

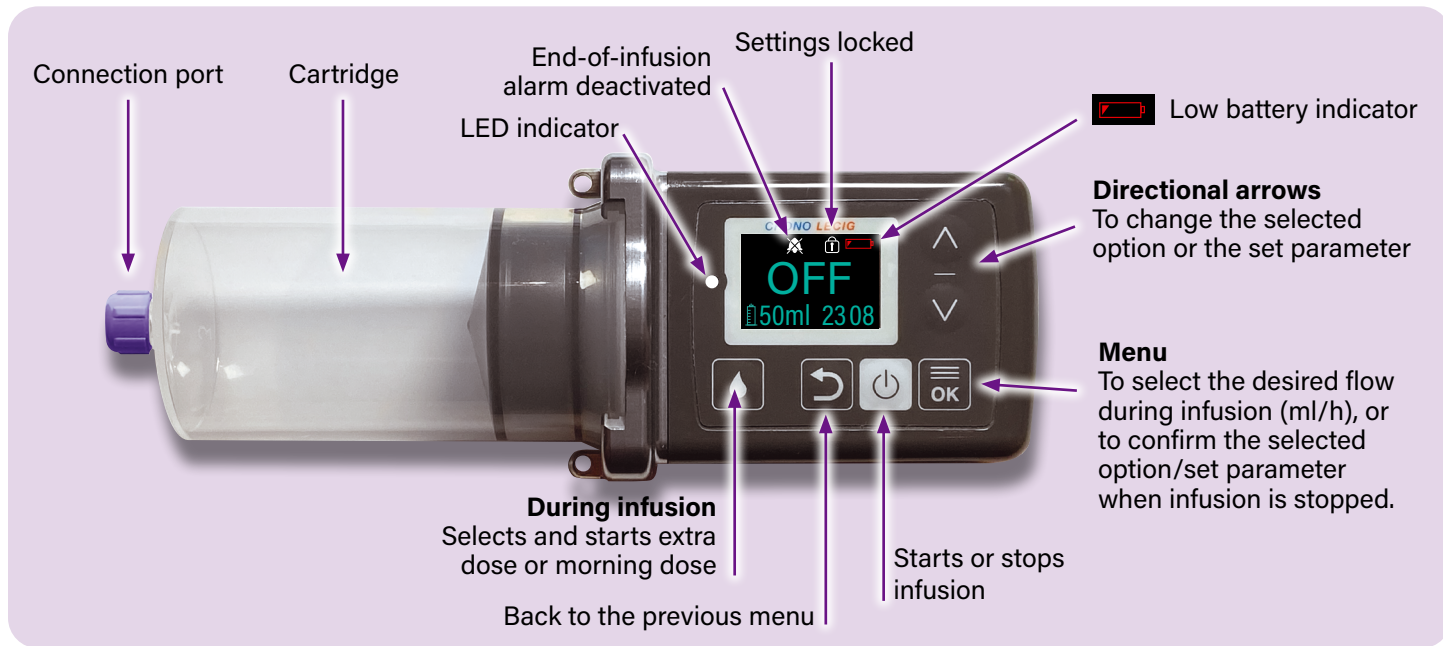
For reporting of side effects - please see the last page

This user guide has been developed by Britannia Pharmaceuticals Ltd. and is intended for UK patients who have been prescribed LECIG only. This user guide is not a substitute for the package leaflet contained in the pack, which you should also read.

The LECIG components



Getting to know the screen and buttons



Pump alarm

In case of a Pump Alarm, the display will show an error code, and the LED indicator will light up.

CODE: OCCL

Cause: Occlusion – the pump or tube is blocked.

Corrective action:

Remove the cause of the blockage, and ensure the PEG-J tube is not folded/kinked (please see "How to Remedy an Occlusion" on page 81 of the Pump User Manual).

CODE: BATT

Cause: The battery is dead and the pump can no longer function.

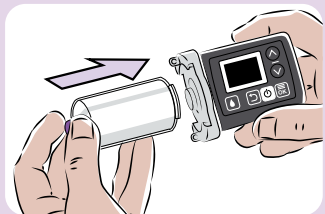
Corrective action:

Replace the battery (please see "Replacing the Battery" on page 76 of the Pump User Manual).

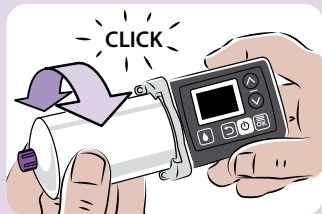


For full details, please see page 80 of the Pump User Manual.

1. Preparing an infusion using the direct PEG-J tube



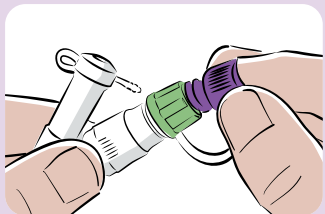
1. Take out a pre-filled cartridge from the fridge. To attach the cartridge to the Crono® LECIG Pump, align the plastic edges with the gaps on the pump.



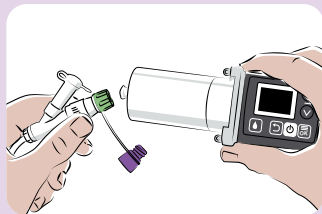
2. Turn the cartridge in either direction until it locks into place on the Crono® LECIG Pump.



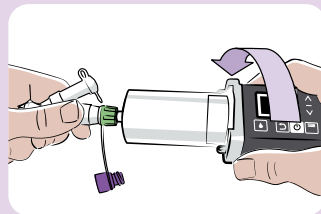
3. Unscrew the purple protective cap/seal from the connection port on the LECIG cartridge.



4. Undo the purple cap of the Y-connector at the end of the PEG-J tube.



5. Connect the cartridge to the intestinal port (labelled 'i') on the Y-connector. (Do not connect the cartridge to the gastric port.)



6. To connect the cartridge, hold the PEG-J Y-connector with one hand securely whilst gently rotating the cartridge and pump clockwise onto the PEG-J Y-connector with the other hand.

Notes

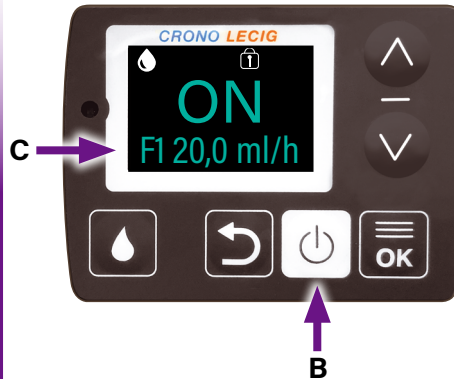
- Press any button to activate the display.
- After 40 seconds, the display goes black (standby mode), but the infusion will continue.
- The cartridge must be refrigerated when stored. It can withstand room temperature for a maximum of 24 hrs.
- Please note that the medicine cannot withstand room temperature for more than 24 hrs.
- When changing the tube, fill it with an Extra Dose.
- If using an extension tube:
 - Connect the cartridge to the extension tube. Then connect the other end of the extension tube to the intestinal port.
 - Remove before bedtime and connect its ends to form a loop for storage.
 - Do not flush out the tube.

IMPORTANT: twist the cartridge and pump, NOT the PEG-J tube or Y-connector

2. Starting the pump with a continuous dose (F1)



- A.** Press any button on the Crono® LECIG Pump to turn on the display.

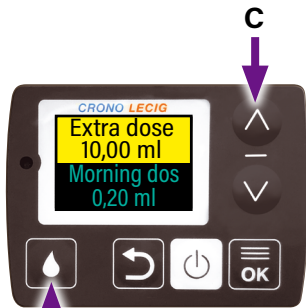


- B.** Press and hold the **ON/OFF** button until **ON** shows on the display.
- C.** The preset Continuous Flow starts (F1).



- D.** The **droplet symbol** on the display blinks to indicate the infusion is active.
- E.** The **hourglass** indicates the remaining infusion time.
- F.** The **yellow dotted line** indicates the amount of drug remaining in the cartridge.

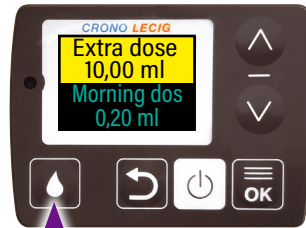
3. Extra dose, morning dose or switching programmed flows (F1–F3)



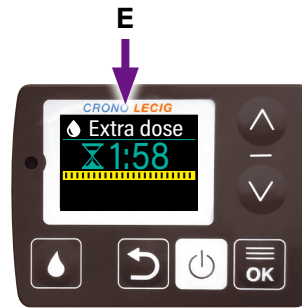
A. Press any button on the Crono® LECIG Pump to turn on the display.

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

C. Select Extra dose or Morning dose using the **ARROW** buttons.



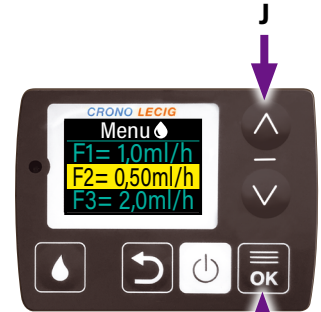
D. Start the selected dose by pressing and holding the **DROPLET** button.



E. The **droplet symbol** and **Extra dose** will blink on the display.

F. Once the dose is delivered, the pump automatically returns to **Continuous Flow**.

G. Morning dose and Extra dose have preset time locks, which can be changed by your healthcare professional.



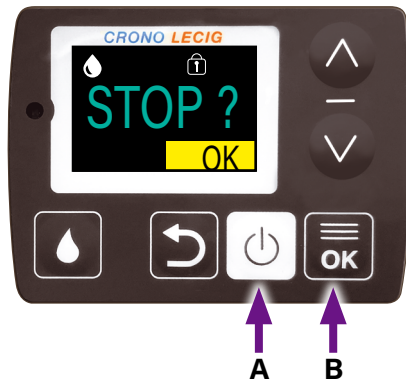
Switching between programmed flows:

H. Press any button to turn on the display.

I. When the pump is **ON**, press the **OK** button.

J. Select your desired flow using the **UP/DOWN** arrows. Press the **OK** button to confirm.

4. Temporarily stopping or restarting an infusion



- A.** For a brief temporary stop, e.g. before taking a shower, press any button to turn on the display. Press and hold the **ON/OFF** button. The prompt 'STOP?' shows on the display.
- B.** Press the **OK** button to stop the infusion.



- C.** The word 'STOP' appears on the display, and the infusion is stopped.

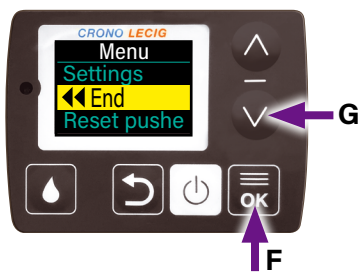


- D.** Press any button to turn on the display. Press and hold the **ON/OFF** button to restart the infusion.
- E.** The word 'ON' shows on the display.

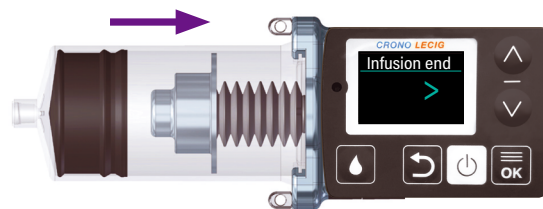
5. Stopping the infusion and setting up pump for new infusion



- A.** Press any button to turn on the display. Stop the infusion by pressing and holding the **ON/OFF** button.
- B.** The prompt '**STOP?**' shows on the display.
- C.** Press the **OK** button to stop the infusion. '**STOP**' appears on the display, and the infusion is stopped.
- D.** Unscrew the cartridge from the intestinal port (do not turn the PEG-J tube).



- E.** Replace the purple protective caps. *NB! Do not proceed to step F unless you are going to change the cartridge in the evening.*
- F.** To change the cartridge: press any button to turn on the display. Press and hold the **OK** button until the display shows the Main Menu.
- G.** Press the Down arrow to select '**END**'. Press the **OK** button to confirm the retraction of the pusher.



IMPORTANT: Keep the cartridge on the pump until the pusher has fully retracted

- H.** After 10 seconds the pusher will begin to retract. This takes approx. 6 minutes.
- I.** When retracted fully, remove the cartridge from the pump.
- J.** The pump will turn itself off, ready to start a new infusion.
- K.** While waiting for the pusher to retract fully, please follow step 6 (see next page).

6. PEG-J tube and stoma care

Looking after your PEG-J tube and stoma (the site where the tube enters your abdomen) is really important. One action you will have to take is flushing your PEG-J tube. Your healthcare team will tell you how often you need to do this.

How to flush your PEG-J tube

- A.** Draw up 20 ml drinking water into an ENFit 20 ml syringe.
- B.** Screw the syringe onto the intestinal port.
- C.** Flush using drinking water. There may be some initial resistance.
- D.** Remove the syringe and replace the protective cap.
- E.** Refill the syringe with 20 ml drinking water, place the syringe onto the gastric (stomach) port and flush.
- F.** Remove the syringe and replace the protective cap.

Stoma care

Do this at least twice a week, ideally when taking a shower.

1. Open the blue lock on the external retention plate and release the PEG-J tube.
2. Move the external retention plate away from the stoma.
3. Clean the stoma, external retention plate and PEG-J tube with soap and water.
4. Push the PEG-J tube 4–5 cm straight into the stoma (do not twist it), then pull back the PEG-J tube by the same distance. Wipe the tube dry.
5. Fix the PEG-J tube onto the external retention plate and close the blue lock. Check the distance from the skin to the external retention plate. It should be 5mm.

Minor reddening around the stoma is normal.

7. Talking to your doctor or nurse

If you have any questions or concerns regarding either your LECIG medication or the PEG-J tube, do not hesitate to contact your doctor or nurse.

The more information that you can provide to them during your appointment, the better that they will be able to help you.

Practical tips to make full use of your appointment:

- ✓ Record your symptoms in a daily diary which you can refer to during your appointment.
- ✓ Make a list of things that you would like to talk to your doctor or nurse about prior to your appointment.



8. Additional support

Where can I get further information?

To help you get the most out of your treatment, the Crono® LECIG Pump delivery system comes with a range of support:

LECIG Technical Helpline – **0808 196 4242**

- ✓ For technical support with the Crono® LECIG Pump.
- ✓ Emergency replacement of the Crono® LECIG Pump or LECIG components.

If you have any medical queries, please contact your Parkinson's care team.

LECIG Technical Helpline – 0808 196 4242

24 hours a day, 365 days a year



REPORTING OF SIDE EFFECTS

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. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**. By reporting side effects you can help provide more information on the safety of this medicine.