

# DUODOPA<sup>®</sup>

# Patient Guide

(Levodopa/Carbidopa Intestinal Gel)

Educational Material for Risk Minimisation (Risk Management Plan)

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## About This Guide

This guide is for patients and caregivers of patients who are using Duodopa®.

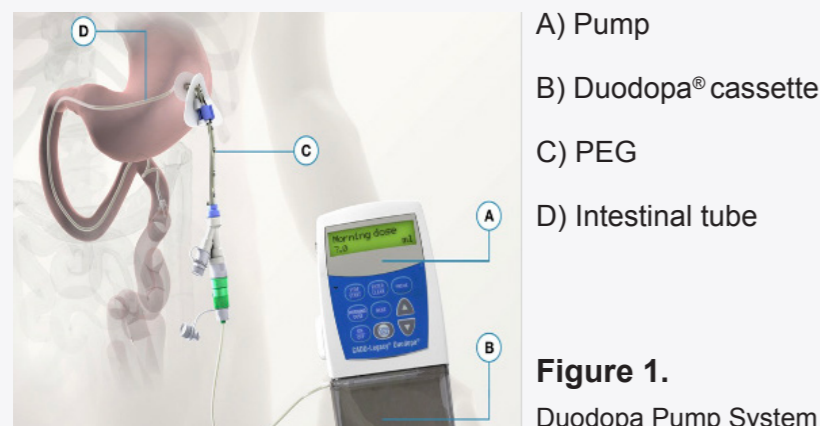
### What is Duodopa used for

Duodopa is used to treat advanced Parkinson's disease (PD). Patients with PD experience severe recurring movement problems (motor fluctuations) and excessive movement (hyperkinesia) or involuntary, uncontrollable movement (dyskinesia).

### The Duodopa System

Duodopa® is a gel that has two medicines called Levodopa and Carbidopa. As a patient, you had 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. Duodopa® is delivered directly to your small intestine by a pump through this tube (Figure 1).

The pump continuously gives you a small dose throughout the day. This means that the level of the medicine in your blood stays similar. It also means some of the movement side effects are lower.



**Figure 1.**  
Duodopa Pump System

### Purpose of this Patient Guide

This guide provides at-home care instructions for patients and their caregivers to minimise possible gastrointestinal (stomach and gut) problems from the procedure or tube. Some of these problems could require surgery or may even lead to death, if left untreated.

The instructions in this guide include step-by-step directions and images.

The instructions below are divided into two sections:

1. Post-Procedure Care (What to do in the days after your procedure)
2. Long-Term Care (What to do after your stoma is fully healed from your procedure)

Please read the Patient Information Leaflet for more important safety information about Duodopa®. For full instructions on using the Duodopa® system, please read the manual for each device/instruction for use (IFU).

## Possible Side Effects



Below are some of the important stomach and gut procedure-related and tube-related problems you may have. **Tell your healthcare professional about any problems or changes in the way you feel, even if they are not listed here.**

**Very Common:** may affect more than 1 in 10 people

- Stomach pain.
- Infection where the tube goes into your stomach – caused by surgery.
- Thick scarring where the tube goes in your stomach.
- Problems around where the tube goes into your stomach – red or raw skin, sores, discharge, pain, or irritation.

**Common:** may affect up to 1 in 10 people

- Incision site infection, post procedural infection after the tube is placed in the intestine.
- Inflamed wall of stomach.
- Infection in the gut (intestine) or where the tube goes into your stomach.
- The tube moves around in the gut or gets blocked – which could cause lower amounts of medicine to be absorbed.
- Pain when breathing, feeling short of breath, chest infections (pneumonia, including aspiration pneumonia).

**Uncommon:** may affect up to 1 in 100 people

- Inflamed colon (colitis).
- Inflamed pancreas (pancreatitis).
- The tube goes through the wall of the large intestine.
- Blockage (obstruction), bleeding or ulcer in the gut.
- Sliding of one part of the gut into an adjacent part of the gut (intussusception).
- Food getting stuck around the tube causing it to block.
- Pocket of infection (abscess) – this could happen after the tube is placed in your stomach.

**Not Known:** it is not known how often these happen

- Reduced blood flow in the small intestine
- The tube goes through the wall of the stomach or small intestine.
- Infection in the blood (sepsis).

Please read the Duodopa® Patient Information Leaflet for complete information including the side effects of Duodopa®.

# Important Reminders

To minimise stomach and gut problems from the PEG-J procedure or the tubes, please follow these important reminders.

## Stoma and Tube Care Checklist

- Do not remove the dressing or get the stoma wet after your procedure.
- After your procedure or as directed by your healthcare professional, inspect and clean your stoma once each day.
- Re-secure the fixation plate close to the skin for the first 24-72 hours after your procedure.
- Once your stoma has healed, move the tube once each day.
- When directed by your healthcare professional (typically 24-72 hours after your procedure), maintain 5-10 mm space, or space for one finger, between the skin and the fixation plate.
- Flush both tube connectors with at least 20 mL of room temperature water once each day.

## Do's and Do Not's



### Do's

- Do follow the Post-Procedure Care routine once each day until your stoma is healed. This will decrease the chance of stomach and gut problems.



### Do Not's

- To prevent the formation of loops and dislocation, do not turn or rotate the tube coming out of the stomach.
- Do not use any ointments on your stoma or tube unless a healthcare professional recommends it as this may result in the tube becoming loose.
- Do not lift heavy objects for one month or until your healthcare professional says it is okay.
- Do not bathe (submerge your stoma in water) until your healthcare professional says it is okay as this may increase the chance of infection.

### After your procedure:

- Apply and change dressings as directed by your healthcare professional
- **Do not** wet the stoma site

### For the first 24-72 hours after your procedure:

- **Do not** move your tube

# Aftercare

Aftercare consists of Post-Procedure Care and Long-Term Care intended to reduce possible gastrointestinal (stomach and intestine) problems.

- **Post-Procedure Care**
- **Long-Term Care**

Each of the following two sections contain once each day care routines.

**Post-Procedure Care** focuses on ensuring stoma healing and proper tube care.

**Long-Term Care** focuses on maintaining a healthy stoma after healing and proper tube management.

# Post-Procedure and Long-Term Care

## Post-Procedure Care

Post-Procedure Care is the at-home care that you provide for yourself or receive from caregivers while your stoma is healing. This care starts immediately after your procedure and continues for 10 days to several weeks until your stoma is fully healed.

During this time, you may notice some symptoms which are normal as your stoma heals including:

- some stomach pain or soreness at the procedure site.
- a thin red circle, up to 5 mm (width of a pencil eraser), on skin around the stoma.
- a small amount of slippery and stringy fluid substance called mucus.

These symptoms should resolve as your stoma heals. If these symptoms continue, contact your healthcare professional.

## Long-Term Care

Long-Term Care begins after your stoma has healed. This may happen between 10 days to several weeks after the tube is placed in your stomach. Your healthcare professional can help you determine when this has occurred. The steps for the Long-Term Care Routine are similar to the Post-Procedure Care Routine. The instructions provided below are intended to maintain a healthy stoma area and **reduce long-term stomach and gut complications from the tube in your stomach**. Always follow any additional instructions from your healthcare professional.

## Post-Procedure and Long-Term Care Routine

**First 24 hours after day of placement:** Duodopa® treatment can normally be initiated directly after uncomplicated PEG/J placement, after consultation with your healthcare professional. Oral feeding might be possible 2 hours after PEG/J placement as directed by your healthcare professional. Apply appropriate dressings to surgical site as directed by your healthcare professional. Observe for symptoms such as pain and bleeding.

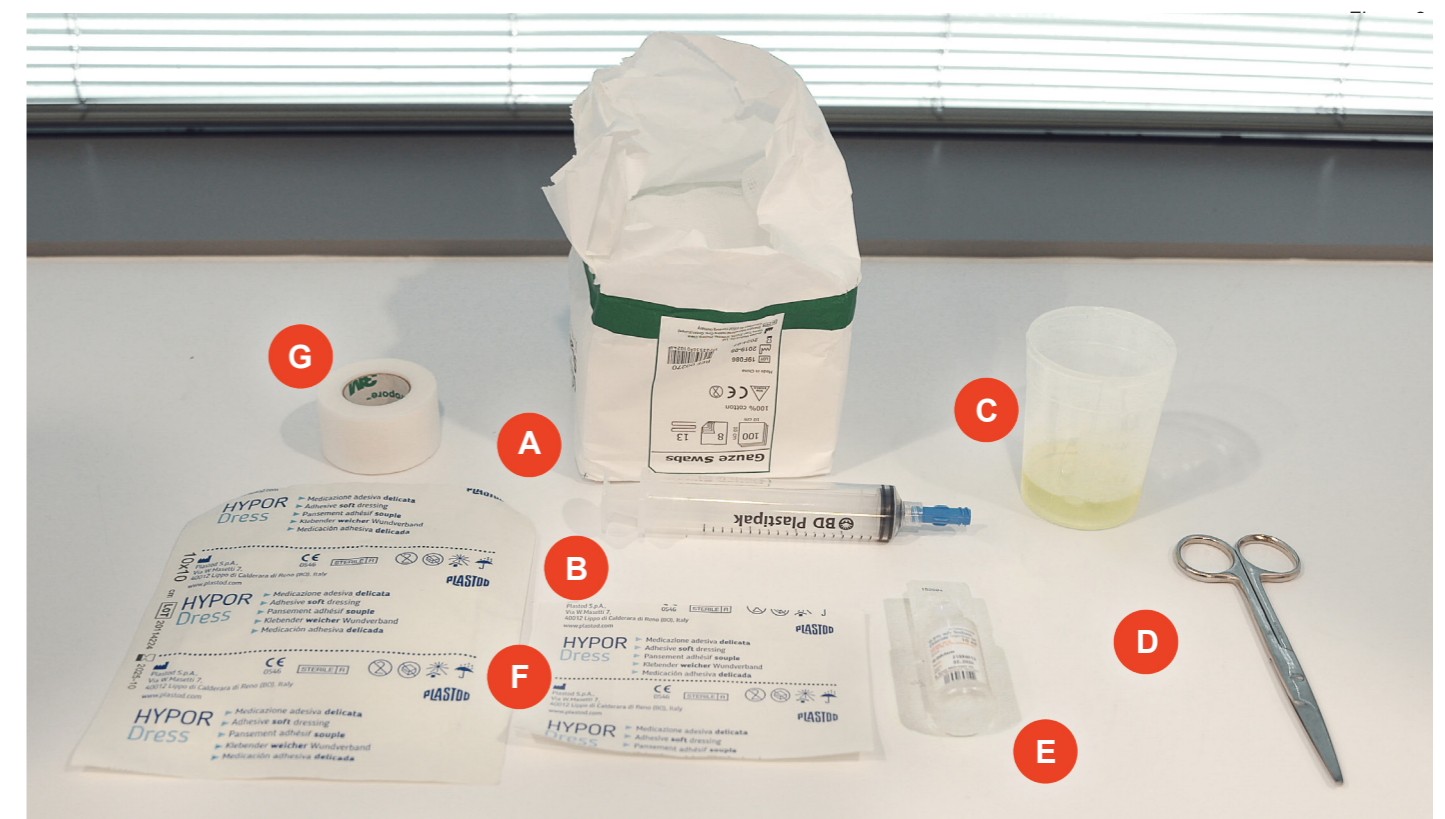
After your procedure or as directed by your healthcare professional, follow these instructions below to complete steps 1 to 6. Do all of these steps **once each day**. This will help the stoma to heal properly and reduce possible stomach and intestine-related problems as described in the Possible Side Effects section on page 3.

Talk with your healthcare professional if you have any questions or have any difficulties following this care routine.

## Preparation

When you first return home, it may take some time to get used to these steps. The help of a caregiver can be valuable. Wash your hands thoroughly and collect dressing change items from the post-procedure take-home supplies you have been given. Remember, following all of these steps is essential for reducing risks during recovery.

Figure 2.



You may use any materials that are available to you or that are recommended by your healthcare professional. Displayed: A) gauze, B) syringe with connector, C) container of soapy water, D) clean scissors, E) cleaning solution provided by your healthcare professional, F) dressings, and G) adhesive tape.

## Step 1. Release Tube



Figure 3.

The dressing (with fixation plate under it) before performing the care routine.



Figure 4.

**Step 1.1** Remove the dressing.



Figure 5.

**Step 1.2** Open the tube clip by swinging the blue closure on its hinge.



Figure 6.

**Step 1.3** Gently pull the tube up to release it from the plate. Loosen the fixation plate by sliding it a short distance from the stoma.



During the first week after your procedure, avoid walking with the tube released.

## Step 2. Inspect

### Why do I need to inspect my stoma?

Checking for signs of irritation or infection will help you get them treated early on. When problems are treated quickly, it will decrease the risk that they become more serious.

**Step 2.1** Check your stoma for signs of increasing redness, swelling, or foul-smelling pus (thick whitish-yellow fluid) around the stoma. If you detect any of these signs, please contact your healthcare professional immediately.

## Step 3. Clean

### Why is cleaning my stoma important?

Properly cleaning and disinfecting around the stoma will help decrease the risk of infection and severity of problems that can occur.



Figure 7.

Sanitise or wash your hands again before handling the PEG tube.



Figure 8.

**Step 3.1** Apply the cleaning solution provided by your healthcare professional to gauze, or dip a cotton swab into a container of soapy water.

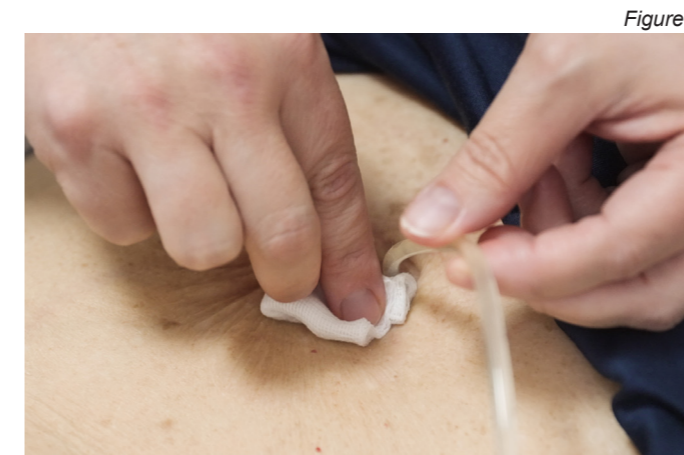


Figure 9.

**Step 3.2** Gently lift the tube and clean around the stoma.



Figure 10.

**Step 3.3** After cleaning, let the area air dry. If your stoma has not healed or is still healing as directed by your healthcare professional, skip step 4 & proceed directly to step 5.1. You may proceed to step 4 only when your stoma has healed or as directed by your healthcare professional.



Always leave the area clean and dry as much as possible.



Do not use any ointments on your stoma or tube unless a healthcare professional recommends it.



Do not use hydrogen peroxide or other harsh cleaning solutions to clean the stoma. These can slow down the wound healing. When directed by your healthcare professional (once your stoma has healed) you may stop applying a dressing after each cleaning.

## Step 4. Move Tube

### Why is moving my tube important?

By carefully moving the tube, you reduce the potential for a rare problem called buried bumper syndrome (BBS). BBS happens when the inside bumper of the PEG tube erodes into the stomach wall. This can lead to an infection in the wound, internal infection in the belly area, leakage from the tube, or a blockage in the tube.

You should continue to skip this step and proceed directly to step 5.1 until your stoma has healed and your healthcare professional tells you to begin moving your tube. **After your healthcare professional says it is okay, do this step each day.**

1. Wash hands thoroughly with soap and water.
2. If dressing is used, remove the dressing and release the external fixation plate to allow free movement of the PEG-J tube.
3. Carefully push the tube 3 to 4 cm into the stomach and gently pull back until you feel resistance of the internal retention plate. Do not twist the tube.
4. Inform your healthcare professional if there are any signs of complications.
5. Replace the fixation plate allowing free movement of 5 to 10 mm. Apply a Y-dressing. A plaster fixation is recommended for agitated patients.

Figure 11.



Take note of the starting mark before pushing the tube into the stomach.

Figure 12.



**Step 4.1** Gently push the tube 3-4 cm (about half the length of your thumb) into the stomach.

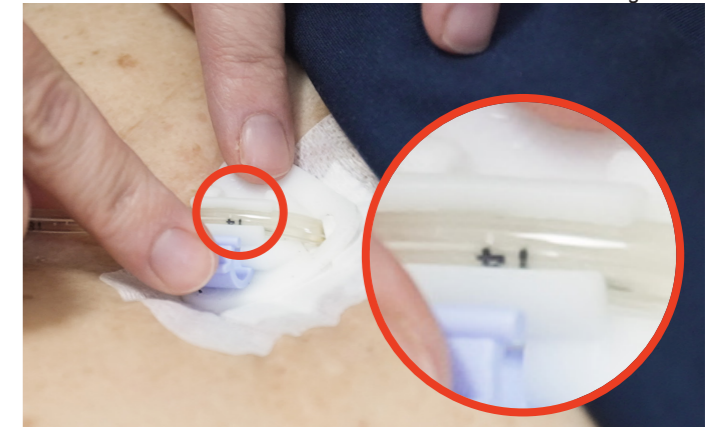
## Step 4. Move Tube

Figure 13.



**Step 4.2** Apply the split dressing and gently pull the tube back until you feel resistance.

Figure 14.



The tube should now be close to where the starting mark was before starting this step.



**Do not twist the tube.** This can cause kinks or knots in the tube.



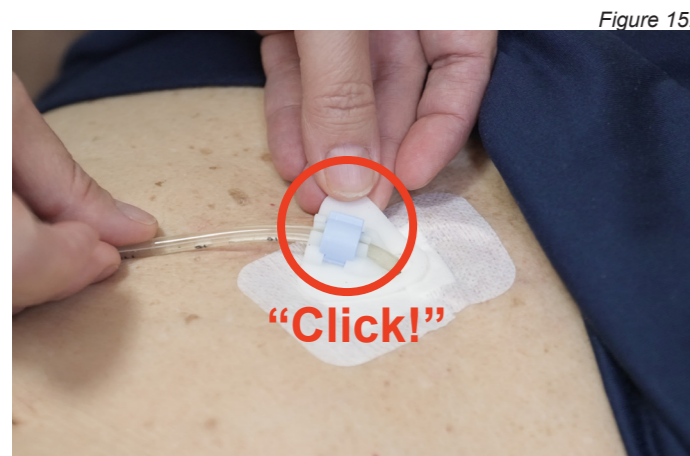
**If the tube does not push inside your stomach easily,** contact your healthcare professional immediately.

## Step 5. Re-Secure Tube

### Why is re-securing my tube important?

Securing the tube in place reduces the risk of accidental slipping and dislocation of the tube inside your stomach.

Follow the instructions below to keep the tube securely in place.



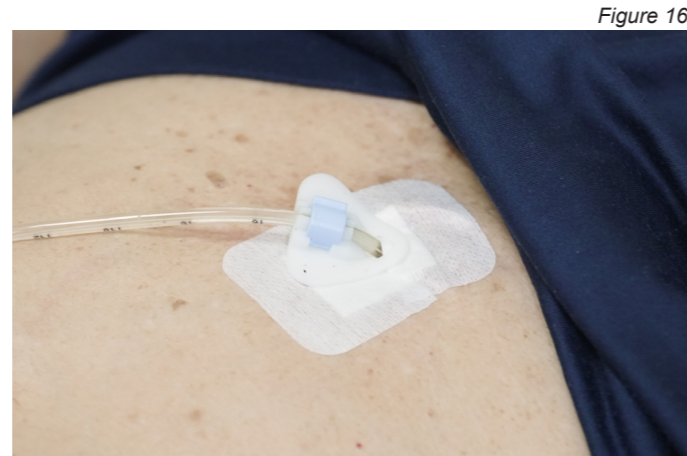
(If step 4 has been skipped, apply split dressing before re-securing the fixation plate)

**Step 5.1** Re-secure the fixation plate by swinging the blue closure back on its hinge and pushing it into the bumper until you feel a click.

**Until the stoma has healed**, follow the instructions in **Step 5.2** and **Step 5.3** to apply the dressing. After the stoma has healed, the dressing is no longer required and the procedure site may be left clean and dry with no dressing.



**Step 5.2** Apply a dressing over the fixation plate if needed.



*Re-secure the fixation plate close to the skin for the first 24-72 hours after your procedure, or as your healthcare professional instructs. When directed by your healthcare professional (typically 24-72 hours after your procedure) re-secure the fixation plate, allowing 5-10mm or space for one finger between the skin and the plate.*



**Step 5.3** Secure the dressing and tube using a dressing or medical tape.

## Step 6. Flush Tubes

### Why do I need to flush my tubes?

This step will help prevent blockage of the tubes. If your tube becomes blocked, it will not properly deliver medication.

There are two tubes that should be flushed once each day. First, flush the AbbVie J Tube through the longer straight green connector. Then, flush the AbbVie PEG Tube through the shorter angled (white, blue, or violet) connector.



**Step 6.1** Stop the pump and disconnect the tubing.



**Step 6.2** Push the blue syringe connector into the end of the syringe to connect them together.



**Step 6.3** Fill the syringe with at least 20 mL of room temperature tap or drinking water.



**Step 6.4** Twist the syringe to connect it to the longer straight green connector on the PEG-J and push the syringe plunger to dispense the full 20 mL syringe to flush the tube.  
**Note:** You should never twist the tube itself, only the syringe.

## Step 6. Flush Tubes

Figure 23.



**Step 6.5** After flushing the tube with water, remove the syringe and syringe connector.

Figure 24.



**Step 6.6** Replace the white cap on the connector.

Figure 25.



**Step 6.7** Flush the shorter angled connector (white, blue, or violet) by twisting the white cap off the shorter angled connector.

Figure 26.



**Step 6.8** Connect the blue syringe connector to the shorter angled connector and repeat steps 6.3-6.6.



**Do not twist the stomach tube.**



**Do not** use hot water as it could burn the wall of your stomach and intestine.



**Do not** force the syringe if flushing the tube is difficult. Call your healthcare professional if you are unable or have difficulty flushing your tube.

# Possible Long-Term Problems and How to Prevent Them

During the Long-Term Care period, you may develop certain problems from the tube. Below are some of the problems that have been reported and how you can help to prevent them. If any of these problems happen to you, contact your healthcare professional.

Possible Problem	What Can I Do To Prevent This Problem
Tube Problems (blockages, kinks, knots).	Flush your tubes once each day as described in Post-Procedure and Long-Term Care Routine Step 6 to reduce risk.
Connectors loosen or disconnect, and your inner tube slides out of the outer PEG tube by accident.	Follow the recommended tube care routine once each day to prevent this problem. If the tube does come out, call your healthcare professional right away.
Stoma Discharge (noticeable discharge such as redness or liquid from the stoma).	Discharge is often due to infection or inflamed skin tissue. Keep the stoma clean and dry. When directed by your healthcare professional (typically 24-72 hours after your procedure), maintain 5-10 mm space, or space for one finger, between the skin and the fixation plate as described in Post-Procedure and Long-Term Care Routine in Step 5.
Bezoar, where food gets stuck around the tube causing it to block. Symptoms may include nausea, vomiting, and abdominal pain.	Avoid foods that are high in fiber (such as celery, asparagus, sunflower seeds) in order to decrease the risk for this problem.
Leakage or blockage of the tube could be a sign of buried bumper syndrome, which is when the inside bumper of the PEG tube erodes into the stomach wall. This can lead to an infection in the wound, an internal infection in the belly area, leakage from the tube, or blockage of the tube.	Upon healing of the stoma, move the tube 3-4 cm in and out once each day. Allow 5-10 mm, or space for one finger, between the skin and the fixation plate.  Refer to Post-Procedure and Long-Term Care Routine Steps 4 and 5 for more detail.

# Frequently Asked Questions

**Q: When I plan to swim, shower or take a bath, what steps should I take to avoid problems in the tube or stoma area?**

**A:** Remember to disconnect your pump and put a cap on both the gastric and intestinal ports of the Y-Connector. Make sure that the stoma is healed before considering swimming or bathing.



Figure 27.



Figure 28.

Washing or showering with regular soap and water will become possible again usually two weeks after insertion of the PEG tube. To reduce the risk of stoma infection, it is very important to leave the area clean and dry. Bathing and swimming (after complete initial wound healing) is possible as directed by your healthcare professional.

Early in the morning you may find that you feel stiffer than normal. At this point you should connect the tube, take your morning dose and wait approximately 10 to 30 minutes until normal mobility returns.

Together with your healthcare professional, you will learn the maximum length of time that you can stop the pump (for example before showering) before symptoms return. This period varies from individual to individual.

After showering: ensure that the area around the stoma is kept clean and dry and reconnect the cassette tube and turn on the pump to start the infusion again.

Please contact your healthcare professional for additional instructions.

**Q: Water, liquid, or medication sometimes leaks out from my tube, especially where it goes into my gut or stoma site. How can I prevent this leak?**

**A:** If the leak is between the tube and the stoma, check that the tube is secured in the correct position. When directed by your healthcare professional (typically 24-72 hours after your procedure), maintain 5-10 mm space, or space for one finger, between the skin and the fixation plate. If adjusting the tube position does not stop the leakage, contact your healthcare professional.

If the leak is coming from the connectors, immediately call your healthcare professional.

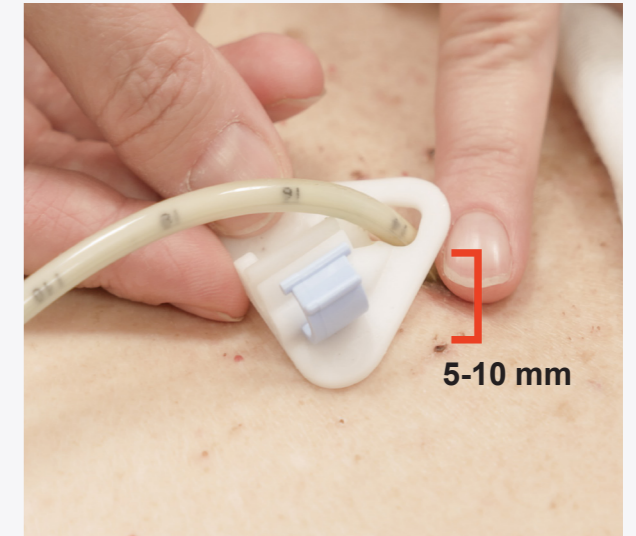


Figure 29.

**Q: What should I do if the tube becomes discoloured?**

**A:** Tube discolouration is expected and does not indicate any malfunction. If there is a concern, follow up with your healthcare professional.



Figure 30.

**Q: I am having difficulty flushing my tube. How can I resolve this problem?**

**A:** Difficulty flushing your tube may be caused by tube blockage, kinking or knotting. Sometimes the high-pressure alarm from your pump also suggests blockage, kinking or knotting.

Twisting of the tube may cause kinking or knotting of the tube itself. You should avoid twisting of the tube when moving it in and out once each day as described in Post-Procedure and Long-Term Care Step 4, Move Tube. Call your healthcare professional if you are getting a high-pressure alarm or have difficulty flushing your tube.

**Q: I am having difficulty moving the tube in or out of the stoma. What steps should I take?**

**A:** This difficulty may be related to a significant safety risk called buried bumper syndrome (BBS). Immediately contact your healthcare professional if BBS is suspected. To prevent BBS, please follow instructions on how to move the tube as described in Step 4 Move Tube.



# 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 this leaflet. You can also report side effects directly to HPRA Pharmacovigilance; website: [www.hpra.ie](http://www.hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

## Further Information

If you would like additional copies of this patient guide, please contact 1800 945 024 or visit [www.hpra.ie](http://www.hpra.ie) to download a copy. A complete digital version of this guide is available on the HPRA's website, [www.hpra.ie](http://www.hpra.ie). Enter 'Duodopa' in the 'Find a medicine' search box and click 'EdM' next to the medicine that appears.

If you need copies of the Pump Manual, please contact 1800 945 024.

This medicinal product is authorised in the Member States of EEA under the following name: Duodopa® (Levodopa/Carbidopa Intestinal Gel).

This material was developed by AbbVie as part of Duodopa® Risk Management Plan.

Date approved: April 2025