DUODOPA® Healthcare Professional Guide

(Levodopa/Carbidopa Intestinal Gel)

Educational Material for Risk Minimisation
(Risk Management Plan)

abbvie

IE-DUOD-240009. Version 1.0.

Date approved: April 2025

About this Guide

This guide is an educational material as part of the additional risk minimisation program for Duodopa®. This guide is intended to inform gastroenterologists, neurologists and other healthcare professionals (HCPs) with recommended measures to minimise gastrointestinal, gastrointestinal device, and gastrointestinal procedure related events.

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About Duodopa®

Duodopa® is indicated for the treatment of advanced levodopa-responsive Parkinson's disease with severe motor fluctuations and hyperkinesia or dyskinesia when available combinations of Parkinson medicinal products have not given satisfactory results.

Duodopa® is an intestinal gel which contains a combination of carbidopa and levodopa.

Duodopa® is administered into the jejunum through a percutaneous endoscopic gastrostomy (PEG) with a jejunal tube (AbbVie PEG and J) using a pump.

Duodopa® Pump System

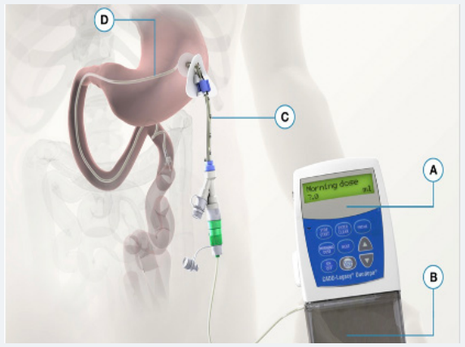


Figure 1.

Duodopa® Pump System:

A) Pump

B) Duodopa® cassette

C) PEG

D) Intestinal tube

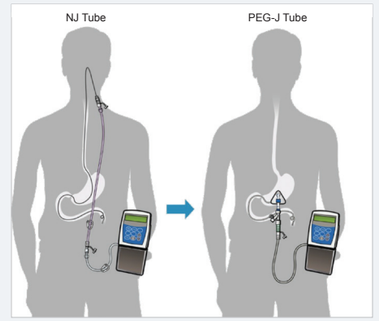
The information provided in this guide applies to AbbVie PEG and AbbVie J devices. Images of the device and tubes used are for demonstration purposes only.

Duodopa®: Levodopa - Carbidopa Intestinal Gel System

Long-term administration of Duodopa uses the PEG-J delivery system.

A temporary NJ tube may be used to determine if the patient responds favourably before a permanent PEG-J is placed.

Figure 2.



Administration of Duodopa®

Short-term Temporary Therapy (Prior to PEG-J tube placement)	**Long-term Therapy** (Requires placement of a PEG trans-abdominal tube and inner jejunal tube by percutaneous endoscopic gastrostomy or radiological gastrojejunostomy if necessary)
• Treatment may be initiated by a Naso-jejunal (NJ) tube with observation of the patient's clinical response.	• Duodopa® is dispensed from medication cassette specifically designed to be connected to only a Duodopa® pump. • PEG-J insertion and placement should be performed by a gastroenterologist or other healthcare professional experienced in this procedure.

Please read the Summary of Product Characteristics (SmPC) for Duodopa® available on www.medicines.ie or on the HPRA website: www.hpra.ie, for comprehensive safety information or Instruction for Use (IFU) for AbbVie PEG and J Tube information. If you have questions about the pump, please refer to the pump manual.

PEG Insertion and Placement

This guide is intended to provide approaches to minimise gastrointestinal (GI) safety risks from the PEG-J procedure and device. For complete step-by-step PEG-J procedural instructions, please refer to AbbVie PEG PERCUTANEOUS ENDOSCOPIC GASTROSTOMY KIT 15 FR / 20 FR IFU and AbbVie J INTESTINAL TUBE 9 FR for PEG 15 and 20 FR IFU.

Important Pre-Procedure Steps to Minimise Risks

All endoscopic procedures should be guided by local hospital protocols and/or national guidelines. The healthcare professionals need to stay updated with these latest guidelines and adapt their practices accordingly to ensure optimal patient care.

In addition, also follow the recommended contraindications criteria to ensure proper patient selection for the PEG-J procedure and minimise the safety risks (Table 1).

Table 1. Contraindications

- Known or suspected intestinal obstruction.*
- Serious coagulation disorders (INR >1.5, Quick <50%, PTT >50s, platelets <50,000/mm^3).++
- Sepsis.*
- Active peritonitis.*
- Lack of transillumination and positive needle aspiration test are an absolute contraindication for AbbVie PEG insertion.*
- Relative contraindications include ascites, neoplastic, inflammatory, and infiltrative diseases of the gastric and abdominal walls.*
- Interposed organs (e.g., liver, colon), marked peritoneal carcinomatosis, severe ascites, anorexia nervosa, severe psychosis and a clearly limited life expectancy.+++

Please refer to the Summary of Product Characteristics (SmPC) for Duodopa® available on www.medicines.ie or on the HPRA website: www.hpra.ie, and AbbVie PEG and AbbVie J IFUs for a comprehensive list of contraindications.

Caution:

- Previous surgery of the upper abdomen can cause difficulties when performing a gastrostomy or jejunostomy. The AbbVie PEG is for placement by healthcare professionals ONLY. Errors in placement may result in serious harm.

Please read the AbbVie PEG IFU and J IFU prior to initiating the placement procedure.

Additional Pre-Procedure Steps include:

Prior to the procedure, the patient should be:

1. Fasting for at least 8 hours.
2. Provided with oral hygiene.
3. Given antibiotic prophylaxis as per institutional protocol.
4. Placed in a supine position for the procedure.
5. Managing their anti-coagulation as per institutional protocol.
6. Confirmed to be in stable medical condition, no recent infection, and reasonable nutritional status (albumin > 30g/L).

On the morning of the procedure, the patient should:

1. Continue their current Parkinson's disease medications to prevent stiffness during the procedure.
2. Drink clear fluids only, up to 2 hours prior to the PEG-J procedure.

* Source: Instructions for Use for AbbVie PEG Percutaneous Endoscopic Gastrostomy Kit 15 FR / 20 FR and AbbVie J Intestinal Tube 9 FR for PEG 15 and 20 FR.
++ = Löser C, Aschl G, Hebutérne, et al. ESPEN guidelines on artificial enteral nutrition – Percutaneous endoscopic gastrostomy (PEG). Clinical Nutrition 2005;24:848-861.
+++ = Fugazza A et al. Percutaneous endoscopic gastrostomy and jejunostomy: Indications and techniques. World J Gastrointest Endosc 2022; 14(5): 250-266. Gheorghe C et al. Percutaneous Endoscopic Gastrostomy with Jejunal Extension Tube for the Delivery of Levodopa Carbidopa Intestinal Gel: Clinical Practice Guidelines of the Romanian Society of Digestive Endoscopy. Gastrointestin Liver Dis 2019; 28 (3): 349-354

Important PEG-J Placement Steps to Minimise Risks

PEG Placement: Important Highlights

The PEG tube should be placed according to standard procedure as published in the ESPEN-Guidelines and recommended by the tube manufacturer.[4]

- Reserve at least 40 minutes for the PEG-J procedure; it is essential to reserve enough time for the whole procedure.
- The standard PEG pull through method takes approx. 12 minutes; intestinal tube insertion generally requires 10 to 30 minutes.
- The skin incision at the puncture site should be slightly larger than the PEG tube.
- Parkinson's patients tend to be thin. Be careful not to make skin incisions too deeply into their skin.
- Angle the PEG toward the pylorus to enable direct access of the inner intestinal tube to pylorus.
- PEG length: 35 cm
  After placement of the PEG, make a straight cut outside of the body as per clinical practice.
- Before connector assembly, ensure parts are dry and connectors are engaged.
- The Duodopa® administration system utilises reverse Luer connectors. These are Luer connectors that are reversed in orientation compared to an IV set. The AbbVie PEG-J tubing and the Duodopa® cassettes both utilise this configuration.Please refer to the AbbVie J IFU for additional details.

Intestinal Tube Placement – Endoscopic Insertion[4]

The intestinal tube can in general be placed in two different ways: endoscopic insertion or interventional radiology using standard equipment.

Endoscopic placement/replacement of the AbbVie J should be with direct visualisation of the tip of the tube as it is advanced. Blind advancement of the tube by pushing with the grasping forceps is to be absolutely avoided.

- **Endoscopic insertion:**
  - Long enough endoscope; the Intestinal tube is placed by using an endoscope long enough to reach the ligament of Treitz.
  - Avoid intestinal perforation; make sure to lock the guide wire inside the intestinal tube before insertion.
- Endoscopic instruments to be used; grip the distal end of the intestinal tube using one of the following instruments:
  - The foreign body forceps, 2:1 teeth,
  - The two-arm gripper or
  - The three-arm polyp gripper.

- Distal end of intestinal tube beyond ligament of Treitz:
  - Advance the endoscope and the distal end of the intestinal tube under observation until it has safely passed the ligament of Treitz to reduce risk of dislocation of the tube back into the gastric lumen.

Confirm with X-ray that the distal end of the intestinal tube is located beyond ligament of Treitz.
Please refer to the AbbVie J IFU for additional details.

PEG-J and Stoma Aftercare

After the patient has gone through the pre-procedure and procedure phases, it is critical to observe the patient's stoma for signs of inflammation or infection. The sections below provide HCPs resources:

- to identify GI complications following the PEG-J procedure and long-term use of PEG-J tube.
- to enable appropriate clinical interventions to minimise risks.

This part of the guide is divided into:

- Post-Procedure Care: focused on ensuring stoma healing and proper tube management.
- Long-Term Care: focused on maintaining a healthy stoma after healing and proper tube management.

Post-Procedure Care

< 24 Hours After PEG-J Placement

- The Duodopa® treatment can normally be initiated directly following an uncomplicated PEG-J placement, after consultation with the gastroenterologist.
- Oral feeding might be possible after 2 hours but it is preferred to wait until the next morning.
- Apply appropriate dressings to surgical site per institutional protocol if appropriate.
- Observe for signs of complications such as pain and bleeding.
- Prior to discharge from hospital, the patient should have his/her stoma site examined by a member of the treating team to ensure there are no signs of infection.

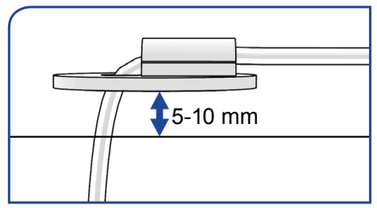
1. Stoma Assessment: Check the stoma site for any signs of inflammation, infection, or leakage and treat accordingly.

2. Stoma Hygiene: Remind the patient to maintain stoma hygiene and to keep the fixation plate clean and dry.

>24 hours up to 10 days following PEG-J Placement (i.e. until stoma healing)

- Inspect the wound area regularly within the first week and prior to discharge from hospital for signs of infection (bleeding, erythema, secretion, induration, allergic skin reaction).
- Clean, disinfect, dry completely and redress the wound under aseptic conditions daily as follows:
  - Disinfect hands and put on disposable gloves.
  - Remove the dressing, open the fixation plate tube clip and release the tube from the plate.
  - Clean (aseptic technique) and disinfect the wound.
  - Always keep the stoma clean and as dry as possible.
  - Never apply an ointment on a PEG stoma or an inflamed PEG wound.
- Remind the patient not to move the tube for at least 24-72 hours after the procedure, or as advised by the gastroenterologist.
- After 24-72 hours, replace the retention plate allowing free movement of 5-10 mm as shown in Figure 3, and apply appropriate dressing to surgical site per institutional protocol.
- Keep the puncture site, PEG Tube, and the underside of the Fixation Plate clean and dry using aseptic technique or per institutional protocol. Dressings should be changed per institutional protocol.
- Ensure the patient/their caregiver has a copy of the patient guide.

Figure 3.



Stoma

Stoma Assessment: Check the stoma site for any signs of inflammation, infection, or leakage and treat accordingly.

While the stoma is healing, your patient may experience some symptoms which are normal and should resolve spontaneously:

- some stomach pain or soreness at the procedure site.
- up to 5 mm of redness of skin around the stoma.
- a small amount of mucus from the stoma.

PEG Tube

1. PEG Tube Tension: The PEG tube should remain under moderate tension for 24-72 hours. **Do NOT** move the PEG tube or external fixation plate for 24-72 hours postplacement. After 72 hours, the fixation plate should be loosened to leave 5-10 mm of free play between the outer stomach wall and fixation plate to prevent inflammation and subsequent Buried Bumper Syndrome.
2. PEG Tube Movement: Recommended to initiate tube mobilisation only after the stoma site has healed or otherwise follow institutional protocol. The PEG tube should not be turned or rotated under any circumstances to prevent the formation of loops and dislocation of the AbbVie J tube. Do not rotate the AbbVie J Tube or click adapter cap as kinking or knotting may occur. (Please refer to AbbVie PEG and AbbVie J IFUs for additional details).
3. PEG Tube Function: Confirm that tube can be flushed using the standards as recommended in the blue box below.
4. PEG Tube Leakage: Confirm that tube is not leaking. Leaks are usually a complication of suboptimal healing of the stoma tract due to infection or ischemia. Promptly treat infection if present.

If the leak is from the space between the tube and the stoma within the first 72 hours after PEG-J placement, verify that the tube tension is appropriate given the length of time in place.

Leaks may also occur if the connectors are loose or damaged. Follow up with an AbbVie Duodopa® Specialist or a gastroenterologist as needed, to check the tightness and correct accordingly.

Important follow-up considerations:

- Check stoma healing and signs of infection.
- Check PEG-J connectors and tube functioning.
- Counsel patients not to use petroleum-based lubricants (e.g., baby oil, petroleum jelly) on the tube and stoma.
- HCPs should advise their patients to avoid high fiber foods (such as celery, asparagus, sunflower seeds) while on the Duodopa® system.
- Reduced ability to manipulate the system (pump, tubular connections) may lead to complications. In these patients, a caregiver (e.g. nurse, caregiver or close relative) must assist the patient. Treating healthcare professionals should monitor and determine, based on clinical practice and experience, when device requires replacement.
- Sudden or progressive worsening of bradykinesia may indicate obstruction of the device for some reason and require investigation. Replace tubes or components with unresolvable damage, dislodgement, occlusion or mispositioning upon discovery.

Recommended Standards to Flush the AbbVie PEG-J Tube

- Flush the AbbVie PEG Tube (via white, blue, or violet “g”port) with at least 20 ml room temperature tap or drinking water daily and after it has been used for feeding. Failure to adequately flush the AbbVie PEG Tube may result in occlusion or blockage.
- Flush the AbbVie J Tube (via green “i”port) with at least 20 ml room temperature tap or drinking water daily after administration of Duodopa. Failure to adequately flush the AbbVie J may result in occlusion or blockage.
- Do not flush the lumen of the AbbVie J Tube using force or unblock using a wire. There is the risk of AbbVie J Tube disconnection or tube perforation. Check for patency of the tube. If the tube becomes occluded, replace with new tube.

Sometimes the patient’s Y-connector from the PEG-J is dislocated after the procedure. The following steps should be taken to properly restore the Y-connector

To properly connect the PEG tube to the Y-Connector, follow the instructions in the IFU.

Specifically note the following steps:

1. Ensure that the PEG tube is cut perpendicular (90-degree angle) to the tube and not on a diagonal.
2. Push the PEG tube fully onto the Y-Connector prior to fastening the fixation screw. Visually verify the tubing has been pushed all the way onto the pin of the Y-Connector.
3. Tighten the fixation screw onto the Y-Connector. Confirm there is no space between the fixation screw and the Y-Connector.

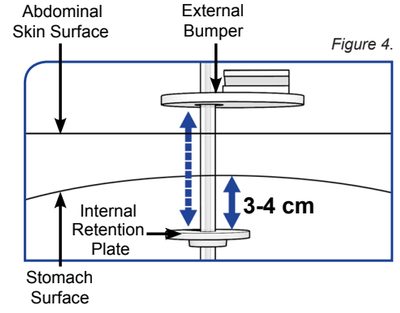
Please refer to the AbbVie J IFU for additional details.

Long-Term Care >10 days following PEG-J Placement

Tube Care

1. PEG Tube Tension: Counsel patient to continue to secure the external fixation plate to leave 5-10 mm of free play between the outer stomach wall and the fixation plate.
2. PEG Tube Movement: Once the stoma is healed, instruct the patient to mobilise the PEG tube each day to prevent Buried Bumper Syndrome. Carefully, push the PEG tube 3-4 cm into the stoma, then gently pull the PEG tube until resistance is felt. The PEG tube should not be turned or rotated under any circumstances to prevent the formation of loops and dislocation of the AbbVie J tube. Do not rotate the AbbVie J Tube or click adapter cap as kinking or knotting may occur. (Please refer to AbbVie PEG and AbbVie J IFUs for additional details).

Figure 4.



3. PEG Tube Leakage: If the leak is from the space between the tube and the stoma after the first 72 hours after PEG-J placement:
   - The tube clip should be opened and the fixation plate loosened. For long term maintenance, leave 5-10 mm free play between the outer stomach wall and the fixation plate.

Please refer to Post-Procedure Care for further information.

Figure 5.

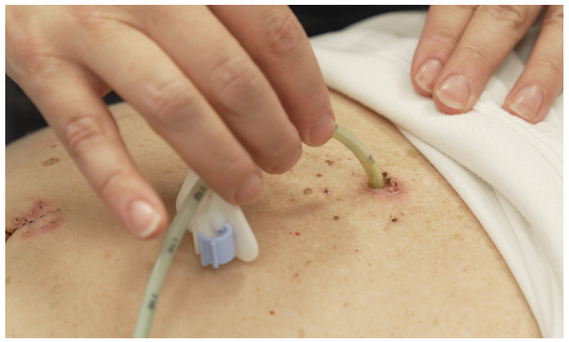
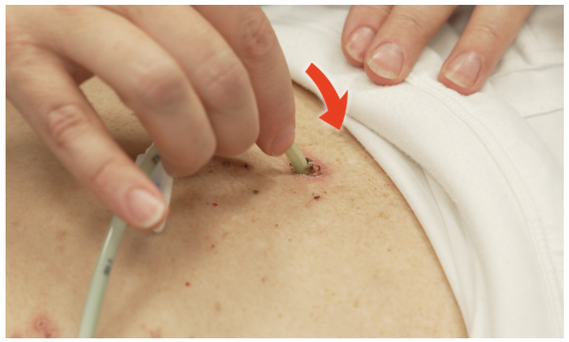


Figure 6.



Demonstration of PEG tube movement.

⚠ **Buried Bumper Syndrome (BBS)**
A severe complication in which the internal fixation device migrates alongside the tract of the stoma outside to the stomach.[1] The device can end up anywhere between the stomach mucosa and the surface of the skin.[2] BBS is primarily due to excessive compression of tissue between the internal and external fixation bumpers.[3] This is an uncommon severe complication after long-term PEG-J placement and can be prevented by proper tube movement and proper tube tension.

If the patient is within the post-procedure phase (until the stoma is fully healed - approximately 10 days):

- Remind the patient to apply and change dressings per institutional protocol if appropriate.
- Remind the patient not to move the tube for at least 24-72 hours after the procedure, or as advised by the gastroenterologist.
- Ensure the patient/their caregiver has a copy of the 'Patient Guide'.
- Remind the patient to follow steps 1 to 6 of the 'Post Procedure and Long-Term Care Routine' in the 'Patient Guide'. This will help the stoma to heal properly and reduce possible GI complications:
  - Step 1. Release Tube.
  - Step 2. Inspect
  - Step 3. Clean.
  - Step 4. Move tube (Remind the patient not to move the tube back and forth until the stoma has healed).
  - Step 5. Re-secure tube.
  - Step 6. Flush tube.

Stoma Care

If the patient is within the long-term care phase (beginning when the stoma is fully healed – approximately 10 days to several weeks after the procedure):

- Ensure the patient has access to the 'Patient Guide'.
- The steps for the Long-Term Care Routine are similar to the Post-Procedure Care Routine. Remind the patient to follow the 'Post-Procedure Care Routine' in the 'Patient Guide'.
- The patient may now stop applying a dressing to the stoma after each cleaning.
- Local care of the stoma site following PEG-J placement is important; carefully examine the stoma site at each visit and at any time the patient or caregiver is concerned about the site.
- The stoma area should be cleansed using an aseptic technique or refer to facility procedures for stoma care.
  - Disinfect hands and put on disposable gloves.
  - Remove the dressing, open the fixation plate tube clip and release the tube from the plate.
  - Clean (aseptic technique) and disinfect the wound.
  - Always keep the stoma clean and as dry as possible.
  - Never apply an ointment on a PEG stoma or an inflamed PEG wound
- Stoma Assessment: Check the stoma site for any signs of inflammation, infection, or leakage and treat accordingly.

For identification and recommended follow up care of stoma complications, refer to the local hospital protocols and/or National Guidelines to enhance patient outcomes and minimise complications.

⚠ **Recommendations to minimise the risk of bezoars in patients with advanced Parkinsons disease using Duodopa®**
HCPs should advise their patients to avoid high fiber foods (such as celery, asparagus, sunflower seeds) while on the Duodopa® system.

Notes

Reporting Adverse Reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance; website: www.hpra.ie.

Further Information

- Please contact AbbVie Medical Information at 01-4287900 if you have any questions or require additional copies of the Patient Guide.
- For more details on prescribing Duodopa®, please refer to the Summary of Product Characteristics.
- A complete digital version of this guide is available on the HPRA's website, www.hpra.ie.

Enter 'Duodopa' in the 'Find a medicine' search box and click 'EdM' next to the medicine that appears.

References

1. Bischoff, S. C, Austin, P, Boeykens, K, Chourdakis, M, Cuerda, C, Jonkers-Schuitema, C, et al. ESPEN guideline on home enteral nutrition. Clinical Nutrition 2020;39: 5-22.
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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.
The educational material fulfils the conditions of the marketing authorisation holder and has been approved by the HPRA.