

DUODOPA[®]

Patient Guide

(Levodopa/Carbidopa Intestinal Gel)

Educational Material for Risk Minimization (Risk Management Plan)

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About This Guide

This guide is for patients and caregivers of patients who are using Duodopa® as a treatment for advanced Parkinson's disease (PD). Patients with PD experience severe recurring movement problems (motor fluctuations) and excessive movement (hyperkinesia) or involuntary, uncontrollable movement (dyskinesia).

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).

This guide provides at-home care instructions for patients and their caregivers to minimize possible gastrointestinal (stomach and intestine) problems from the procedure or tube. Some of these problems could require surgery, 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)

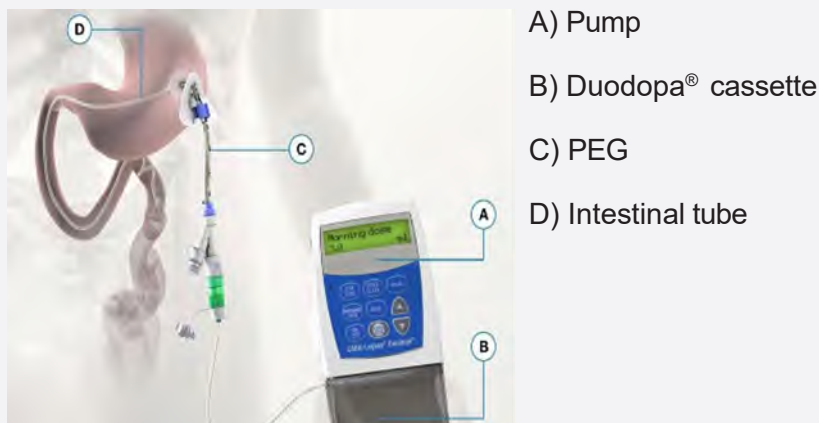


Figure 1.

Duodopa Pump System

Please read the Patient Information Leaflet for more important safety information about Duodopa®. Read accompanying pump manual/instruction for use (IFU).

Possible Side Effects



Below are some of the important gastrointestinal procedure-related and tube-related problems you may have. **Tell your healthcare provider 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.
- 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 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

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

Please refer to the Duodopa® Patient Information Leaflet for more information.

At-Home Care

At-Home Care 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 and proper tube 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 provider.

Do's and Don'ts



Do's

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



Don'ts

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



**For the first 48 hours
after your procedure**

- **Do not** remove your bandage
- **Do not** wet the stoma site



**For the first 72 hours
after your procedure**

- **Do not** move your tube

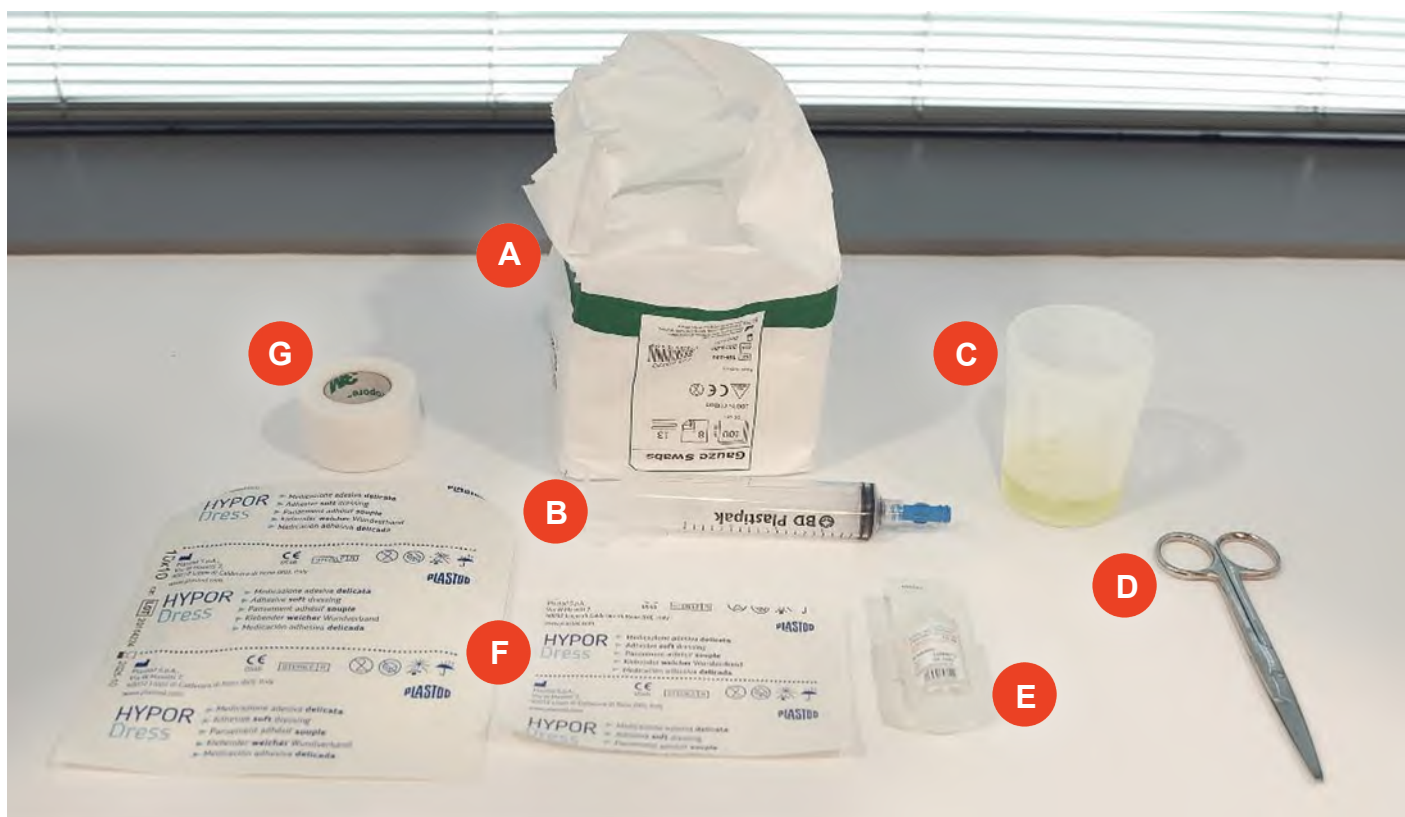
Post-Procedure Care Routine

Starting 48 hours after your procedure, 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 provider if you have any questions or have any difficulties following this care routine.

Preparation

When you first return home, these steps will take some time to get used to. The help of a caregiver may be valuable. Wash your hands thoroughly and collect dressing change items from the post-procedure take-home supplies you have been given. Please remember that 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 provider. Displayed: A) gauze, B) syringe with connector, C) container of soapy water, D) clean scissors, E) cleaning solution provided by your healthcare provider, F) bandages, and G) adhesive tape

Step 1. Release Tube

Figure 3.



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

Figure 4.



Step 1.1 Remove the bandage or 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 retention 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.

Figure 7.



Figure 8.



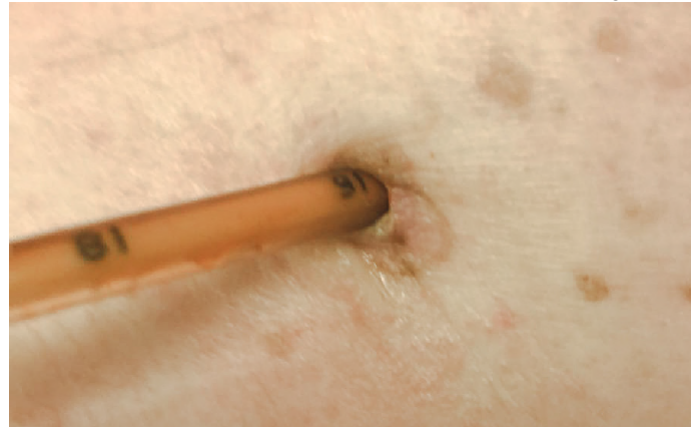
Step 2.1 Check your stoma for signs of increasing redness, swelling, or foul-smelling pus (thick whitish-yellow fluid) around the stoma. If you detect any of these signs, please contact your healthcare provider immediately.

Figure 9.



An example of a healthy stoma after the initial healing period.

Figure 10.



An example of a healthy stoma after 1 month.

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 11.



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

Figure 12.



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

Figure 13.



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

Figure 14.



Step 3.3 After cleaning, let the area air dry. During the first 72h or as directed by your healthcare provider, 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 provider.



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



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



Do not use hydrogen peroxide or other harsh cleaning solutions to clean the stoma. These can slow down the wound healing.

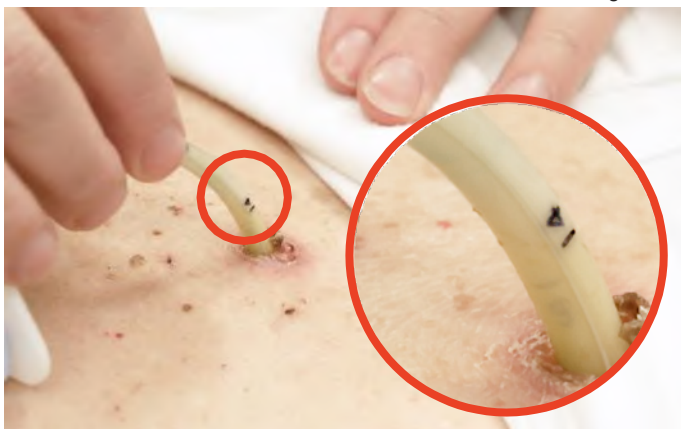
Step 4. Move Tube

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.

Do not move your tube in the first 72 hours after your procedure. You should continue to skip this step and proceed directly to step 5.1 until your stoma has healed and your healthcare provider tells you to begin moving your tube. **After your healthcare provider says it is okay, do this step each day.**

Figure 15.



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

Figure 17.



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

Figure 16.



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

Figure 18.



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 provider 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.

Figure 19.

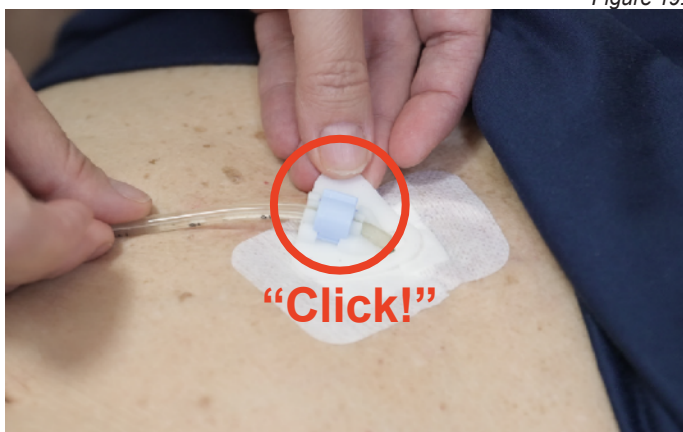
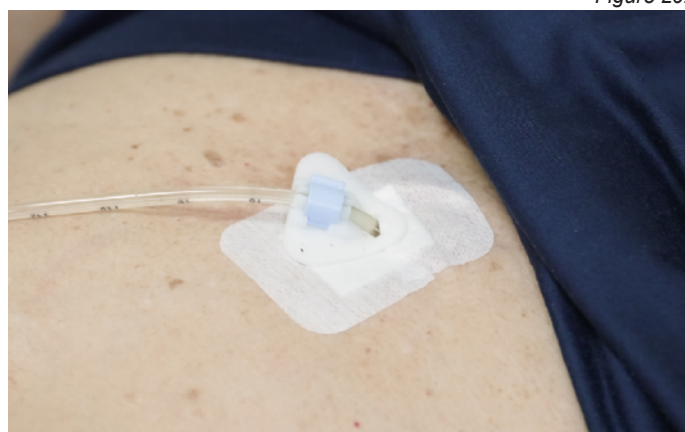


Figure 20.



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

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

Re-secure the retention plate close to the skin for the first 72 hours after your procedure, or as your healthcare provider instructs. After 72 hours (or as directed by your healthcare provider) follow step 5 of page 15 to re-secure the retention plate, allowing 5-10mm or space for one finger between the skin and the plate.

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.

Figure 21.



Figure 22.



Step 5.2 Apply a bandage over the retention plate if needed.

Step 5.3 Secure the dressing and tube using a bandage 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.

Figure 23.



Step 6.1 Stop the pump and disconnect the tubing.

Figure 25.



Step 6.3 Fill the syringe with 10 mL of room temperature tap or drinking water.

Figure 24.



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

Figure 26.



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 10ml of water through the connector. Repeat steps 6.3. and 6.4 to ensure a total volume of 20ml of water is used to flush through this end of the connector. **Note:** You should never twist the tube itself, only the syringe.

Step 6. Flush Tubes

Figure 27.



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

Figure 28.



Step 6.6 Replace the white cap on the connector.

Figure 29.



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

Figure 30.



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 provider if you are unable or have difficulty flushing your tube.

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 provider can help you determine when this has occurred. The Long-Term Care routine instructions provided below are intended to maintain a healthy stoma area and **reduce long-term gastrointestinal complications from the tube in your stomach**. Always follow any additional instructions from your healthcare provider.

Long-Term Care Routine

The steps for the Long-Term Care Routine are similar to the Post-Procedure Care Routine. Please refer to the Post-Procedure Care Routine section for in-depth instructions for each of these steps.



You may now stop applying a bandage to your stoma after each cleaning.

Step 1. Release Tube

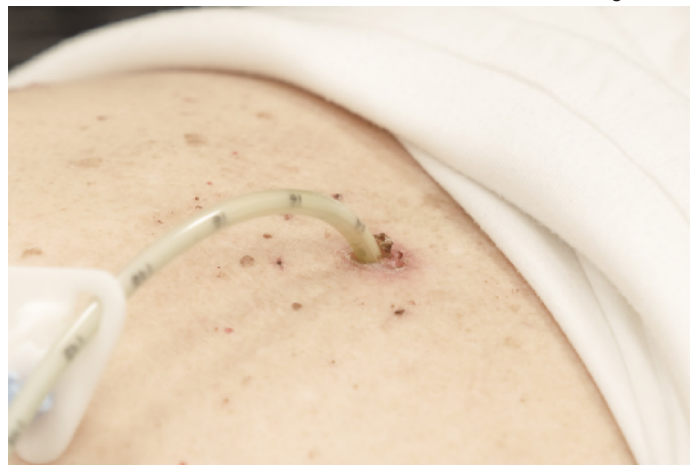
Figure 31.



Open the tube clip and release the tube.

Step 2. Inspect

Figure 32.



Check your stoma for signs of increasing redness, swelling, or pus (thick whitish-yellow fluid) around the stoma. If you see any of these signs, please contact your healthcare provider immediately.

Step 3. Clean

Figure 33.



Clean the area around the tube and let it air dry.

Note: Do not use hydrogen peroxide or other harsh cleaning solutions.

Step 4. Move Tube

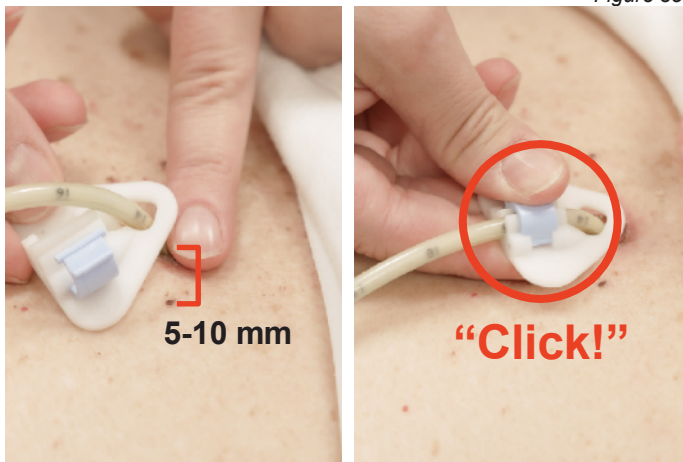
Figure 34.



Upon healing of the stoma, gently push the tube 3-4 cm into the stomach and pull back until you feel resistance. Do this each day or as instructed by your healthcare provider.

Step 5. Re-Secure Tube

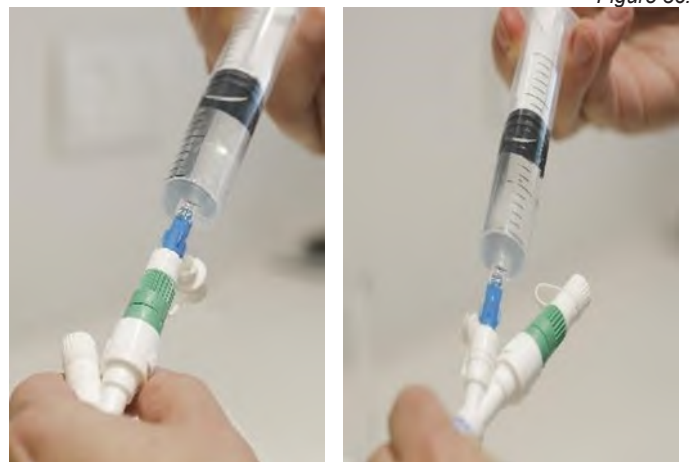
Figure 35.



Re-secure the retention plate, allowing 5-10 mm, or space for one finger, between the skin and the plate.

Step 6. Flush Tubes

Figure 36.



Flush both the longer straight connector and the angled connector with at least 2 X 10 mL of room temperature tap or drinking water. Do this each day to prevent occlusion.

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 provider.

Possible Problem	What Can I Do To Prevent This Problem
Tube Problems (blockages, kinks, knots).	Flush your tubes once each day as described in 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 provider 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. Starting 72 hours after your procedure, maintain 5-10 mm space, or space for one finger, between the skin and the retention plate as described in 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.
Buried bumper syndrome 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.	<p>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 retention plate.</p> <p>Refer to Long-Term Care Routine Steps 4 and 5 for more detail.</p>

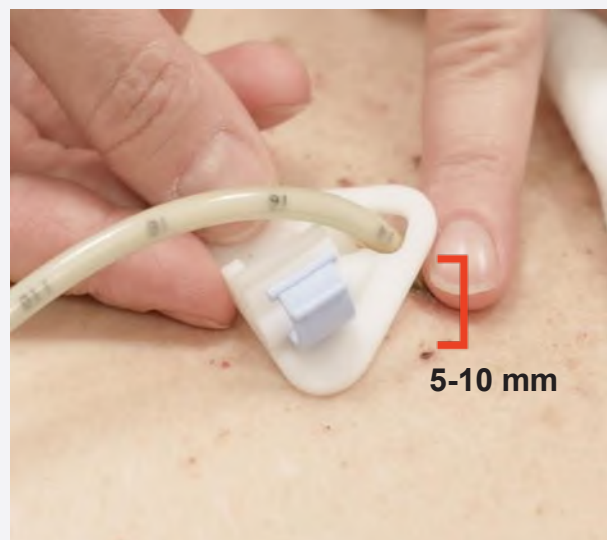
Frequently Asked Questions

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?

Figure 37.

A: If the leak is between the tube and the stoma, check that the tube is secured in the correct position. For the Long-Term Care Routine, there should be 5-10 mm, or space for one finger, between the skin and the plate. If adjusting the tube position does not stop the leakage, contact your healthcare provider.

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



Q: What should I do if the tube becomes discolored?

Figure 38.

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



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

A: Difficulty flushing your tube may be caused by tube kinking or knotting. Sometimes the high-pressure alarm from your pump also suggests 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 Care Step 4, Move tube. Call your healthcare provider 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 call your healthcare provider to resolve this problem. To prevent BBS, please follow instructions on how to move the tube as described in Step 4 Move Tube.

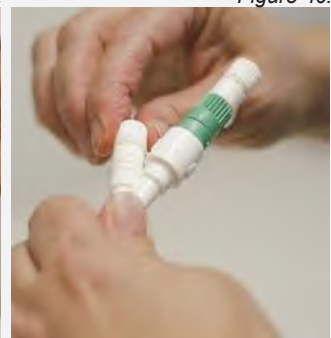
Q: When I plan to swim or take a bath, what steps should I take to avoid problems in the tube or stoma area?

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. Please contact your healthcare provider for additional instructions.

Figure 39.



Figure 40.



Important Reminders

To minimize gastrointestinal problems from the PEG-J procedure or the tubes, please follow these important reminders.

Stoma and Tube Care Checklist

- ☐ Do not remove the bandage or get the stoma wet in the first 48 hours.
- ☐ Starting 48 hours after your procedure, inspect and clean your stoma once each day.
- ☐ Re-secure the retention plate close to the skin for the first 72 hours after your procedure.
- ☐ At least 72 hours after your procedure and once your stoma has healed, move the tube once each day.
- ☐ Starting 72 hours after your procedure, maintain 5-10 mm space, or space for one finger, between the skin and the retention plate.
- ☐ Flush both tube connectors with at least 2 X 10 ml of room temperature water once each day.
- ☐ Perform the steps once each day as instructed by your healthcare provider.

Contact

If you would like to report any side effects with Duodopa® or require additional information, please contact AbbVie Biopharmaceuticals GmbH via Email: PV.MEA@abbvie.com , Hotline: 00966 55 828 2010.

And National Pharmacovigilance Center Saudi Food and Drug Authority via SFDA Unified Call Center: 19999, E-mail: npc.drug@sfdagov.sa , Website: <https://ade.sfdagov.sa/>



If you would like additional copies of this patient guide, please contact PV.MEA@abbvie.com , Hotline: 00966 55 828 2010

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

This document is approved by The Executive Directorate of Pharmacovigilance, at SFDA.

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