Important risk minimisation information for patients which is essential to ensure the safe and effective use of Duodopa® (Levodopa/Carbidopa Intestinal Gel) – do not discard

DUODOPA® (Levodopa/Carbidopa Intestinal Gel) Patient Guide

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About This Guide

This guide is for patients and caregivers of patients who are using Duodopa to treat advanced Parkinson's disease (PD).

As a patient, you had a procedure to make a small hole (called a "stoma") in your stomach wall to place a tube (called a PEG-J tube) in your gut (small intestine). The PEG-J is 1 long tube made up of 2 smaller tube parts. One tube part is called the PEG Tube. The PEG Tube connects from the pump (outside of your body) to the second tube part, called the Intestinal Tube. The Intestinal Tube starts where it connects to the PEG Tube and goes into your gut. Duodopa medicine is continuously delivered to your gut through these tubes by a pump.

You may be using an AbbVie® PEG or AbbVie PEG for ENFit® tube:

For illustration purposes, they are commonly referred to as 'PEG' Tube in this guide.

You may be using an AbbVie J or AbbVie ENFit® J tube:

For illustration purposes, they are commonly referred to as 'Intestinal' Tube in this guide.

Contact your healthcare professional if you are unsure of the device that you're using. You can also contact the Duodopa Support Helpline on 0800 458 4410.

The device or parts you receive may look different than what is shown in the illustrations in this guide. Always follow the instructions from your healthcare professional for how to use your specific device.

This guide provides instructions for how to care for the stoma and tube to reduce possible gastrointestinal (stomach and intestine) problems and complications from the procedure or tube. Some of these problems could require surgery or may lead to serious health issues, if they are not treated.

Unless otherwise specified, the information in this guide, including the Post-Procedure Care and Long-Term Care section, applies to AbbVie PEG, AbbVie PEG for ENFit®, AbbVie J, or AbbVie ENFit® J devices.

Please read the Patient Information Leaflet for more important safety information about Duodopa. If you require any further guidance on how to use the Duodopa system, please contact your healthcare professional or the Duodopa Support Helpline.

Possible Side Effects Following PEG-J Tube Placement

The main risks of Duodopa treatment are gastrointestinal (stomach and intestine) problems and complications from the procedure or tube.
Tell your doctor right away if you have any of the following symptoms:

- Increasing redness, swelling, foul-smelling pus (thick yellow liquid), or pain at the stoma site
- Stomach pain or discomfort
- Feeling bloated
- Passing more gas than usual
- Nausea
- Vomiting
- Fever
- Bleeding
- Black or tarry stool

Tell your healthcare professional about any problems or changes in the way you feel, even if they are not listed above.

Please refer to the Duodopa Patient Information Leaflet for more information including the full list of possible side effects. See back page of this guide for details of where to access this.

Important Reminders

To reduce the chance of problems caused by the PEG-J procedure or the tubes, please follow these important reminders.

Stoma and Tube Care Checklist

- [ ] Do not get your stoma wet until your healthcare professional says you can.
- [ ] Do not remove the dressing until your healthcare professional says you can.
- [ ] After your procedure, and when instructed by your healthcare professional, inspect and clean your stoma once per day.
- [ ] In the first 24 to 72 hours after the procedure (as advised by your healthcare professional), keep the Fixation Plate close to the skin.
- [ ] Once your stoma has healed and when instructed by your healthcare professional, move the tube 3 to 4 cm in and out once per day.
- [ ] When instructed by your healthcare professional (typically after 72 hours following your procedure), maintain 5 to 10 mm of space between the skin and the Fixation Plate.
- [ ] Flush both tube connectors with at least 20 mL of room temperature tap or drinking water daily.
- [ ] Perform the stoma and tube care steps starting on page 9 once per day or as instructed by your healthcare professional.

Do's and Don'ts



Do's

- Follow the stoma and tube care steps routine once per day.
- **In the first 24 hours** after your procedure, apply and change dressings as instructed by your healthcare professional.
- **In the first 24 hours** after your procedure, keep the stoma site, PEG Tube, and the underside of the Fixation Plate clean and dry.
- **In the first 24 to 72 hours** after your procedure, keep the Fixation Plate close to the skin.



Dont's

- **In the first 24 hours** after your procedure, **don't** move your tube or Fixation Plate.
- **Don't** turn or rotate the tube coming out of the stomach. Turning or rotating could cause the tube to loop, knot, or detach and slide out of the stomach.
- **Don't** use any ointments on your stoma or tube unless a healthcare professional recommends it. Ointments may cause the Fixation Plate to move.
- **Don't** lift heavy objects for one month or until your healthcare professional says you can.
- **Don't** bathe (submerge your stoma in water) until your healthcare professional says you can. This may increase the chance of infection.
- **Don't** use any cleaning products on your stoma unless recommended by your healthcare professional.

Aftercare

Aftercare consists of the Post-Procedure Care and Long-Term Care sections. The information in these sections is meant to reduce possible gastrointestinal (stomach and intestine) problems and complications from the PEG-J procedure or the tubes.

Post-Procedure Care starts right after your procedure and continues until your stoma is fully healed.

Long-Term Care begins after your stoma has fully healed.

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 right after your procedure and continues until your stoma is **fully healed**. Your healthcare professional will help determine when the stoma is fully healed, and when the post-procedure care instructions no longer need to be followed

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

- some stomach pain or feeling sore at the procedure site.
- slight redness on the skin around the stoma.
- a small amount of clear fluid may be seen from the stoma.

These symptoms should go away 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 several days to several weeks after the tube is placed in your stomach. Your healthcare professional will tell you when your stoma has fully healed. The Long-Term Care routine instructions below help keep your stoma area healthy and reduce possible long-term health issues. Contact your healthcare professional if there are any signs of complications.

Post-Procedure and Long-Term Stoma and Tube Care Routine

In the first 24 hours after the procedure: Apply any bandages (dressings) to the surgical site as instructed by your healthcare professional. Look for symptoms such as pain and bleeding.

From 24-72 hours after your procedure, follow the steps in this stoma and tube care routine **once per day.** This will help the stoma to heal properly and reduce possible gastrointestinal (stomach and intestine) problems and complications from the PEG-J procedure or the tubes as described in the Possible Side Effects Following PEG-J Tube Placement section on page 4. Talk with your healthcare professional 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. Following all of these steps will help reduce your risks during recovery. You may need help from a caregiver to complete these steps. Before you begin, wash your hands well and collect the following items:

- Gauze
- Syringe
- Syringe adaptor (if required)
- Clean scissors
- Cleaning solution or alternative (as recommended by your healthcare professional)
- Dressings (if recommended by your healthcare professional)
- Adhesive tape
- Disposable gloves

You may also use other materials recommended by your healthcare professional.

Step 1. Release tube from Fixation Plate and inspect the stoma

⚠ When inspecting or cleaning the stoma site:

- Always sanitize or wash your hands before handling the Fixation Plate or the tube
- Wear disposable gloves

Avoid walking with the tube released during the first week after your procedure.

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 1.1 If there is a dressing over the Fixation Plate, remove the dressing. See Figure 1.

Figure 1.



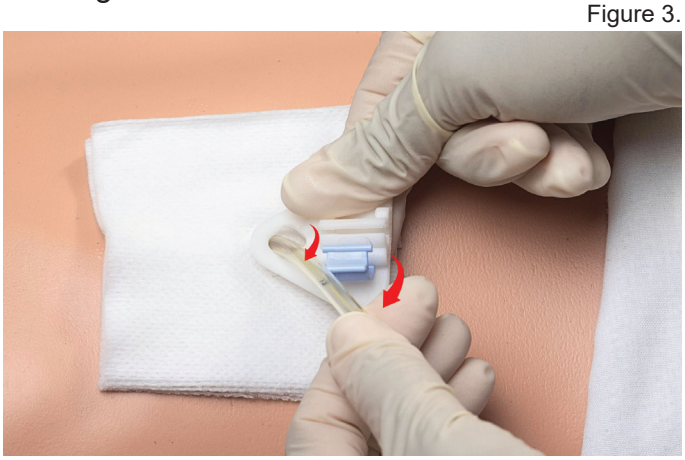
Step 1.2 Swing the blue closure on its hinge to open the Tube Clip. See Figure 2.

Figure 2.



Step 1.3 Gently pull the tube up to release it from the Fixation Plate. Slide the Fixation Plate a short distance from the stoma to loosen it. See Figure 3.

Figure 3.



Step 1.4 Check your stoma once per day for signs of increasing redness, swelling, foul-smelling pus (thick yellow fluid), or pain at the stoma site. If you notice any of these signs, contact your healthcare professional right away.

Step 2. Clean the stoma

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.

Step 2.1 Apply the cleaning solution provided by your healthcare professional to gauze, or clean the area as advised by your HCP.

Step 2.2 Gently lift the tube and clean around the stoma site, the tube, and the back of the Fixation Plate. See Figure 4.

Figure 4.



Step 2.3 After cleaning, let the area air dry. Until your stoma has healed and when instructed by your healthcare professional, skip step 3 & go directly to step 4.1. You may go to step 3 only when your stoma has healed and when instructed by your healthcare professional.

Apply the cleaning solution your HCP recommends. **Do not use** any other cleaning products on your stoma other than the cleaning solution recommended by your healthcare professional.

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

After cleaning, always leave the area clean and dry as much as possible.

Step 3. Move the tube

Why is moving my tube once per day 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 breaks down into the stomach wall. This can lead to an infection in the wound, infection in the stomach area, leakage from the tube, or a blockage in the tube. Let your healthcare professional know if you are having trouble moving the tube in or out of the stoma, or if there are any signs of complications.

You should continue to skip this step and go directly to step 4.1 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.**

Step 3.1 Gently move the tube 3-4 cm in and out of the stomach. See Figures 5a, 5b, and 5c.

Figure 5a.

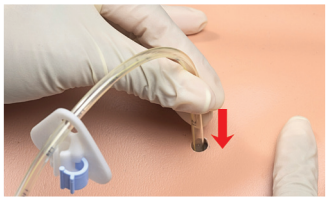
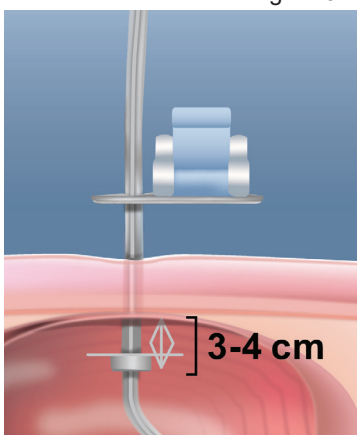


Figure 5b.



Figure 5c.



Step 3.2 Apply a new dressing if your healthcare professional has advised you do this. Gently pull the tube back until you feel resistance. See Figure 6.

Figure 6.



If the tube does not push inside your stomach easily, contact your healthcare professional right away.

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

Step 4. Re-secure the tube

Why is re-securing my tube important?

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

Follow the instructions below to keep the tube securely in place.
(If step 3 has been skipped, apply a new dressing as instructed by your healthcare professional before re-securing the Fixation Plate).

Step 4.1 Swing the blue closure back on its hinge and push it into the bumper until you feel a click to re-secure the Fixation Plate. See Figure 7.

Figure 7.



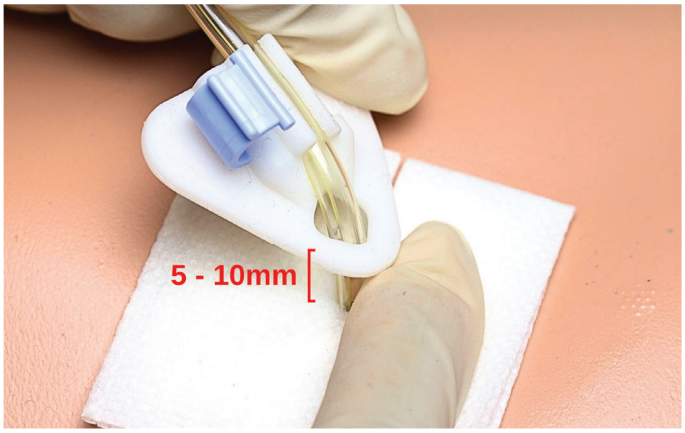
In the first 24 to 72 hours after the procedure (as advised by your healthcare professional), keep the Fixation Plate close to the skin. See Figure 8.

Figure 8.



When instructed by your healthcare professional (typically after 72 hours following your procedure) maintain 5 to 10mm of space between the skin and Fixation Plate. See Figure 9.

Figure 9.



Step 4. Re-secure the tube

Apply and change dressings as instructed by your healthcare professional. If a dressing is used while the stoma is still healing, follow the instructions in **Step 4.2** and **Step 4.3** to apply the dressing. After the stoma has healed and when instructed by your healthcare professional, the dressing may no longer be required, and the stoma site may be left clean and dry with no dressing.

Step 4.2 Apply a new dressing over the Fixation Plate as instructed by your healthcare professional. See Figure 10.

Figure 10.



Step 4.3 Secure the dressing and tube using a bandage or medical tape. See Figure 11.

Figure 11.



Step 5. Flush the 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 deliver medication properly.

Do not twist the tube coming out of your stomach.

Use room temperature tap or drinking water to flush the tubes.

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.

There are two tubes that should be flushed daily. First, flush the Intestinal Tube through the longer straight connector. Then, flush the PEG Tube through the shorter angled connector.

The device or device parts you receive may look different than what is shown in the illustrations in this section.

To ensure the tubes can be flushed properly, it is important that you understand the device parts that you're using to flush the tubes. Contact your healthcare professional if you are unsure of the device that you're using.

If you are unsure what to do or have any issues flushing the tubes you can also contact the Duodopa Support Helpline on 0800 458 4410.

Step 5. Flush the tubes

Review the table below to check which section you should go to for flushing guidance based on your combination of device parts. Contact your healthcare professional if you don't know which device you're using, you can also contact the Duodopa Support Helpline on 0800 458 4410.

Combination ID	Y-connector type	Type of syringe used for flushing	Type of adaptor	Guidance for flushing
A	AbbVie PEG-J (white caps) 	B Braun® Injekt® 10mL syringe (Green plunger) 	Blue adaptor (push-type) 	Go to section 1
B	AbbVie PEG-J (white caps) 	ENFit® syringe (Purple plunger) 	Purple Cedic™ Adaptor (screw type) 	Go to section 1
C	ENFit® Y-connector (purple caps) 	B Braun® Injekt® 10mL syringe (Green plunger) 	Blue adaptor (push type) + Clear Cedic™ Adaptor (screw type)  	Go to section 1
D	ENFit® Y-connector (purple caps) 	ENFit® syringe (Purple plunger) 	No adaptor is required	Go to section 2

For illustration purposes, the images in Section 1 show device parts from Combination A. If you are using device parts shown in Combination B, C, or a combination of device parts that require a syringe adaptor which are not listed in the above table, please refer to Section 1 for guidance on flushing the tubes.

Section 1 - Flush the tubes using a syringe which requires an adaptor

The device or device parts you receive may look different than what is shown in the illustrations in this section.

Step 5.1 Stop the pump and disconnect the tubing. See Figure 12.

Figure 12.



Step 5.2 Connect the adaptor to the end of the syringe. How you connect the adapter can vary depending on the adaptor and syringe that you're using. See Figure 13.

Figure 13.



Step 5.3 Fill the syringe with 20 mL of room temperature tap or drinking water.

A push-type adaptor (shown in Figure 13) will require pushing the syringe adaptor into the end of the syringe to connect them together.

A screw-type adaptor will require twisting the adaptor to the right (in a clockwise direction) to connect to the syringe end. Contact your healthcare professional or Duodopa Support Helpline (0800 458 4410) if you are unsure of the device that you're using.

Step 5.4 Twist the syringe to connect it to the longer straight green connector on the PEG-J. Push the syringe plunger to dispense the full 20 mL of water through the connector. See Figure 14.
Note: You should never twist the tube itself, only the syringe.

Figure 14.



Section 1 - Flush the tubes using a syringe which requires an adaptor

Step 5.5 After flushing the tube with water, remove the syringe and syringe adaptor. See Figure 15.

Figure 15.



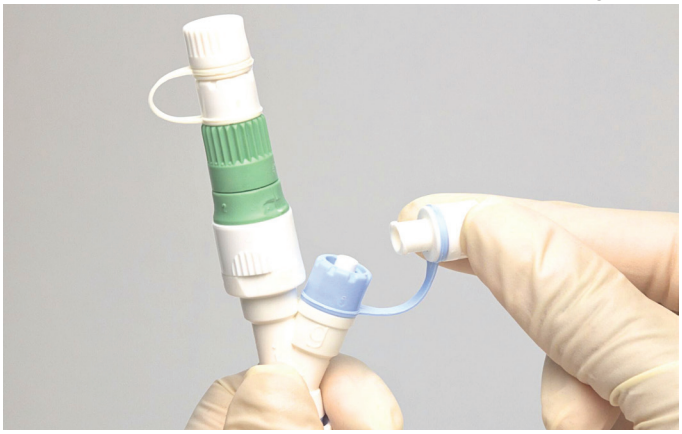
Step 5.6 Close the longer connector with the cap. See Figure 16.

Figure 16.



Step 5.7 Twist the cap off the shorter angled connector (white, blue, or violet). See Figure 17.

Figure 17.



Step 5.8 To flush the shorter angled connector **repeat steps 5.3-5.6.** See Figures 18a and 18b.

Figure 18a.



Figure 18b.



The tubes must both be flushed with at least 20 mL room temperature tap or drinking water. Follow any advice your healthcare professional gives you on this, for example if you are instructed to use a 10 mL syringe and flush each tube twice.

Section 2 - Flush the ENFit® tubes using an ENFit® syringe

If you're using an ENFit® Y-connector (with purple caps) and ENFit® syringe (with purple plunger), an adaptor is NOT required for flushing the tubes. Follow the steps in this section to flush the tubes. Check with your healthcare professional if you're unsure if the Y-connector or syringe you're using is an ENFit® device. You can also contact the Duodopa Support Helpline on 0800 458 4410.

Step 5.1 Stop the pump and disconnect the tubing.
(Note: The device or device parts you receive may look different than what is shown in the illustrations in this step). See Figure 19.

Step 5.2 Fill the syringe with 20 mL of room temperature tap or drinking water.

Step 5.3 Twist the syringe in a clockwise direction to connect it to the longer straight connector on the PEG-J. Push the syringe plunger to dispense the full 20 mL of water through the connector. See Figures 20a and 20b.
Note: You should never twist the tube itself, only the syringe.

Figure 19.



Figure 20a.



Figure 20b.



Step 5.4 After flushing the tube with water, remove the syringe. See Figure 21.

Figure 21.



Step 5.5 Close the longer connector with the cap. See Figure 22.

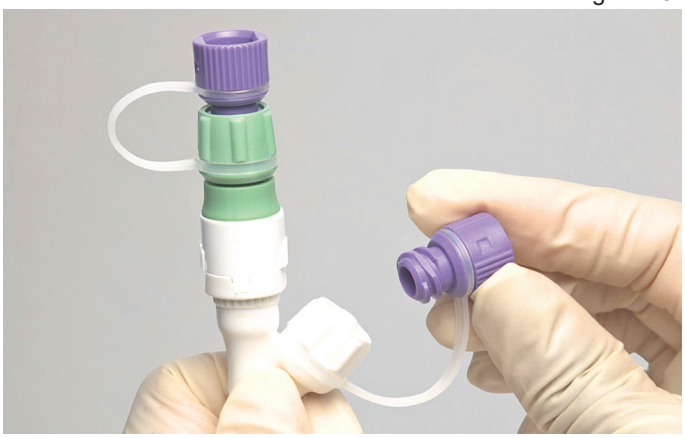
Figure 22.



Section 2 - Flush the ENFit® tubes using an ENFit® syringe

Step 5.6 Twist the cap off the shorter angled connector. See Figure 23.

Figure 23.



Step 5.7 To flush the shorter angled connector **repeat steps 5.2-5.5** of this section. See Figures 24a and 24b.

Figure 24a.



Figure 24b.



Possible Long-Term Problems and How to Prevent Them

During the Long-Term Care period, you may have certain problems from the tube. **If any of these problems happen to you, contact your healthcare professional.**

Possible Problem	What Can I Do To Prevent This Problem
Tube problems (such as blockages, loops, or knots).	Flush your tubes once per day as described in Post-Procedure and Long-Term Stoma and Tube Care Routine Step 5 to reduce risk.
Connectors loosen or disconnect, causing your intestinal tube (inside your gut) to disconnect from your PEG tube (outside your body).	Follow the stoma and tube care steps once per day to prevent this problem. If the intestinal tube disconnects from the PEG tube, call your healthcare professional right away.
Signs of stoma irritation or infection, such as increasing redness, swelling or foul-smelling pus (thick yellow liquid).	Discharge is often due to infection or inflamed skin tissue. Keep the stoma clean and dry. When instructed by your healthcare professional (typically after 72 hours following your procedure), maintain 5 to 10 mm space between the skin and the Fixation Plate as described in Post-Procedure and Long-Term Stoma and Tube Care Routine in Step 4.
Food gets stuck around the tube causing it to block (bezoar). Symptoms of tube blockage caused by a bezoar 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 of a bezoar.
Buried bumper syndrome is when the inside bumper of the PEG tube breaks down 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.	Once your stoma has healed and when instructed by your healthcare professional, move the tube 3 to 4 cm in and out once per day. Allow 5 to 10 mm of space between the skin and the Fixation Plate. Refer to Post-Procedure and Long-Term Stoma and Tube Care Routine Steps 3 and 4 for more detail.

If you have any of the problems listed above, contact your healthcare professional.

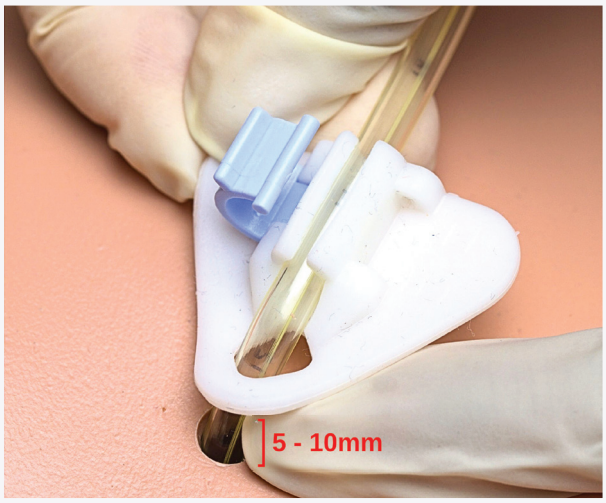
Frequently Asked Questions

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?

A: If the leak is between the tube and the stoma, check that the tube is secured in the correct position. When instructed by your healthcare professional (typically after 72 hours following your procedure) allow 5 to 10 mm of space between the skin and the Fixation Plate. If adjusting the tube position does not stop the leak, contact your healthcare professional. See Figure 25.

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

Figure 25.



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

A: Tube discoloration is expected and does not mean there is a problem. If you are concerned, contact your healthcare professional.

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

A: This may be related to a serious problem, such as buried bumper syndrome (BBS). Call your healthcare professional right away to resolve this problem. To prevent BBS, please follow instructions on how to move the tube as described in Post-Procedure and Long-Term Stoma and Tube Care Routine Step 3 Move the Tube.

Q: What should I do when I want to swim or take a bath?

A: Remember to disconnect your pump and put a cap on both the longer straight connector and the shorter angled connector. Make sure that the stoma is healed before you swim or bathe. Please contact your healthcare professional for more instructions. See Figures 26 and 27.

Figure 26.



Figure 27.



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

A: Trouble flushing your tube may be caused by tube looping or knotting. Sometimes the high-pressure alarm from your pump may also be caused by tube looping or knotting.

Twisting of the tube may cause looping or knotting of the tube itself. You should avoid twisting of the tube when moving it in and out once per day as described in Post-Procedure and Long-Term Stoma and Tube Care Routine Step 3, Move the tube. Call your healthcare professional if you are getting a high-pressure alarm or have trouble flushing your tube.

Q: What precautions should I take if I have an appointment for an MRI scan?

A: The AbbVie J tube and AbbVie ENFit® J tube contain small pieces of metal in the tube tip. This can be seen in magnetic resonance imaging (MRI) scans. Let your doctor or the person providing the scan know before your MRI scan.

How To Report Adverse Events

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 from the Apple App Store or Google Play Store

Alternatively you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm. You can leave a message outside of 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.

The complete list of possible side effects can be found in the Duodopa Patient Information Leaflet that comes with Duodopa. You can also access this online at www.medicines.org.uk or use the QR code below.

Contact

If you would like additional copies of this patient guide, please contact the Duodopa Support Helpline on 0800 458 4410, visit www.medicines.org.uk or use the QR code below.

For a digital copy of this guide:

To access the Patient Information Leaflet:

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