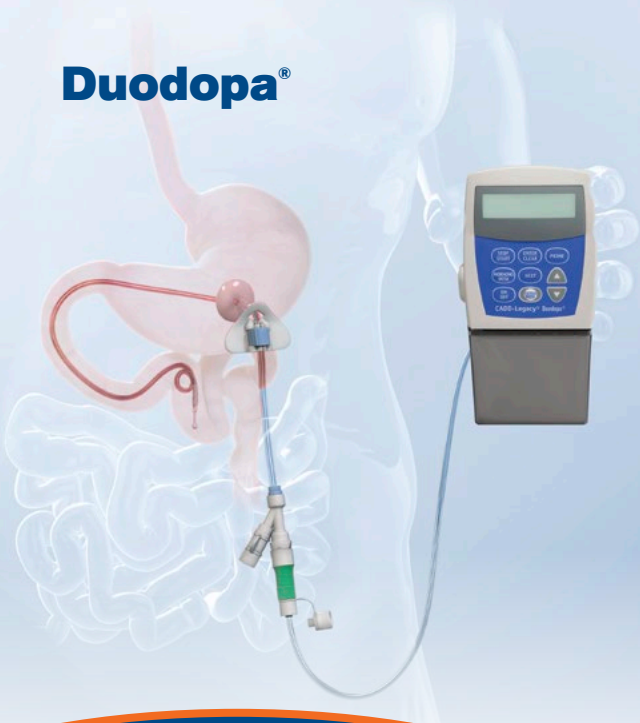


Duodopa[®]



Important Risk Minimisation Information

Patient Pocket Guide

EDUCATIONAL MATERIAL FOR RISK MINIMISATION

abbvie

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Patient Pocket Guide

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This pocket guide contains a short explanation of the Duodopa® treatment. It includes important information that is designed to minimise potential problems inserting the stomach and intestinal tubes as well as potential long-term problems with the intestinal tube.

For further information, please read the manual for each device and the Duodopa® patient information leaflet. If you have any further questions, ask your doctor, pharmacist or nurse.

Introduction to Duodopa®

What Duodopa® is used for

Duodopa® is used to treat advanced Parkinson's disease.

The symptoms of Parkinson's disease include tremor, feeling rigid, slow movements and balance problems.

Duodopa® is available in cassettes, which contains

- Levodopa 20 mg/mL
- Carbidopa monohydrate 5 mg/mL
- Carmellose sodium (thickening agent)
- Purified water

The Duodopa[®] System

The Duodopa[®] system (Figure 1) consists of a pump, intestinal tube and cassette (which contains the medication levodopa/carbidopa). You will need to have 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.

The Duodopa[®] medicine is a gel contained in a plastic cassette. The cassette is connected to a pump. The pump is connected to the PEG-J tube which is placed into your gut (small intestine). 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. Your doctor or nurse will talk to you about the stoma procedure.



- A. Pump
- B. Duodopa[®] Cassette
- C. PEG
- D. Intestinal Tube

FIGURE 1

Daytime Treatment

The following is a short guide for patients who use one cassette per day (up to 16 hours). For further instructions please read the manual for each device and the Duodopa® patient information leaflet.

Morning Procedure

Getting Started

1. Attach a new cassette to the pump (see below). Place the pump in your carrying accessory before you put it on.
 - Fit the hooks of the cassette onto the pivot pins at the pump's base.
 - Place the pump on a level surface.
 - Hold the cassette steadily and put a coin in the slot of the lock knob.
 - Lock the cassette by pushing the coin or the Duodopa® key and turning it 90 degrees counter-clockwise until it stops.



Please note: It is absolutely essential that the cassette is properly attached, or the pump mechanism may not work. If the cassette comes loose you will hear an alarm signal, even if the pump is in stopped mode.

2. Undo the white cap of the PEG-J tube.
3. Remove the red protective cap from the cassette tube and open any tube clamps.
4. Connect the cassette tube to the intestinal port of the PEG-J. Do this by holding the PEG-J with one hand securely whilst gently rotating clockwise the cassette tube onto the PEG-J with the other hand (Figure 2). Make sure to twist the cassette tube and NOT the PEG-J tube (Figure 3).
5. Activate the pump, start it and give the morning dose (see 'Operating the Pump').
6. The continuous infusion will commence once the morning dose has been given.

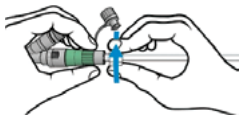


FIGURE 2



FIGURE 3

**Do not connect
cassette to gastric port**

Administering a Morning Dose

Press the MORNING DOSE button twice to administer the morning dose. The continuous dose will follow automatically.

The morning dose should result in satisfactory mobility within one hour. If there is intense dyskinesia (unwanted or uncontrolled movements) the pump may be turned off for 5-30 minutes or until you feel the dyskinesia wearing off. If problems with intense dyskinesia occur several times, the rate of the pump should be decreased.

It is important that prior to any changes in your medication dosing, you should first contact your physician, PD Nurse or the AbbVie Care Support Team.


Daily Procedure

Keep the pump running the entire day. When symptoms of Parkinson's appear, use an extra dose by pressing the EXTRA DOSE button (one touch).

The amount of the extra dose is manually set. It usually varies between 0.5-2.0 mL/occasion and is normally determined during the test period. The extra dose can only be given once an hour has passed. If the need for extra doses exceeds five per day the maintenance dose should be increased, as long as there is no dyskinesia. And for this, you should contact your doctor, PD Nurse or the AbbVie Care Support Team.

A preset extra dose can be programmed. It will always give the same dose when activated, but can be changed when needed.



- Press the key . Two beeps will sound. The pump will begin delivering the dose. When main screen is displayed, DOSE will appear.¹

¹ CADD-Legacy Duodopa® Patient Information User's Manual.

Evening Procedure

Discontinuing the Infusion and Flushing the Intestinal Tube

Duodopa® infusion is usually stopped when you go to bed. The tube is rinsed with 40 mL drinking water to prevent the medication from coagulating in the tube causing an obstruction.

1. Stop the pump, switch it off (see 'Operating the Pump').
2. Disconnect the Duodopa® cassette tube from the intestinal port of the PEG-J. (Figure 2) Make sure to twist the cassette tube NOT the PEG-J tube. (Figure 3)
3. Disconnect the cassette from the pump.
4. Connect a female/female connector to the intestinal port of the PEG-J. (Figure 4).
5. Use a syringe to flush with at least 40 mL of drinking water until the tube is clean and clear. (Figure 4).
6. Connect the white cap attached to the PEG-J to the end of the PEG-J tube.

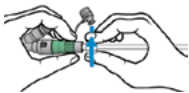


FIGURE 2



FIGURE 3

**Do not connect
cassette to gastric port**



FIGURE 4

7. Detach the cassette from the pump:
- Place the pump with the cassette upright on a hard level surface.
 - Put a coin or the Duodopa® key in the slot of the lock knob and turn 90 degrees clockwise. The lock knob will pop out slightly when the cassette is unlocked.
 - Remove the hooks of the cassette from the pivot pins of the pump.
 - Discard the used cassette if it is not to be used later the same day.



Stoma Care

Before the stoma procedure, tell your healthcare provider if you have ever had stomach-related surgery or problems with your stomach. Talk to your healthcare provider about what you need to do to care for your stoma.

After the procedure, you and your healthcare provider will need to regularly check the stoma for any signs of infection. Observe for signs of complications such as pain and bleeding

First 24 hours after day of placement

Duodopa® treatment can normally be initiated directly after uncomplicated PEG/J placement, after consultation with the gastroenterologist. Oral feeding is possible 2 hours after PEG/J placement.

Tube Mobilisation to Prevent Buried Bumper Syndrome

After initial wound healing this procedure should be performed every two to three days. Daily dressing is no longer necessary.

1. Wash hands thoroughly with soap and water.
2. If dressing is used, remove the dressing and release the external retention 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. (Figure 5)
4. Inform your physician if there are any signs of complications.
5. Replace the retention plate allowing free movement of 5 to 10 mm. Apply a Y-dressing. A plaster fixation is recommended for agitated patients. (Figure 6)

Daily Procedure

Flush the space between intestinal tube and PEG tube after it has been used for feeding, or at least once a week with 40 mL of drinking water, as well as once a day after any feedings given through the side port. (Figure 7).

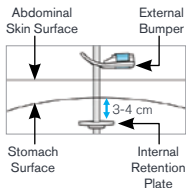


FIGURE 5

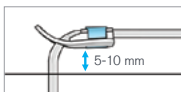


FIGURE 6

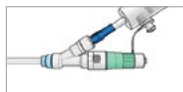


FIGURE 7

Important Information

Duodopa[®], 20 mg/mL + 5 mg/mL, intestinal gel
levodopa and carbidopa monohydrate

Read all of this information carefully before you start taking this medicine.

If you have any further questions, ask your doctor, pharmacist or nurse. Additional information is also provided in the patient information leaflet.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this patient information leaflet or pocket guide.

If your PEG-J tube becomes kinked, knotted, or blocked this may cause you to have worsening of your Parkinson's symptoms or recurring movement problems (motor fluctuations). Call your doctor or nurse if your Parkinson's symptoms get worse or you have slow movement while you are treated with Duodopa[®].

Driving and Using Machines

Do not drive or use any tools or machines until you are sure how Duodopa[®] affects you.

- Duodopa[®] may make you feel very sleepy, or you may sometimes find yourself suddenly falling asleep (sleep attacks)
- Duodopa[®] may lower your blood pressure, which can make you feel light-headed or dizzy

Do not drive or use any tools or machines until you feel fully awake again or you no longer feel light headed or dizzy.

If you have had more Duodopa[®] than you should, talk to your doctor or go directly to a hospital. Take the medicine pack with you. The following effects may happen:

- Problems opening your eyes (blepharospasm)
- Muscle spasms you cannot control in your eyes, head, neck and body (dystonia)
- Movement you make without wanting to (dyskinesia)
- Unusual fast, slow or uneven heart beats (arrhythmia)

If you forget to use Duodopa[®]

Start your pump, with your normal dose, as soon as possible. Do not increase your dose to make up for a forgotten dose.

If You Stop or Lower Your Dose of Duodopa®

It is important that you do not stop having Duodopa® or lower your dose until told to do so by your doctor. Suddenly stopping or lowering your Duodopa® dose may result in a serious problem called **Neuroleptic Malignant Syndrome**.

The signs may include:

- Fast heart beat, changing blood pressure and sweating followed by fever
- Faster breathing, muscle stiffness, lower consciousness and coma
- Higher levels of a protein in your blood (an enzyme called creatine phosphokinase). This is measured by your doctor.

This problem is more likely to happen if you are also taking a medicine called an **antipsychotic**.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

The following very common complications have been reported for the tube delivery system:

- Leaks at the connections and leakage of gastric fluid
- Blockade of flow of Duodopa® due to occlusion, kinking and knotting of the tubing
- Dislocation of the tube (e.g., to the stomach, resulting in decreased treatment response)

Tube blockage

If you are unable to flush the inner tube, you may try the following. If unsuccessful on the first step, try the next:

- Ensure that all clamps are open and the tube is not kinked.
- Flush with 60 mL warm water.
- Flush with 20 mL carbonated (fizzy) water.
- If the above clears the blockage, flush again with 40 mL drinking water.

When trying to flush, use a pumping action with the plunger on the syringe. If you fail to unblock the tube on the first attempt, repeat the procedure 30 minutes later and throughout the day.

Never use excessive force and never attempt to unblock the tube by inserting sharp instruments. If still unsuccessful, try gently pushing the PEG-J tube into the stomach 3-4cm, as described in "Stoma Care". If this does not work contact your Doctor, PD Nurse or the AbbVie Care Support Nurse.

Most common complications and actions to take

A circular erythema (redness of the skin) with a diameter of less than 5mm is normal and not necessarily a sign of wound infection. Careful observation on a daily basis is advised. Never apply an ointment on a PEG-J stoma nor an inflamed PEG-J wound. If you are not sure, please consult a physician.

The following are the most common complications that can occur and the actions that should be taken in consultation with your physician:

- Signs of inflammation: if there are signs of inflammation consult your physician.
- Severe discharge: consult your physician. The wound should be kept as dry as possible.

Side Effects From the Pump or Tube

The following side effects have been reported for the pump and tube, and tube delivery system. Tell your doctor or nurse if you notice any of these.

- If you become less able to handle the pump and tube, your Parkinson's disease symptoms get worse or it is harder to move (bradykinesia) — the pump and tube may not be working properly
- If you have pain in your stomach area, feel sick (nausea) and are sick (vomit) tell your doctor straight away — you might have a problem with your pump or tube

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 from having the tube put in (e.g., pain or swelling in the mouth or throat, difficulty swallowing, stomach discomfort, pain or swelling, injury to the throat, mouth or stomach, bleeding, being sick/vomiting, wind/flatulence, or anxiety)
- 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)
- Tube goes through the wall of the large intestine
- Blockage (obstruction), bleeding or ulcer in the gut
- Food getting stuck around the tube causing it to block
- Sliding of one part of the gut into an adjacent part of the gut (intussusception)
- 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
- Tube goes through the wall of the stomach or small intestine
- Infection in the blood (sepsis)

Please read the patient information leaflet for complete information including the side effects of Duodopa[®].

How to Store Duodopa[®]

- Keep the cassettes with gel out of the reach and sight of children.
- Do not use Duodopa[®] after the expiry date which is stated on the carton label after EXP.
- Store in a refrigerator (2°C to 8°C).
- Keep the cassettes in the outer carton in order to protect from light.
- A cassette of the gel may be used for up to 24 hours once it is out of the refrigerator.
- The drug cassettes are for single use only and should not be used for longer than 24 hours even if some gel remains.
- Do not re-use an opened cassette.
- The gel might become slightly yellow — this does not affect the medicine.

How to Dispose of Duodopa[®]

Do not throw away any medicine via wastewater or household waste. Ask your pharmacist how to throw away medicine you no longer use. These measures will help to protect the environment.

Return used cassettes to your nearest pharmacy - do not re-use.


About the Pump

Operating the Pump


Morning Dose

Switch on the pump, start it and give the morning dose. Make sure that there is no cap or locked tubing clamp on the tube.




1. Press the key  and hold it down until the display turns on. Release 'ON/OFF'. The pump will power up and automatically review all screens. The pump runs the programme and displays the set values. This takes approx. 30 seconds.





2. Press the key  and hold it down for three seconds until the three dashes in the display disappear. The pump runs through the set values again. This takes approximately 15 seconds. The text 'RUN' is shown in the display. This means the pump is running and administering the continuous dose.




3. Press the key  once. The set morning dose is shown in the display.



4. Press the key  again. The pump will begin delivering the morning dose and after a few minutes it automatically goes on to the continuous dose.

5. If 'LLO' is shown in the display when pressing  key, the pump is not running.


 NEXT

Press the  key and go back to step 2.


See 'Daytime Treatment' on attaching the cassette to the pump.

Stopping the pump/Turning the pump off

Stop the pump, switch it off and rinse the tube.

1. Stop the pump by pressing the key  and hold it down until the three dashes are displayed (three seconds). 'STOPPED' will appear on the main screen.

 ON
OFF

2. Press the key  and hold it down until you see 3 sets of dots appear (three seconds). The display turns off.

See 'Daytime Treatment' on detaching the cassette from the pump.

Caution

Fluid and water can damage the pump. Before showering and bathing always disconnect the pump.

Showering

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.

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 physician, 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.

Showering Procedure

1. Press the STOP/START button and then turn off the pump with the ON/OFF button.
2. Disconnect the cassette tube.
3. Put the cap on the PEG tube.
4. Put the cap on the cassette tube.
5. Once the cap is in place, the tube may hang freely.
6. After showering, be very careful to ensure that the area around the stoma is kept clean and dry.
7. Reconnect the cassette tube and turn on the pump to start the infusion.



Travelling

When travelling, plan the trip in advance. Consult your Duodopa[®] contact in case you have any questions. Ensure that the stoma wound has healed properly before traveling. In case of doubt consult your physician.

Plan your trip well in advance. Ensure that you have adequate cool packaging for the journey, and that you have refrigeration for the Duodopa[®] cassettes at your destination.

Take the following:

1. Duodopa[®] prescription (copy)
2. Sufficient Duodopa[®] medication
3. Patient's Pump Manual
4. Rescue tablet medication
5. Reserve pump (if traveling abroad)
6. Adapters, female/female
7. Syringes
8. Reserve batteries, size AA
9. Wound dressing material
10. This Duodopa[®] Patient Pocket Guide

Examples of Pump Alarms

The table below shows some of the common alarms that you may hear from the pump. With all alarms, read the display before pressing.

Display	Alarm	Cause	Action
Error	Two-tone alarm signal	An error has occurred	Contact the hospital/ clinical department; the pump needs to be returned to AbbVie for service.
[blank display]	Two-tone alarm signal	The batteries have been removed while the pump is running. The pump is now stopped and unpowered.	Install batteries to clear alarm.
		OR Batteries were removed within approximately 15 seconds after stopping the pump.	Install new batteries, if desired, to clear the alarm. Otherwise the alarm will stop within a short period of time.
High pressure	Two-tone alarm signal	The pump has detected high pressure, which may be resulting from a downstream blockage, kink in the tube or a closed tubing clamp.	Remove the obstruction to resume operation. Or press NEXT or STOP/START to stop the pump and silence the alarm for two minutes. Remove the occlusion and restart the pump.

Display	Alarm	Cause	Action
RunResVol Low	Three single signals	The reservoir volume is low.	Change the cassette without delay.
No disposable, pump will not run	Two-tone alarm signal	You tried to start the pump without a properly connected cassette. A cassette must be properly attached in order for the pump to run.	Press STOP/START or NEXT to stop the alarm signal. Attach the cassette properly and press STOP/START to restart the pump.
Reservoir Volume Empty	Two-tone alarm signal	The reservoir volume has reached 0.0 mL.	Press STOP/START or NEXT to silence the alarm. Change to a new cassette if necessary and reset the reservoir volume.
LowBat	Three two-tone alarm signals every five minutes	The battery power is low but the pump is still operating.	Change the batteries without delay. Press and hold STOP/START button to restart the pump.
Value not saved	No alarm	The input value was not saved, i.e., the key ENTER/CLEAR was not pressed.	Press NEXT to resume programming. Save the value before moving on to the next program window or before starting the pump.

Display	Alarm	Cause	Action
Battery depleted	Two tone alarm	The battery power is too low to operate the pump. The pump is now stopped.	Change the batteries immediately. Press and hold STOP/START to restart the pump.
Remote Dose Cord Removed	Two single-tone signals if the pump is stopped. Two-tone alarm signal if the pump is on.	The remote dose cord was removed	Reinsert connector or press NEXT to silence the alarm.
[Screen displays current pump status]	Two beeps (long-short)	The Duodopa [®] reservoir is not aligned with the pump or Duodopa [®] is not flowing from the medication bag inside the Duodopa [®] reservoir to the pumping mechanism.	Press STOP/ START or NEXT to clear the message and silence the tone. The pump continues to run. Make sure the Duodopa [®] reservoir is properly aligned with the pump and Duodopa [®] is flowing from the medication bag to the pumping mechanism. Very cold or extremely thick medication may cause this informational message as well. Allow the Duodopa [®] reservoir to thaw to room temperature before attaching to the pump.

Display	Alarm	Cause	Action
Upstream Occlusion	Two-tone alarm signal	<p>Fluid is not flowing from the cassette to the pump.</p> <p>Check for a kink in the tubing or a closed clamp between the fluid container and pump.</p>	<p>Press NEXT or STOP/START to stop the pump and silence the alarm for two minutes. Remove the obstruction and press STOP/START to restart the pump. If necessary, remove the cassette from the pump and connect it again.</p>
No Disposable, Clamp Tubing	Two-tone alarm signal	<p>The cassette has been removed. Close the tube clamp immediately or disconnect it from the tube. A cassette must be connected before the pump can be started</p>	<p>Press STOP/START or NEXT to stop the alarm. Very cold or viscous medicine has caused the alarm. Allow medicine to reach room temperature before connecting it to the pump. Check if the cassette is empty – change it if necessary.</p>
Power Lost While Pump was On	Two-tone alarm signal	<p>The pump was running when power was removed.</p>	<p>Stop the pump before changing the batteries or removing the power source. Press NEXT or STOP/START to stop the pump and turn off the alarm.</p>

Display	Alarm	Cause	Action
Key Pressed Release Key	Two-tone alarm signal	A key has stuck in its down position.	Release the key if possible. If the alarm continues, close the tubing clamp and remove the pump from use. Contact the hospital/clinical department; the pump needs repairing and must be returned.
Programming Incomplete	Two-tone alarm signal when starting the pump	A flow rate (mL/h) or dose must be programmed before the pump can be started	Press STOP/START or NEXT to stop the alarm signal.
Service Required	Two-tone alarm signal	The clock-battery age or the total number of motor revolutions indicates that the pump requires service.	This message is shown at LLO for 60 days, then at all lock levels until the pump is returned for service. Have service.

Further Information

Some Technical Pump Data

- Do not operate the pump at temperatures below 2°C (36°F) or above 40°C (104°F).
- Do not store the pump at temperatures below -20°C (-4°F) or above 60°C (140°F).
- Do not immerse the pump in cleaning fluid or water, or allow solution to soak into the pump, accumulate on the keypad, or enter the battery compartment.
- Use a normal soap solution when cleaning the pump. Do not clean it with acetone, other plastic solvents, or abrasive cleaners.

Like all medicines, Duodopa® can cause side-effects, although not everybody gets them. If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet.

You can also report side effects directly via HPRA Pharmacovigilance. Website: www.hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

Marketing Authorisation Holder

AbbVie Limited, Citywest Business Campus, Dublin 24, Ireland

Manufacturer

Fresenius Kabi Norge AS, Svinesundsveien 80, NO-1788 Halden, Norway

This medicinal product is authorised in the Member States of EEA under the following name: Duodopa®.

This material was developed by AbbVie, Inc. as part of the Risk Minimisation Plan for Levodopa/Carbidopa Intestinal Gel.