Important Risk Minimisation Information

Patient Pocket Guide

Duodopa® (levodopa – carbidopa)

EDUCATIONAL MATERIAL FOR RISK MINIMISATION
(RISK MANAGEMENT PLAN VERSION 7.2, 13 MARCH 2017)

Index Duodopa®
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®
(levodopa – carbidopa)

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
- Purified water

The Duodopa® System

The Duodopa system 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.

Daytime Treatment

The following is a short guide for patients who use one cassette per day. 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. Place the pump in your carrying accessory before you put it on.
2. Remove the red protective cap from the cassette tube and open any tube clamps.
3. Connect the cassette tube to the intestinal port of the PEG-J. (Figure 1) Make sure to twist the cassette tube and NOT the PEG-J tube. (Figure 2)
4. Press and hold the ON/OFF button for three seconds to start the pump.
5. Press and hold the STOP/START button for three seconds to start the continuous infusion.

Administering a Morning Dose

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

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).

Evening Procedure

Discontinuing the Infusion and Flushing the Intestinal Tube

1. Press and hold the STOP/START button for three seconds to stop the infusion.
2. Press and hold the ON/OFF button for three seconds to turn the pump off.
3. Disconnect the cassette tube from the intestinal port of the PEG-J. (Figure 1) Make sure to twist the cassette tube NOT the PEG-J tube. (Figure 2)
4. Disconnect the cassette from the pump.
5. Connect a female/female connector to the intestinal port of the PEG-J. (Figure 3)
6. Use a syringe to flush with at least 40 mL of drinking water. (Figure 3)

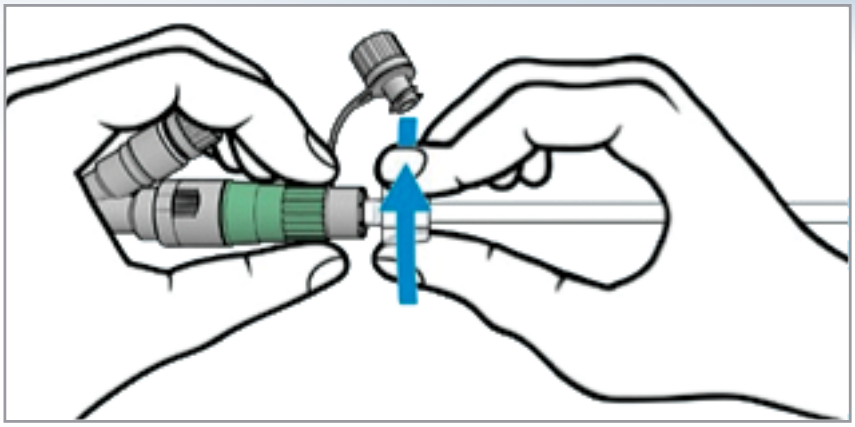

FIGURE 1.

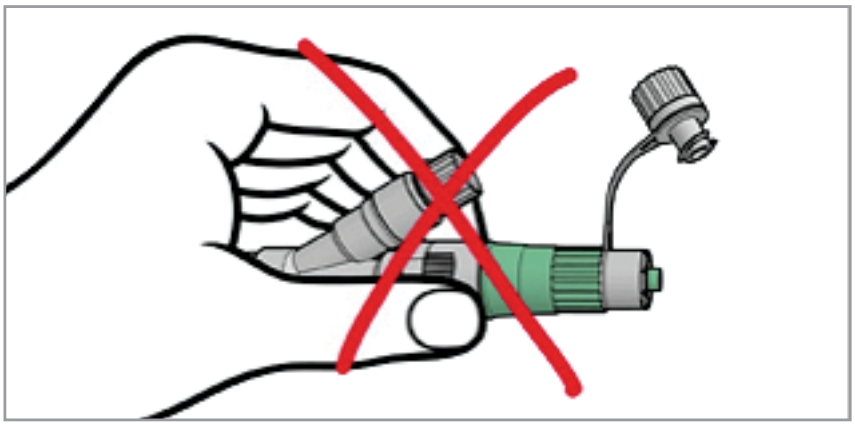

FIGURE 2.
Do not connect cassette to gastric port

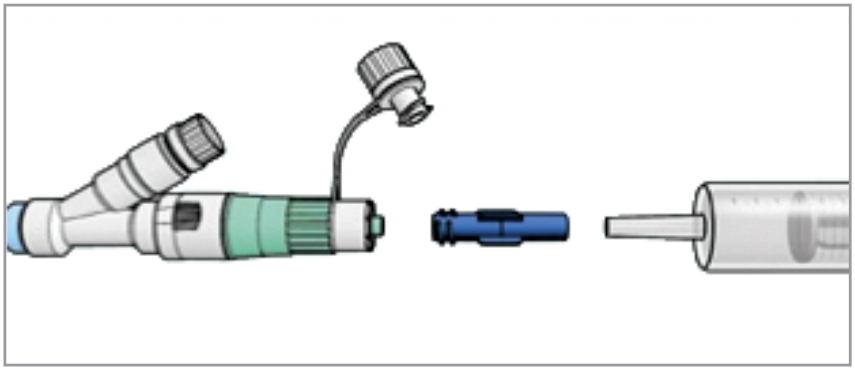

FIGURE 3.

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.

Tube Mobilisation to Prevent Buried Bumper Syndrome

After initial wound healing this procedure should be performed every two to three days.

1. If dressing is used, remove the dressing and release the external retention plate to allow free movement of the PEG-J tube.
2. 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.
3. Inform your physician if there are any signs of complications.
4. Replace the retention plate allowing free movement of 5 to 10 mm. Apply a Y-dressing. A plaster fixation is recommended for agitated patients.

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.

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 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.

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

Possible Side Effects

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)
- Local infection around the site of tube entering the stomach area (stoma), inflammation of the abdominal cavity (peritonitis), and perforation of adjacent organs, bleeding and abdominal pain, especially during tube placement

If you are experiencing serious side effects, or if you notice any side effects not listed here, please tell your doctor or pharmacist as soon as possible.

Side Effects From the Pump or Tube

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

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

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 (2ºC to 8ºC).

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

Caution:

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

Traveling

When traveling, 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.

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.
No message	Two-tone alarm signal	The batteries have been removed while the pump is running. The pump is now stopped and not powered. Or the batteries were removed within approxi-mately 15 seconds after stopping the pump.	Install the batteries to silence the alarm.
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.
RunResVol Low	Three single signals	The reservoir volume is low.	Change the cassette without delay.

Display	Alarm	Cause	Action
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.

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.

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

Local Representative
This medicinal product is authorized 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.
Version no: 7.2, 13 March 2017

AbbVie AG

To report any side effects for Duodopa® please contact:
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Fax: +966 11 205 7662
SFDA Unified Call Center: 19999
E-mail: npc.drug@sfda.gov.sa
Website: https://ade.sfda.gov.sa/