

Duodopa[®]

Levodopa 20mg/ml, Carbidopa 5mg/ml Intestinal Gel



Duodopa[®]

User Manual

Table of Contents

3. Getting to Know Duodopa®

4. The Duodopa System

5. Daytime Treatment

8. PEG Port Treatment

10. Important Information

13. Information about the Pump

13. Precautions

13. Travelling

14. Pump Alert Examples

16. Additional Information

Getting to Know Duodopa[®]

This manual includes a summary explanation about treatment with Duodopa. It contains important information intended to minimize potential problems involved in the preliminary Duodopa PEG procedure, as well as potential long-term problems involved in the intestinal tubes.

For additional information, please read the manual for each device and the Duodopa consumer's leaflet. Consult with your doctor, pharmacist or nurse if you have any further questions.

What is Duodopa[®] used for?

Duodopa is used to treat advanced-stage Parkinson's disease that responds to treatment in levodopa, and is accompanied by extraordinary and severe excessive movements and involuntary movement disorders, when existing combinations of medical preparation for treatment of Parkinson's disease were ineffective.

The symptoms of Parkinson's disease include shaking, a sense of rigidity, slow movement and balance problems.

A Duodopa[®] cassette contains:

- Levodopa 20 mg/ml
- Carbidopa monohydrate 5mg/ml
- Carmellose sodium
- Distilled water

The Duodopa® System

The Duodopa system (Illustration 1) includes a pump, an intestinal tube and a cassette (contains the medicine levodopa/carbidopa). The patient undergoes a procedure to make a small cut in the gut wall in order to insert the gut tube into the gut. A smaller tube passes through the gut to the small intestine (called the PEG-J tube).

Duodopa is a gel found in a plastic cassette. The cassette is connected to your pump. Your pump is connected to the PEG-J tube which is inserted to the intestine (the small intestine).

The pump provides a small dose consecutively throughout the day. This means that the level of your medication remains constant in your body.

This also means reduction in some of the side effects related to movement. Your doctor or nurse will elaborate on the PEG procedure.

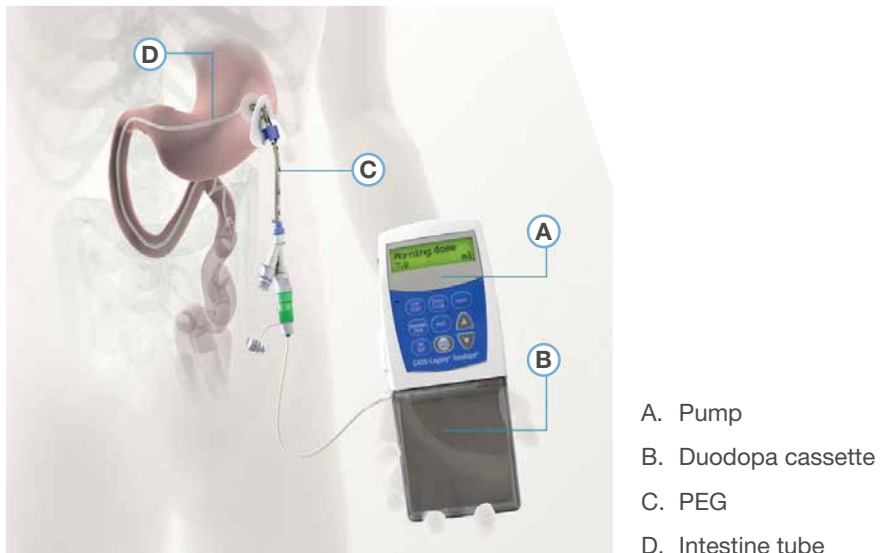


Illustration 1

Daytime Treatment

Below is a short manual for patients using one cassette per day (up to 16 hours). For further instructions, please read the manual for each device and the Duodopa consumer's leaflet.

Morning procedure

Start

1. Connect a new cassette to the pump. Before wearing the carrier bag, place the pump inside.
2. Remove the protective cap (red) from the cassette tube and open all tube clamps.
3. Connect the cassette tube to the PEG-J intestinal port connector. (Illustration 2) Make sure to twist the cassette tube rather than the PEG-J tube. (Illustration 3).
4. Press and hold the ON/OFF button for three seconds to start your pump.
5. Press and hold the START/STOP button for three seconds to start consecutive infusion.

Administering the Morning Dose

Press the MORNING DOSE button twice to administer the morning dose. After finishing the morning dose, consecutive administration will start automatically.

Daily procedure

Make sure that the pump is operating throughout the day. You can use an additional dose by pressing the EXTRA DOSE button (once) according to your doctor's instructions.

Evening procedure

Infusion termination and intestinal tube flush

1. Press and hold the START/STOP button for three seconds
2. to stop the infusion.
3. Press and hold the ON/OFF button for three seconds to turn off the pump.
4. Disconnect the cassette tube from the PEG-J intestinal port connector (Illustration 2)
5. Make sure to twist the cassette tube rather than the PEG-J tube (Illustration 3).
6. Disconnect the cassette from the pump.
7. Connect the connector (blue) to the intestinal tube port of the PEG-J (Illustration 4).
8. Use a flushing syringe with at least 40ml drinking water (Illustration 4).
9. At least once a week, also flush the short PEG-J tube with about 40 ml drinking water.
10. Make sure you close the lid after washing.
11. Throw away the used cassette

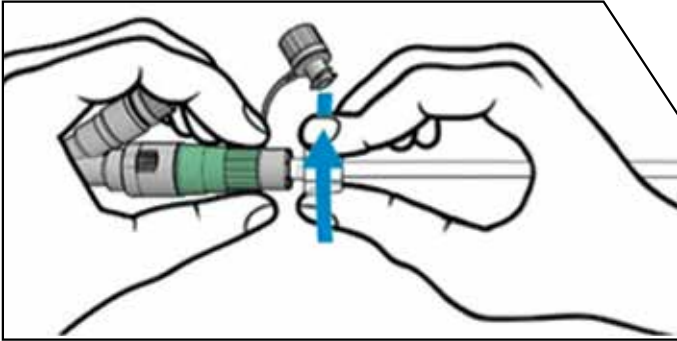


Illustration 2

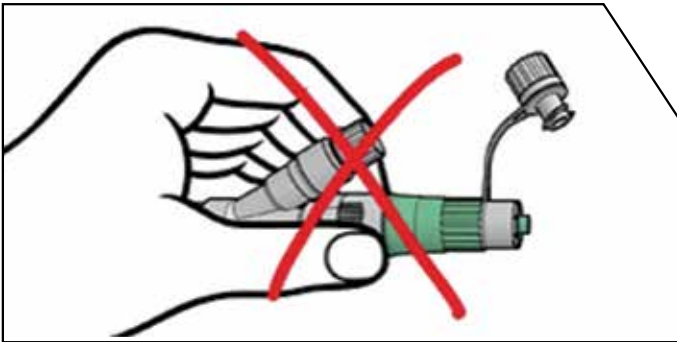


Illustration 3

Do not connect the cassette to the gastric tube port

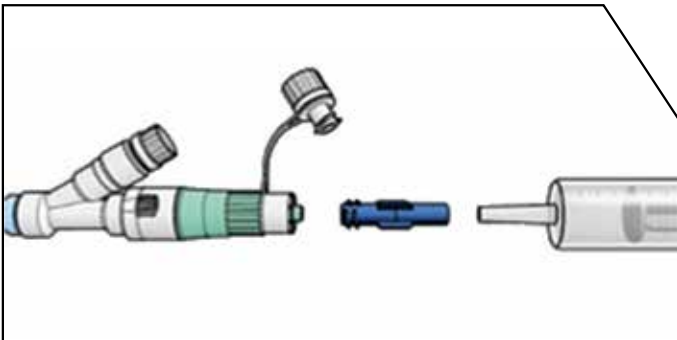


Illustration 4

Procedure for treating the PEG port

Before the PEG procedure, notify the healthcare team if you underwent procedures related to the gut or the digestive system and other gastric problems. Talk to the healthcare team regarding the procedure for treating the PEG port. After the procedure, the patient and the healthcare team both should regularly inspect the PEG port for any signs of contamination.

Mobilizing the tube to prevent Buried Bumper Syndrome

After the initial healing of the wound, this procedure should be performed every two or three days. There is no longer need for daily bandaging.

1. If using bandages, remove the bandage and release the external holding plate (triangle-shaped) in order to allow free movement of the PEG-J tube.
2. Push the tube carefully 3-4 cm into the gut and gently pull back until you feel resistance from the inner holding place.
3. Do not twist the tube (Illustration 5).
4. Report to your doctor on any signs that testify on complications such as: red or bruised skin, wounds, emissions, pain or itching.
5. Replace the holding plate to allow free movement of 5-71 mm. Place Y bandage. Band-Aid fixing is recommended for patients who wiggle a lot (Illustration 6).

Daily procedure

Flush the gap between the intestinal tube and the PEG tube after it is used for feeding (in case of combined feeding PEG), or at least once a week with 40 ml drinking water, and once a day after every feeding taking place through the side connector. (Illustration 7)

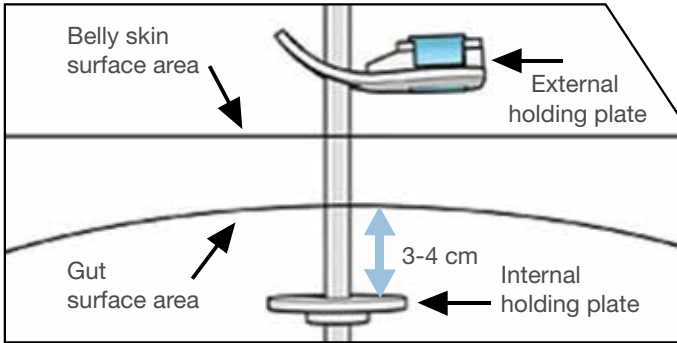


Illustration 5

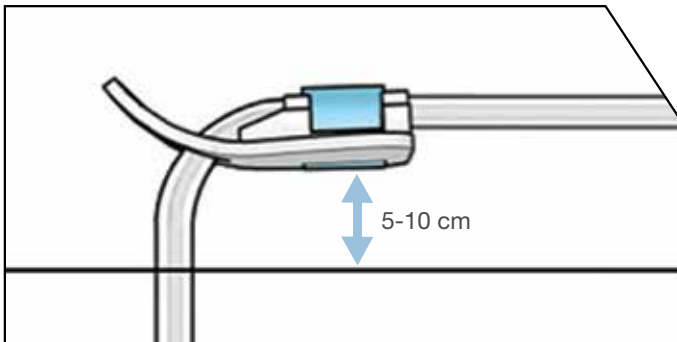


Illustration 6

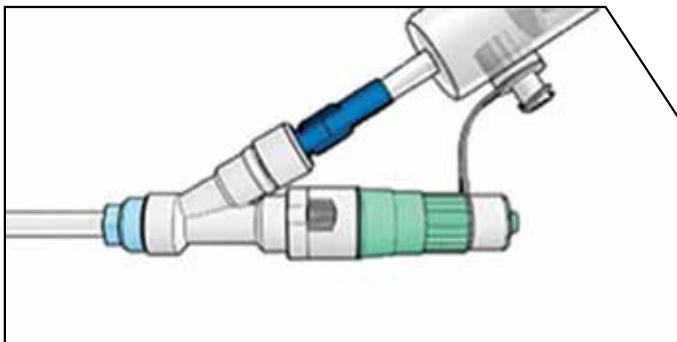


Illustration 7

Important Information

Duodopa, levodopa 20 mg/ml + carbidopa monohydrate 5 mg/ml, intestinal gel

Read the information presented below carefully before starting to take this medication.

Consult with your doctor, pharmacist or nurse if you have further questions. Additional information can also be found in the consumer's leaflet.

This medication is issued with prescription intended for you. Do not give it to others. It may harm them, even if their symptoms are similar to yours.

Consult with your doctor, pharmacist or nurse if you experience any side effects. These side effects may also include those not listed in the consumer's leaflet or this manual.

Twisting, knots or clogs in the PEG-J tube may worsen your Parkinson's disease symptoms or the recurrence of movement problems (motor fluctuations). Consult with your doctor or nurse if your Parkinson's disease symptoms aggravate or if your movements are slow when you are treated with Duodopa.

Driving and using machinery

You may not drive or use tools or machinery before you make sure how Duodopa affects you.

Duodopa may cause you to be very sleepy, or sometimes you may suddenly fall asleep (sleep episodes).

Duodopa may lower your blood pressure, making you dizzy.

Do not drive or use machinery or tools until you feel once again fully alert or the dizziness passes.

If you took a higher dose

If you accidentally took a higher dose or overdose of Duodopa, immediately turn to your doctor or a hospital ER and bring a package of the medication with you.

In such cases, the following may occur: troubles opening your eyes; involuntary muscle spasms that affect the eyes, head, neck and body (dystonia); involuntary movements (dyskinesia); fast, slow, or extremely irregular heartbeats (arrhythmia).

If you forgot to take Duodopa[®]

Turn on your pump with your regular dose as soon as possible. Do not increase the dose to compensate a forgotten dose.

If you stopped taking Duodopa[®] or reduced the dose

Do not stop the treatment or lower the Duodopa dose unless your doctor instructed you to do so, as sudden termination or fast decrease of the Duodopa dose may cause a serious phenomenon called “Neuroleptic Malignant Syndrome”. The signs of this phenomenon may include:

- Fast heartbeat, change in blood pressure and sweating accompanied by fever
- Accelerated breathing, muscle rigidity, low consciousness and coma
- High levels of protein in your blood (an enzyme called “keratin phosphokinase”). This enzyme is measured by your doctor

The odds for occurrence of this phenomenon increase if you also take anti-psychotic drugs. Consult with your doctor, pharmacist or nurse if you have further questions about the product.

How to Store Duodopa®

Keep the cassettes with the gel away from the reach and sight of children and/or babies.

Do not use Duodopa after the expiration date indicated on the cardboard label after the word “EXP”.

Store in the refrigerator (temperature between 2°C to 8°C).

Keep the cassette in the external box to protect it from light.

A gel cassette may be used up to 16 hours after it was removed from the refrigerator. Once opened, use it immediately. Discard remaining medication.

The medication cassettes are intended for single use alone and should not be used for over 16 hours, even if a small amount of gel remains.

Do not reuse an opened cassette.

The gel may turn slightly yellowish - this has no effect on the medication.

How to discard Duodopa®

Do not throw any medication to the domestic garbage grinder or bin.

Consult with your pharmacist on how to discard unused medication.

These means will help protect the environment.

Do not reuse cassettes.

Information about the Pump

Precautions

Water and fluids may damage the pump.

Always disconnect the pump before washing or taking a bath.

Travelling

Preplan your trip when you want to travel. Consult your Duodopa contact nurse if you have any questions. Make sure that the stoma has properly healed before travelling. Consult with your doctor in case of doubt.

Pre-plan the trip sufficient time in advance.

Make sure you have enough cool-packs for the ride and that the destination has a refrigerator for the Duodopa cassettes.

You should take the following:

1. Duodopa prescription (copy)
2. Sufficient amount of Duodopa medication
3. Treatment certificate
4. Patient's manual for operating the pump
5. Oral medicines in case of need and according to your doctor's instructions
6. Back-up pump (if travelling abroad)
7. Connectors (blue)
8. 20 ml syringes
9. Backup AA batteries
10. Bandages for the stoma
11. This Duodopa user manual

The table below includes some of the common alerts you may hear from your pump. When an alert is heard, read the writing on the screen before pressing.

Screen	Alert	Cause	Action
ERROR	Two-tone alert sound	An error has occurred	Contact the hospital/ clinical department; the pump needs to return to AbbVie for repair.
NO MESSAGE	Two-tone alert sound	Batteries were removed while the pump is on. The pump stopped and is not working. or the batteries were removed within about 15 seconds after stopping the pump.	Install batteries in order to silence the alert.
HIGH PRESSURE	Two-tone alert sound	The pump has identified high pressure, that may be caused by clogging in the direction of the bloodstream, bend in the tube or closed clamp on the tube.	remove the blockage to renew the action. or Press “NEXT” or “START/STOP” to stop the pump action and silence the alert for two minutes. Remove the clogging and reactivate your pump.
RunResVol Low	Three single signals	Cassette volume low.	Replace cassette immediately.

Screen	Alert	Cause	Action
NO DISPOSABLE, PUMP WILL NOT RUN	Two-tone alert sound	You tried starting the pump without connecting the cassette properly. Connect the cassette properly in order for the pump to work.	Press “STOP/ START” or “NEXT” to stop alert sound. Connect the cassette properly and press “STOP/ START” to restart the pump.
RESERVOIR VOLUME EMPTY	Two-tone alert sound	The reservoir volume has reached 0.0ml.	Press “STOP/ START” or “NEXT” to stop to silence the alert. Replace a new cassette if needed and restart the reservoir volume.
LowBat	Three alert sound with two beeping tones every five minutes	The battery is low, but your pump is still working.	Replace batteries without delay. Press and hold the “STOP/ START” button to restart the pump.
VALUE NOT SAVED	No alert	Input value not saved, that is, the “FEED/CLEAN” button was not pressed.	Press “NEXT” in order to renew programming. Save the value before moving to the next software window or before operating the pump.

Additional Information

Technical data for your pump

- Do not operate the pump at temperatures below 2°C or above 40°C.
- Do not store the pump at temperatures below -20°C or above 60°C.
- Do not immerse the pump in detergent or water, or allow fluid to be sucked into the pump, cumulate on the keypad or enter the batteries chamber.
- Use ordinary soap solution when cleaning the pump.
- Do not clear the pump with acetone, other plastic dissolvents or corrosive detergents.

Possible Side Effects

The following very common complications were reported for the medicine administration tube system:

- Leaks in the connectors and leaks of gastric fluid
- Duodopa flow stoppage due to clogging, bending and ties in the tube
- Displacement of the tube (for example, to the gut, which leads to reduced reaction to the treatment)
- Local inflammation around the place in which the tube enters the gut area (the PEG port), peritonitis, puncturing nearby organs, bleeding and stomach aches, specifically during tube placement

If you experience severe side effects or if you notice any side effects not listed here, notify your doctor as soon as possible.

Side effects of using the pump or tube:

The following side effects were reported for the pump and tube.

Contact your doctor if you experience any of these side effects.

- In case you experience decreased ability to operate the pump and tube, in case the Parkinson's disease symptoms aggravate or you find it harder to move (bradykinesia) - these phenomena might indicate that the pump and tube are not working properly.
- If you feel abdominal pain, sickness and vomiting - contact your doctor immediately, you may have a problem with the pump or tube.

Very common side effects (may affect more than 1 out of 10 people):

- Abdominal pain
- Inflammation where the tube enters the belly - caused by the operation
- Thickening of the scar where the tube enters the belly
- Problems caused by the tube placement - pain or swelling in the mouth or throat, difficulty swallowing, gastric inconvenience, pain or swelling, injury to the throat, mouth or stomach, bleeding, vomiting, passing gas, anxiety.
- Problems in the area where the tube enters the belly, red or bruised skin, wounds, discharge, pain or itching

Common side effects (may affect up to 1 out of 10 people):

- Inflammation in the stoma area, inflammation after the procedure for entering the tube to the intestine
- Inflammation in the gut wall
- Inflammation in the intestine or the area in which the tube enters the belly
- Free movement of the tube in the intestine or clogging - which may cause less medicine to be absorbed

Uncommon side effects (may affect up to 1 out of 111 people):

- Large intestine inflammation (colitis)
- Pancreatic inflammation
- Penetration of the tube through the large intestine wall
- Clogging, bleeding or sores in the intestine
- Folding part of the intestine into another adjacent part (intussusception)
- Clogging the tube due to food being stuck around the tube
- Abscess - may occur after the procedure for entering the tube into the gut

Side effect with unknown incidence:

- Decreased blood flow in the small intestine
- Penetration of the tube into the gut wall or small intestine

Please review the consumer's leaflet for the full list of all side effects that may occur while using Duodopa.



Levodopa 20mg/ml, Carbidopa 5mg/ml Intestinal Gel

Manufacturer

Fresenius Kabi Norge AS
Svinesundsveien 80
NO-1788 Halden
Norway

Local representative

This medical product is approved for use in EEA member countries under the name: Duodopa.

This material was developed by AbbVie, Inc.
as part of the risk minimizing plan for the intestinal gel levodopa/carbidopa.
Version no.: 7.2, March 13, 2017.

AbbVie AG

abbvie