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Duodopa's Guide for Health Care Givers

Duodopa User's Guide

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1. Duodopa

This chapter contains information about the Duodopa treatment system. Product specifications are followed by descriptions of testing the nasointestinal tube and permanent treatment using the PEG.

For a complete description on how to handle the pump, please use the operator manual.

1.1 Introduction

Traditional medication

Parkinson's disease is a chronic disease. During the first few years symptoms may disappear or be relieved by L-dopa in tablet form. However, as the disease progresses, achieving satisfactory treatment by tablets may be complicated and difficult to control the symptoms. The irregular emptying of the stomach through its orifice makes the medicine absorption in the bowel uneven. To eliminate this factor, medication may be administered through a tube directly to the small intestine, where L-dopa is absorbed. This ensures a more even and reliable supply of medication.

Duodopa

Duodopa is an L-dopa suspension manufactured and distributed by Solvay Pharma. The purpose with Duodopa treatment is to achieve stable plasma levels of levodopa by administering it through a pump directly to the small intestine via a tube.

The indication for Duodopa is advanced levodopa-responsive Parkinson's disease with severe motor fluctuations and hyper-/dyskinesia when available combinations of Parkinson medicinal products have not given satisfactory results. The treatment of Parkinson's disease using Duodopa intraduodenally started around 1990. Patients treated this way have improved. The treatment may be given to those when available combinations of Parkinson's medicinal products have not given satisfactory results.

1.2 Product specification

Contents

Duodopa contains the following:

- Levodopa (L-dopa) 20 mg/ml
- Carbidopa 5 mg/ml
- Thickening agent (Carmellose sodium)
- Water

A 100 ml cassette contains 2000 mg of L-dopa and 500 mg of carbidopa.
(1 ml contains 20 mg L-dopa and 5 mg carbidopa).

Shelf-life

Duodopa has the following shelf-life:

- 15 weeks in refrigerator

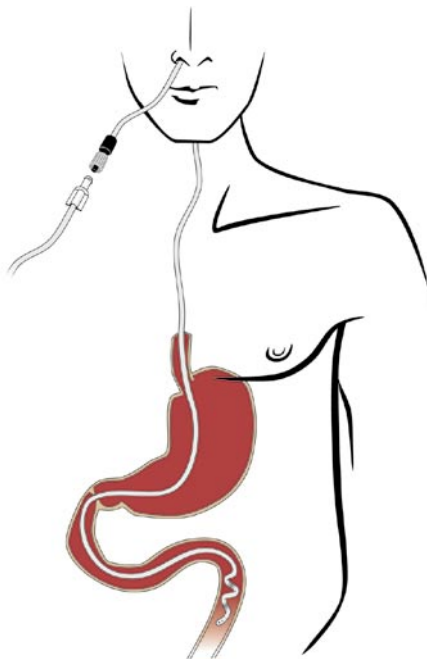
Once out of the refrigerator Duodopa must be used immediately within the first 24 hours. After this period of time, the active ingredients suffer natural degradation. A typical signal of degradation is an altered colour of the Duodopa gel.

1.3 Test treatment

Introduction

In order to test the impact of Duodopa on a patient, a nasointestinal tube is usually used for a test period of one week.

The nasointestinal tube is inserted with the help of x-ray or gastroscope, or simply by a passive passage from the stomach to the duodenum. The technic used for the placement of the tube depends on the experience of the medical doctor and the capacity of the medical center where it will be performed.



Advantages of having an 1-week test using the nasointestinal tube:

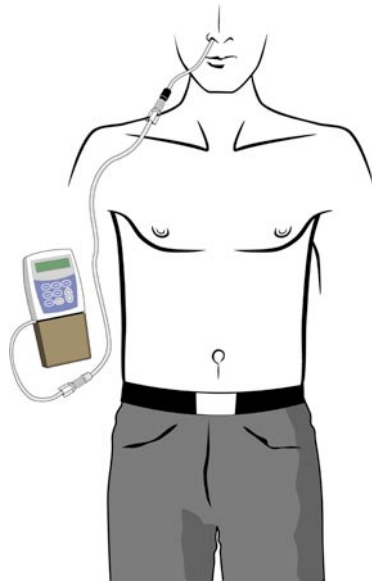
- Only a medical procedure is needed
- The patient can discontinue the medication without problems if necessary

The following section contains information about components, tube insertion tube taping, and how to start the test treatment for the first time.

*How to handle the pump and its functions is described in 2.
The pump – functions and operation on page 19.*

1.3.1 Components

The following picture shows the pump, the cassette and the extension tube connected to the nasointestinal tube.



Please note that:

- *an extension tube is needed between the pump and the nasointestinal tube. The extension tube is normally 50 cm long.*



The components hold the following amount of Duodopa:

Component	Volume of Duodopa
Extension tube 50 cm (Connecta)	4 ml
Benchmark nasointestinal tube Ch10	7 ml

1.3.2 Inserting the tube

Before inserting the tube

Preparations one week before inserting the tube:

Step	Action
1	Write a referral to X-ray with contrast or gastroscopy. Make sure there is an appointment for this when the patient is admitted to the ward. <i>See example 7.1 Referral - Nasointestinal setting of tube on page 55.</i>
2	Check that all materials are in place: <ul style="list-style-type: none">• Nasointestinal kit (Kit 1)<ul style="list-style-type: none">• Nasointestinal tube (Bengmark Ch 10)• Extension tube 50 cm• CADD-Legacy Duodopa pump. Batteries (AA)• Extra Luer Lock• Duodopa
3	How to order Duodopa: <ul style="list-style-type: none">• Calculate the approximate daily consumption <i>See 3.1 Calculating dosage on page 41.</i>• Order two weeks' supply of medicine (1 cassette/day = 2 boxes of 7 cassettes each)

Inserting the tube

It is recommended to give the patient his/her current/normal antiparkinsonian medicines in the morning and until inserting the tube, even if they are on an empty stomach. There are three alternative ways of inserting the tube:

1. X-ray technician inserts the tube to the small intestine with the help of fluoroscopy.
2. Insert the tube into the stomach on the ward just like a regular gastric tube.
Remember to insert an extra 20-30 cm to make sure the tube reaches all the way to the intestine. Get an X-ray after 4-6 hours or the day after to determine the location of the tip of the tube. The tube has a tendency to follow the peristalsis into the intestine. Verify the position with X-ray and contrast.
3. A gastrologist inserts the tube with the help of a gastroscope into the small intestine. Verify the position with X-ray and contrast.

After the insertion of the tube

When the tube is in place in the small intestine (refer to statement from X-ray/gastroenterologist) it can be used for the first time.




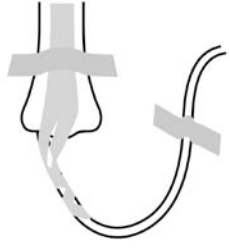
It is important to fix the tube by taping it immediately after the patient gets back from X-ray to the ward.

See 1.3.3 Taping on page 9 for instructions on taping and fixing.

1.3.3 Taping the nasointestinal tube

Fixing

The table below describes how to fix the nasointestinal tube using tape.

Step	Action
1	Cut a 1 cm wide piece of tape into the shape of a pair of trousers. 
2	Wash the skin.
3	Tape over nose and bind one of the strips around the tube. 
4	Bind the other strip around the tube. Tape across the nose. 
5	Place the tube so that it easily rests against the cheek. Fix in place with tape. Possibly also tape the tube behind the ear for better support. 

1.3.4 Starting test treatment

Check that medicine, pump and tubes are in place and that the dose is calculated

Morning

It is easiest to start treatment with the morning dose the morning after the tube insertion in order to get into the routine and not to have to reprogram the pump.

Preparations:

- Check the x-ray to make sure the tip of the tube is in the small bowel.
- Calculate and set the morning dose and continuous dose on the pump.

See 2.5 Dose change on page 24 and onwards.

- Set the extra dose to 1 ml.

See 2.6 Set/change preset extra dose on page 25.



CAUTION!


The nasointestinal tube holds 7 ml and that must be added to the morning dose when it is filled with Duodopa the first morning.
Example: the patient is to have 80 mg of L-dopa => 4 ml + 7 ml = 11 ml for the morning dose.



CAUTION!

It might happen that the pump shows "high pressure". That might be because of cold and slow-flowing medicine.


Connect and start the pump:

Step	Action
1	Attach the pump to the cassette. <i>See 2.9 Attach the cassette on page 28.</i>
2	Connect the cassette to an extension tube (50 cm).
3	Start the pump and fill the extension tube with Duodopa using the "prime" function. <i>See 2.8 The Prime function on page 27.</i>
4	Connect the extension tube to the nasointestinal tube. 
5	Administer the morning dose. <i>See 2.2 Start the pump and administer the morning dose on page 21.</i> Remember to decrease the morning dose with the same amount that the nasointestinal tube holds (7 ml) for the following morning, as the tube is not rinsed and thus contains medicine.

Evening

The nasointestinal tube now holds 7 ml of Duodopa, and should not be rinsed in the evening.

How to shut down the system for the night:

Step	Action
1	Stop the pump: <ul style="list-style-type: none">Press the key STOP/START and hold it down for three seconds until the three dashes are displayed. The text STOPPED is shown in the display.
2	Press the key ON/OFF and hold it down until three dashes appear (•••• •••• ••••) in the display. The pump is stopped.
3	Disconnect the extension tube from the nasointestinal tube and put on a Luer lock.  The nasointestinal tube is plugged with a Luer Lock during the night.
4	Unscrew the extension tube from the used cassette and connect a new cassette for the next day. Put a cap on the tube to prevent leakage. Put the new cassette and the extension tube to the refrigerator.
5	Remove the old cassette from the pump and discard it back to the pharmacy.

1.4 Permanent treatment

When it has been decided that the patient will continue Duodopa treatment, a tube is inserted into the stomach (PEG) with the help of a gastroscope. An "inner tube" is put through the tube (PEG) and led through the stomach orifice into the small intestine.

This chapter describes actions to take before operation, PEG operation, the tube system, how to dress the stoma, and the daily care of the tube wound.

1.4.1 PEG tube

Before PEG surgery

Follow hospital routines during insertion of PEG. Example: fasting, premedication, venflon.

Send the PEG and inner tube with the patient to the gastro clinic.

PEG operation

The PEG tube is operated according to normal procedures according to the suppliers instructions, and the inner tube is led down into the small intestine with the help of the gastroscope.

More information about the PEG operation can be found in 5.1 Guidelines for PEG operation on page 49 and in the film "Inserting the PEG with inner tube for administering Duodopa".

Post-operative care and maintenance of the PEG

The dressed wound should be inspected to make sure that there is no bleeding or leakage. If there is, the bandage should be replaced.

Tension

A mild tension should be applied to the PEG some time after the operation to prevent the PEG from moving around in the surgery wound, and to prevent leakage that may cause peritonitis.

Check the tension as follows:

- Pull the PEG until you feel a mild resistance. If the tension is too tight there is a risk of tissue damage.
- Move the outer stop plate 2 mm clear of the skin and lock it.

Dressing the wound

Daily dressing of the tube wound is necessary the first three weeks after surgery.

See 1.4.3 Dressing stoma on page 15.

Cleaning

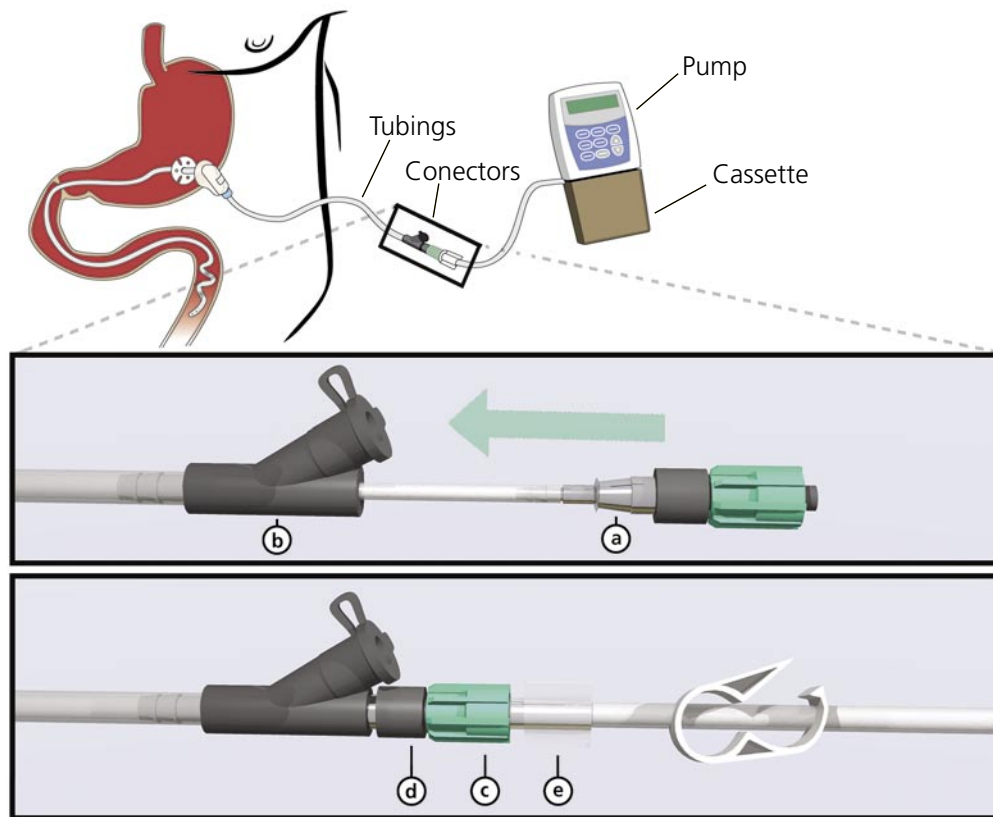
One or two weeks after the operation, the stop plate may be fixed 2 cm from the skin when the wound has healed. The tube orifice should be cleaned with soap and water during showers/baths. Make sure the skin is dried afterwards.

Measures in case of complications

Complication	Action
The tube wound is inflamed.	Rub on water-repellent salva.
The tube wound is infected.	Use NaCl (Saline 9 mg/ml) and cotton balls to clean it, once or twice daily. In complicated cases, a bacteria culture may be taken. Treat with antibiotics if there is no improvement.

1.4.2 The parts of the tube system

The tube system consists of a PEG and an inner tube fixed to the outer connections and leading through the PEG into the stomach and in to the small intestine.



The connections are attached to the PEG and inner tube.

To connect:

Step	Action
1	Insert connector (a) into part (b) ; stop pushing when you feel a click.
2	Insert the distal part of the tube cassette – tube (e) - into (d) and screw (c) into place.

To disconnect:

Unscrew part (c) and carefully turn part (e) anticlockwise for ¼ of a turn, then pull of the tube.





CAUTION!

Always be cautious when you handle the connections to change the cassette.

If you pull too hard you may disconnect the grey connector so that the inner tube may lose its position in the small intestine or move all the way into the intestinal canal.

1.4.3 Dressing stoma

How to dress the wound

Step	Action
1	Open the clamp on the stop plate and make the PEG free from the plate. 
2	Make clean: <ul style="list-style-type: none">• Pull the plate up.• Remove the old compress. Clean the tube wound using saline (isoton NaCl 9 mg/ml) and sterile cotton balls.• Clean the plate on both sides.• Put a new sterile compress around the stoma orifice and attach with plaster.
3	Put the plate back and pull lightly on the tube so that there is a mild tension. Fix the tube onto the plate.
4	Close the tube clamp. 

1.4.4 Starting permanent treatment

Follow these steps when starting Duodopa treatment for the first time after the PEG operation:

Step	Action
1	<p>Check x-ray with contrast in order to verify that the tip of the tube is in right position after surgery i.e. IN THE DISTAL PART OF THE DUODENUM PREFERABLY NEAR THE TREITZ LIGAMENT TO REDUCE THE RISK OF DISLOCATION TO THE STOMACH.</p> <p>The experience has shown that the tip could also be placed just beyond the Treitz ligament, in the proximal jejunum, so that the tube will better stay in place. Available knowledge indicates that the absorption of levodopa does not differ at any site in the upper small intestine, including duodenum and the upper part of jejunum.</p>
2	<p>Set morning dose, continuous dose and extra dose on the pump.</p> <p><i>See 2.5 Dose change on page 24 and onwards.</i></p>
3	<p>Attach the pump to the cassette.</p> <p><i>See 2.9 Attach the cassette on page 28.</i></p>
4	<p>Attach the cassette to the PEG tube.</p>
5	<p>Fill the PEG tube and start the pump.</p> <p><i>See 2.7 Filling the PEG tube on page 26.</i></p>
6	<p>When the system is disconnected for the night, a three-way tap or female-female connection is attached to the tube. The tube is rinsed with drinking-water.</p> <p><i>See 2.4 How to stop the pump in the evening on page 23.</i></p>

1.4.5 First morning after surgery

Reprogramme the pump and add 3 ml to the calculated morning dose during the nasointestinal period.

See 2.3 chapter Changing the morning dose on page 22.

Explanation: 3 ml is to fill up the inner tube in the patient intestines every morning.

1.5 Daily routines

Morning dose

Morning dose of Duodopa is administered when the patient wakes up in order to quickly achieve the concentration required for optimal patient response. The morning dose should result in satisfactory mobility within one hour.

Instructions: 2.2 Start the pump and administer the morning dose on page 21.

Continuous maintenance dose

The dose administered continuously by the pump should maintain a constant concentration at the level of mobility achieved by the morning dose.

Extra doses

Extra doses may be administered if the patient experiences reduced mobility during the day. The amount of the extra dose is manually set. It usually (but can be higher) varies between 10-40 mg/occasion (meaning 0.5 ml – 2.0 ml) and is normally determined during the test period.

Instructions: 2.6 Extra doses on page 25.

Dose escalation increments

If the need for extra doses exceeds 4-5 times/day the continuous rate of the pump should be increased, as long as there is no dyskinesia. Dose escalation increments of 0.1-0.5 ml/hour (meaning 2 mg – 10 mg) should be adequate.

In case of dyskinesia

If there is intense dyskinesia the pump may be shut off for around 5-15 minutes or until the patient senses that the dyskinesia is wearing off. If problems with intense dyskinesia occur several times, the rate of the pump should be decreased.

Instructions: 2.5 Dose change on page 24.

Evening

Duodopa infusion is suspended when the patient goes to bed. During permanent treatment the tube is rinsed with around 20-40 ml regular drinking-water to prevent the medication from coagulating in the tube causing an obstruction easiest by using a 10 ml syringe.



Caution!

During test treatment (nasointestinal period) the tube is not rinsed.

The cassettes is for one-day use, (16 hours).

Instructions: 2.4 How to stop the pump in the evening on page 23.

1.6 Assessment

Dose and treatment

To evaluate the dose and treatment, mobility measurement using an ON-OFF diagram may be used.

See 4.1 Measuring mobility on page 46.

Pump

Use the training program for the pump to ensure that the patient or treating nurse/relative/friend can manage the pump and its functions properly.

See 2.14 Training program for the pump on page 39.

2. The pump – functions and operations

Introduction

This chapter contains information about the pump used in Duodopa treatment. Status modes, instructions for the pump, an alarm and troubleshooting guide and a training program for the pump is included.

2.1 Status modes

The display of the pump shows various status modes and set values for the pump.

Status (display text)	Explanation
STOPPED	The pump is on but does not administer an infusion.
Run	The pump is on and administers the set dose xx.x [ml/hour].
Reservoir volume	<p>If activated, the display shows the amount [ml] of Duodopa remaining in the cassette. Must be reset at each cassette replacement.</p> <ul style="list-style-type: none">• Set the amount of Duodopa [ml] in the cassette• Remaining volume is then decreased as the medicine is used up. You will then be able to see how much is left in the cassette and when it is time to replace it. <p><i>Note: Replacement is only required if you use more than one cassette per day.</i></p> <ul style="list-style-type: none">• If the function is not used it will say "Reservoir volume not used" in the pump display.
Continuous Rate	Shows the continuous infusion rate. Should be set to the prescribed continuous maintenance dose [ml/hour].
Extra dose	Shows the set extra dose amount. It is activated by pressing the key EXTRA DOSE .
Given	<p>Shows how many ml the pump has administered to the patient.</p> <p><i>Note: The volume administered by the function Prime is not included.</i></p>
Morning dose	The amount administered when activating the morning dose.
INFUSION	Shows that the extra dose is activated and is being administered.

ON/OFF

The key **ON/OFF** is used to switch the pump on or off.

How to switch the pump on:

- Press the key **ON/OFF** and hold it down for three seconds.

The pump runs the programs and set values. This takes appr. 30 seconds. The text **STOPPED** is shown in the display. This means the pump is shut off and not emitting any infusion.

How to switch the pump off:

- Press the key **ON/OFF** and hold it down until three dots appear (•••• •••• ••••) in the display.

Start/Stop

The pump is started or stopped during cassette or battery replacement.

How to start the pump:

- Press the key **STOP/START** and hold it down for three seconds until the three dashes in the display disappear.

How to stop the pump:

- Press the key **STOP/START** and hold it down for three seconds until the three dashes appear in the display.

2.2 Start the pump and administer the morning dose


Administer the morning dose

How to administer the morning dose:

Step	Action
1	<p>Switch on the pump:</p> <ul style="list-style-type: none">• Press the key ON/OFF and hold it down for three seconds. <p>The pump runs the program and displays the set values. This takes appr. 30 seconds.</p> <ul style="list-style-type: none">• The text STOPPED is shown in the display. This means the pump is on but not pumping an infusion.
2	<ul style="list-style-type: none">• Press the key STOP/START and hold it down for three seconds until the three dashes in the display disappear. <p>The pump runs through the preset values again. This takes appr. 15 seconds.</p> <ul style="list-style-type: none">• The text RUN is shown in the display. This means the pump is running and administering the continuous dose.
3	<ul style="list-style-type: none">• Press the key MORNING DOSE (one push). <p>The set morning dose is shown in the display.</p> <p><i>Note: If the text LL0 is shown in the display instead this means the pump is not running. Action: press the key NEXT and go back to step 2.</i></p>
4	<ul style="list-style-type: none">• Press the key MORNING DOSE again. <p>The display shows a count down.</p> <p>The pump now administers the set morning dose and after few minutes it automatically goes on to the continuous dose (the infusion rate of morning dose is about 1 ml / min).</p>
5	<ul style="list-style-type: none">• Be sure that the pump is in “RUN” position during the day while delivering the continuous dose.

2.3 Changing the morning dose

How to change the morning dose:

Step	Action
1	Switch on the pump: <ul style="list-style-type: none"> Press the key ON/OFF and hold it down for three seconds
2	Press the key STOP/START and hold it down for three seconds until the three dashes in the display disappear.
3	<ul style="list-style-type: none"> Press the key MORNING DOSE (one push) <p>The set morning dose is shown in the display.</p> <p><i>Note: If the text LL0 is shown in the display instead this means the pump is not running. Action: press the key NEXT and go back to step 2.</i></p>
4	How to change the morning dose: <ul style="list-style-type: none"> Press the arrow keys to change the dose  <ul style="list-style-type: none"> Press the key ENTER/CLEAR to confirm the change <p>Go to step 5 if you want to administer the newly changed morning dose.</p>
5	<ul style="list-style-type: none"> Press the key MORNING DOSE again <p>The pump now administers the newly set morning dose and after that automatically goes on to the continuous dose.</p>



CAUTION!

Be aware that the morning dose will normally be locked for 20 hours.

If there is a need to change the morning dose within the 20 hours see in Biomed Toolbox – 2.12 Change the setting p. 33.

2.4 How to stop the pump in the evening


Evening

How to stop the pump in the evening:

Step	Action
1	Stop the pump: <ul style="list-style-type: none">• Press the key STOP/START and hold it down for three seconds until the three dashes are displayed (•••• •••• ••••). The text STOPPED is shown in the display.
2	<ul style="list-style-type: none">• Press the key ON/OFF and hold it down until three dashes (•••• •••• ••••) appear in the display. The pump is now switched off and there is no need to remove the battery.
3	For permanent treatment (PEG): <ul style="list-style-type: none">• Disconnect the PEG from the cassette.• Connect a three-way tap or female-female connection to the tube and rinse with drinking-water (cold or tepid) with a syringe.• It is normal for the first few millimetres to be sluggish to rinse, but after that there is less resistance.• When rinsed, put a cap on the tube to prevent leakage during the night. During test treatment (nasointestinal period): <ul style="list-style-type: none">• Disconnect the extension tube from the nasointestinal tube and unscrew the extension tube from the used cassette and connect it to a new cassette for the next day. Put a cap on the tube to prevent leakage. Put the new cassette and the extension tube to the refrigerator. <i>Note! The tube going to the intestine holds 7 ml of Duodopa and should not be rinsed during test treatment.</i>
4	Remove the cassette from the pump.

2.5 Change continuous rate (dose change)

How to change the maintenance continuous infusion rate:

Step	Action
1	<p>The pump must be stopped to be reprogrammed.</p> <p>Stop the pump:</p> <ul style="list-style-type: none">Press the key STOP/START and hold it down for three seconds until the three dashes are displayed (•••• •••• ••••). <p>The text STOPPED is shown in the display.</p>
2	<p>Press the key NEXT repeatedly until the rate function is displayed: CONT. RATE ML/H</p>
3	<p>Change the rate using the arrow buttons.</p>  <p><i>If the pump rate won't change there may be a lock level set (LL1 or LL2), see 2.11 Lock levels on page 31.</i></p>
4	<p>Press the key ENTER/CLEAR to confirm.</p>
5	<p>To start the pump:</p> <ul style="list-style-type: none">Press the key STOP/START for three seconds until the three dashes (--- --- ---) disappear from the pump display.


2.6 Extra doses

Extra dose (preset)

Press the key **EXTRA DOSE**. The pump administers the preset dose and then proceeds to administer continuous dosage.


Set/change preset extra dose

How to set or change a preset extra dose:

Step	Action
1	Stop the pump: <ul style="list-style-type: none">• Press the key STOP/START and hold it down for three seconds until the three dashes are displayed (•••• •••• ••••). The text STOPPED is shown in the display.
2	Press the key NEXT repeatedly until the text EXTRA DOSE [X.X ML] is shown in the display.
3	Change the dose using the arrow keys.  The extra dose is increased or decreased.
4	Press the key ENTER/CLEAR to confirm the change. To start the pump: <ul style="list-style-type: none">• Press the key STOP/START and hold it down for three seconds until the three dashes disappear.

2.7 Filling the PEG tube (after surgery)

EXTRA DOSE is used to fill the PEG tube when permanent treatment is started.

Step	Action
1	Stop the pump: <ul style="list-style-type: none">• Press the key ON/OFF and hold it down for three seconds. The text STOPPED is shown in the display.
2	Press the key NEXT repeatedly until the text Extra dose [x.x ml] is shown in the display.
3	Change to the desired dose using the arrow keys. (3 ml to fill the tube + extra dose if needed).  The dose is increased or decreased.
4	Confirm the dose change by pressing ENTER/CLEAR .
5	Press the key STOP/START and hold it down for three seconds until the three dashes disappear.
6	Press the key EXTRA DOSE . The tube is filled.
7	Reset the pump to regular extra dose according to steps 1-4.

2.8 The Prime function for filling extension tube

Prime tube

Prime is used to fill extension tubes with medication:

Step	Action
1	<p>The pump must be stopped to be reprogrammed.</p> <p>Stop the pump:</p> <ul style="list-style-type: none">• Press the key STOP/START and hold it down for three seconds until the three dashes are displayed. <p>The text STOPPED is shown in the display.</p>
2	<p>Press the key PRIME and hold it down for three seconds until the three dashes are displayed. Release the button.</p>
3	<p>Press PRIME.</p> <p>The priming will stop after 10 double buzzes.</p> <p>Hold and release the button in repeatable manner until the tube is filled.</p> <p>One buzz = 0.05 ml.</p> <p>The pump sounds two buzzes/fill => $0.05 \times 2 = 0.10$ ml.</p>

2.9 Replacing the medication cassette

The medication cassette is attached in the morning and detached in the evening.

If one cassette a day is not enough, the first one must be replaced before it is completely empty. The effect of the medication may decrease when the cassette is almost empty. When the bag starts to look transparent and flat a change of cassette is recommended.



Note: The function “reservoir volume” can be used to make the pump issue an alarm when the cassette is running low. See 2.1 The pump – functions and operation on page 19.






WARNING!

It is absolutely essential that the cassette is properly attached, or the pump mechanism may not work.

Attach the cassette

Step	Action
1	Attach the cassette to the pump by fitting the hooks of the cassette onto the pivot pins at the pump's base. 
2	<ul style="list-style-type: none">• Place the pump on a level surface.• Hold the cassette steadily and put a coin in the slot of the lock knob.
3	Lock the cassette by pushing the coin or the Duodopa key and turning it 90 degrees counter-clockwise until it stops. 

How to detach the medication cassette

Step	Action
1	Place the pump with the cassette upright on a level hard surface.
2	<p>Put a coin or the Duodopa key in the slot of the lock knob and turn 90 degrees clockwise.</p>  <p>The lock knob will pop out slightly when the cassette is unlocked.</p> 
3	<ul style="list-style-type: none"> • 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. 

2.10 Replacing batteries

Ordinary alkaline batteries, non- rechargeable of the type LR6/AA should be used. The batteries of the pump must be replaced regularly. An alarm will warn when the battery level is too low.

Step	Action
1	Stop the pump: Press the key STOP/START and hold it down for three seconds until the three dashes are displayed. The text STOPPED is shown in the display.
2	<ul style="list-style-type: none">• Remove the batteries• Put in new batteries Wait until it says Stopped in the display.
3	Start the pump if required.



CAUTION!
Rechargeable batteries are not recommended. Alarm for "battery low" does not function together with rechargeable batteries.

2.11 Lock levels

Using lock levels, you are able to limit the access to certain programming and operating functions. The pump can be set to three lock levels, LL0, LL1 and LL2.

Lock level	Explanation
Lock level 0 (LL0)	At this lock level you can change all the settings of the pump. <i>Note: To change the time lock and the flow sensor it is necessary to enter the Biomed toolbox. See 2.12 Biomed toolbox on page 32.</i>
Lock level 1 (LL1)	A maximum value may be set for the following doses: <ul style="list-style-type: none">• continuous pump rate [ml/hour]• morning dose [ml]• extra dose [ml] The doses may be adjusted from 0 to the maximum value.
Lock level 2 (LL2)	The dose settings cannot be changed.

Setting the lock level/Changing the lock level

Step	Action
1	Stop the pump: <ul style="list-style-type: none">• Press the key STOP/START and hold it down.
2	Press the key MORNING DOSE . You will now see the current lock level.
3	Change to the desired level by pressing the arrow keys.
4	Press the key MORNING DOSE . The text CODE 0 is shown in the display.
5	Press the arrow keys until the code 14 is shown in the display. <i>Note: This is the code used to change the lock level, and it should only be handed out with discrimination.</i>
6	Press the key MORNING DOSE . The new lock level is saved.

2.12 Biomed toolbox

Biomed toolbox

Certain changes require using the Biomed toolbox. In the Biomed toolbox you can:

- change the time lock for extra doses and morning doses
- switch the flow sensor on and off

Time lock

- Time lock for extra doses

Normally the time lock for extra doses is set to 1 hour. Sometimes you may need to change this, if someone needs extra doses more frequently than once every hour.

You may set the time at 15-minute intervals.

- Time lock for morning doses

Normally the time lock for morning doses is set to 20 hours. You may set the time at 1-hour intervals.

Flow sensor

The flow sensor detects if medication is flowing from the cassette. If the flow sensor is activated, the pump will issue a warning

- when the cassette is empty
- If for some reason no medication is flowing from the cassette, i.e. if the system (the pump and the cassette) is turned the wrong way. The correct placement of the cassette and the pump is in vertical position with the cassette facing up (A) and the pump facing down, or horizontally with the tube pointing upwards (B, C).



Correct placement alternatives for the cassette and the pump

If the flow sensor is not activated it will not register any of the above. The flow sensor is turned off at delivery.

Note: If less than one cassette per day is used there is really no need for this function to be activated.

Change the settings

Biomed toolbox is used for changing or reset time lock and to turn on or off the flow sensor.

How to enter the Biomed toolbox and change the settings:

Step	Action
1	Make sure the pump is in stop mode.
2	Press the key MORNING DOSE . The text LOCK LEVEL is shown in the display.
3	Press MORNING DOSE again. The text CODE 0 is shown in the display.
4	Press the arrow keys until the number CODE 114 is shown in the display.
5	Press the key MORNING DOSE
6	Use the key NEXT to browse through the functions. To make changes: <ul style="list-style-type: none">• Browse to the part you want to change using the key NEXT• Change the setting with the arrow keys• Confirm the change by pressing ENTER/CLEAR To exit from the current function: <ul style="list-style-type: none">• Browse to NEXT for Biomed ENTER for main• Press ENTER

Change the time lock:

Step	Action
1	Press NEXT to the part you want to change (morning dose x hours or extradose x hours x minutes).
2	Change the time with the arrow key.
3	Press ENTER/CLEAR to confirm the new time for the time lock.
4	How to leave BIOMED TOOLBOX: <ul style="list-style-type: none">• Press NEXT until you can see biomed ENTER for main• Press ENTER

Reset the time lock:

Step	Action
1	Press NEXT to the part you want to change (morningdose x hours or extradose x hours x minutes)
2	Press ENTER/CLEAR to reset the time (the time will not be change in the display, it's just unlocked).
3	Press NEXT until you can see biomed ENTER for main.
4	Press ENTER .

How to turn on or of the flow sensor:

Step	Action
1	Press NEXT to the part you want to change (Flow sensor on or off).
2	Switch between ON or OFF with the arrow key.
3	Press ENTER/CLEAR to confirm.
4	Press NEXT until you can see biomed ENTER for main.
5	Press ENTER .

2.13 Pump Alarm and Troubleshooting

The pump is equipped with a number of different alarms which will warn when an action is required or when an error needs to be corrected.

Note: The pump must be handled with care. Protect the display from pressure and protect the feeding mechanism and pressure sensor on the base of the pump. Attach an empty cassette or wrap the pump in soft material during transport.

Alarm	Cause	Action
Battery Depleted <i>Two-tone alarm</i>	The battery power is too low to operate the pump. The pump is now stopped.	Change batteries immediately. Press and hold STOP/START to restart the pump.
Battery removed <i>Two-tone alarm</i>	The batteries have been removed while the pump is running, or you have tried to start the pump with depleted batteries. The pump is now stopped.	Press STOP/START or NEXT to stop the alarm. Reinstall batteries or install new batteries. Press and hold STOP/START to restart the pump.
Error <i>Two-tone alarm</i>	An error has occurred.	Remove the pump from service. Contact the hospital/clinical department; the pump needs repairing and must be returned.
Remote Dose Cord Removed <i>Two single-tone beeps if the pump is stopped</i> <i>Two-tone alarm if the pump is running.</i>	The remote dose cord was removed.	Reinsert connector or press NEXT to silence the alarm.
Upstream Occlusion <i>Two-tone alarm</i>	Duodopa is not flowing from the cassette to the pump. Check for a kink in the tubing or a closed clamp between the fluid container and pump.	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.

Alarm	Cause	Action
High pressure <i>Two-tone alarm</i>	The pump has detected high pressure, which may be resulting, from a down-stream blockage, kink in the fluid path, 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. Then remove the obstruction and restart the pump.
RUN ResVol Low <i>Three single beeps</i>	The reservoir volume is low.	Change the cassette without delay.
No Disposable Pump will not run <i>Two-tone alarm</i>	You tried to start the pump without a properly connected cassette. A cassette must be connected to able to run the pump.	Press STOP/START or NEXT to stop the alarm signal. Connect a cassette.
No Disposable Clamp Tubing <i>Two-tone alarm</i>	The cassette has been removed. Close the tube clamp immediately or disconnect it from the tube. A cassette must be properly attached before the pump can be started.	Press STOP/START or NEXT to silence the alarm. Very cold or viscous medicine may caused the alarm. Allow medicine to reach room temperature before connecting it to the pump. Check if the cassette is empty - replace it if necessary.
[No message] <i>Two-tone alarm</i>	With no AC adapter the batteries have been removed while the pump is running. The pump is now stopped and un-powered. OR Batteries were removed within approx 15 seconds after the pump was stopped.	Install batteries to silence the alarm. OR Install new batteries to silence the alarm if desired. Otherwise, the alarm will stop within a short period of time.

Alarm	Cause	Action
Key pressed Release key <i>Two-tone alarm</i>	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.
Motor locked Remove all power <i>Two-tone alarm</i>	Batteries are depleted and the pump was powered up via the AC adapter.	Install new AA batteries, reconnect the AC adapter and restart the pump.
Programming incomplete <i>Two-tone alarm when starting the pump</i>	A flow rate (ml/h) or dose must be programmed before the pump can be started.	Press STOP/START OR NEXT to silence the alarm.
Reservoir Volume Empty <i>Two-tone alarm</i>	The reservoir volume has reached 0.0 ml.	Press STOP/START OR NEXT to silence the alarm. Change to a new cassette if appropriate and reset the reservoir volume.
Service required <i>Two-tone alarm</i>	The clock-battery age or the total number of motor revolutions indicates that the pump requires service.	This message is shown at LL0 for 60 days, then at all lock levels until the pump is returned for service. Action: return for service.
Power lost while pump was on <i>Two-tone alarm</i>	The pump was running when power was removed.	Stop the pump before changing the batteries or removing the power source. Press NEXT OR STOP/START to stop the pump and silence the alarm.
RUN LowBat <i>Three Two-tone alarm every five minutes</i>	The battery charge is low but the pump is still operating.	Change batteries without delay. Press and hold STOP/START to restart the pump.

Alarm	Cause	Action
Value not saved	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.

2.14 Check list for using the pump

Training program

ID number

Name

Training steps

Step	Date/sign	Date/sign	Date/sign	Date/sign	Date/sign	Date/sign	Date/sign
1 Insert batteries							
2 Start and stop the pump							
3 Take extra doses							
4 Connect/disconnect the cassette							
5 Flush the tube							
6 Program start dose + start the pump							
7 Increase/decrease the dose							

Patient able to perform themselves

Step	1	2	3	4	5	6	7
Date/sign							

The following relatives/outpatient care personnel have received information about the Duodopa pump treatment

Name Title/relation to patient Telephone

3. Duodopa dosage

This chapter contains guidelines for dosing Duodopa, calculation of consumption and a conversion table for dosing L-dopa in the case of interrupted treatment.

3.1 Calculation of dosage



RECOMMENDATION!

During the first days of titration, it is important for the physician to follow up the patient's response to the medication.

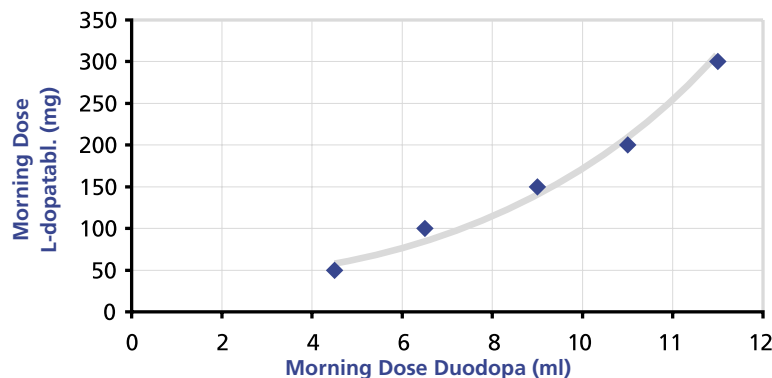
This should be done every hour.

Morning dose

Every morning the patient receives a morning dose to quickly get into a "steady-state" of L-dopa concentration. If the morning dose is too low the patient will be parkinsonistic in the morning. On the other hand, if the dose is too high the patient will quickly become dyskinetic. The morning dose should take effect within an hour, but usually the effect is seen after only a few minutes.

The tube holds approx 3 ml (Ch 8) and this volume should be included when the morning dose is prescribed. The strength of pills used by the patient before can be "translated" by knowing that 100 mg is equal to 5 ml. However, the Duodopa morning dose does not need as much L-dopa as the morning pill dose, since you do not need to achieve a plasma peak, but merely reach the "steady-state" concentration.

A tablet dose of 100 mg is equivalent to 8 ml (including the content of the tube, $5 + 3 = 8$ ml). The morning dose is rarely less than 3 ml or more than 10 ml.



The diagram shows an approximation of the Duodopa morning dose relative to the regular pill dosage. Experience shows that the curve is actually exponential, probably more so than the diagram shows. The morning dose should be kept as low as possible, but the patient should become symptom-free within a half hour.

Morning dose table

Amount of Duodopa (20 mg/ml)	Morning dose/infusion rate
60 mg	3 ml (+3 ml PEG)
80 mg	4 ml (+3 ml PEG)
100 mg	5 ml (+3 ml PEG)
120 mg	6 ml (3 ml PEG)
....
260 mg	13 ml (+3 ml PEG)
280 mg	14 ml (+3 ml PEG)
300 mg	15 ml (+3 ml PEG)

Continuous maintenance dose/Infusion rate

The prior daily dosage of L-dopa can be “translated” into a continuous maintenance dose/infusion rate of Duodopa. If the patient used to take 1000 mg L-dopa a day, 3.1 ml/hour may be an appropriate rate, which means:

1000 mg/day / 20 mg/ml / 16 hours = 3.1 ml/h.

During testing the maintenance dose should initially be low and then increased by 0.2-0.5 ml/hour until optimal condition is reached. Please note that these are very small changes in dosage, which means that changes in the effect appear very gradually. For this reason, an extra dose should be given at the same time.

Once the dosage that allows optimal condition is reached you have identified the therapeutic window, which for most people is rather narrow. After a few months it is common for the patient to become more dyskinetic, and the dose will then have to be lowered by 0.1-0.2 ml/hour.

Of course the dosage varies depending on additional treatment aside from levodopa, e.g. COMT inhibitors and dopamine agonists. If possible, the additional treatment should be interrupted for a few days before starting the patient on Duodopa. If not, the half-life of the medications must be considered.

The continuous maintenance dose is rarely less than 1.0 ml/hour or more than 10.0 ml/hour.

Conversion table for continuous maintenance dose/ infusion rate in Duodopa treatment.

Continuous maintenance dose/Infusion rate (x ml/h)	Daily dose (based on 16 hours)
2.0 ml/hour	640 mg/day
2.5 ml/hour	800 mg/day
3.0 ml/hour	960 mg/day
3.5 ml/hour	1120 mg/day
4.0 ml/hour	1280 mg/day
4.5 ml/hour	1440 mg/day
5.0 ml/hour	1600 mg/day
5.5 ml/hour	1760 mg/day

Note: The morning dose is not included in the daily doses in this table!

Formula for calculating maintenance dose:

$$[x \text{ ml/h} * 20 \text{ mg/ml} * 16 \text{ h}]$$

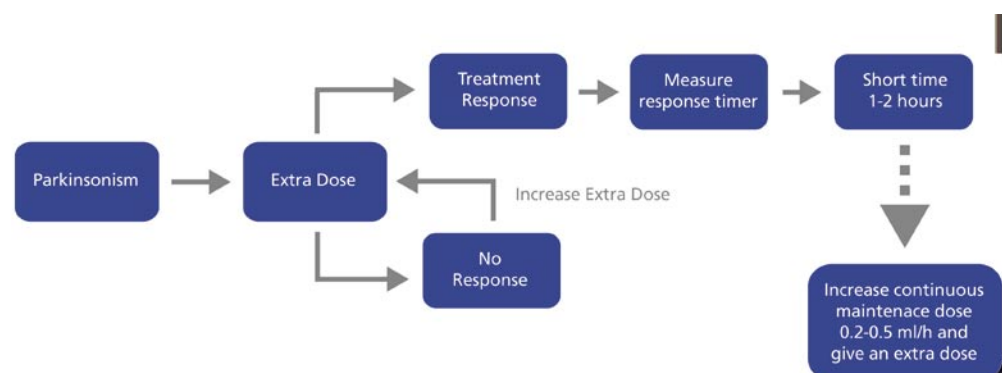
16 hours is taken as the most common treatment time during the awake time.

Extra dose

Continuous application of L-dopa usually does not require more than rather small extra doses. During the trial period you start with 1 ml and observe the effect of that. If no effect is seen the extra dosage can be increased in steps as follows: 2 ml - 4 ml - 6 ml - 10 ml.

Dose titration

A dose titration schedule may be used for individual adjustment of the Duodopa dosage.



3.2 Conversion table for interrupted Duodopa treatment

Please note! These are general recommendations for use in case of technical problems with the tube or pump. The dose should be individually adjusted considering effect and side-effects.

Morning dose

In the example below concerning morning dose we have presumed that the tube holds 3 ml.

Duodopa (20 mg/ml)	The equivalent dose of L-dopa	Madopark Quick mite (50 mg) / Madopark Quick (100 mg)
4.5 - 6 ml	30 - 60 mg	1 Madopark Quick mite
6.1 - 7 ml	62 - 80 mg	1½ Madopark Quick mite
7.1 - 9 ml	82 - 120 mg	1 Madopark Quick
9.1 - 11.5 ml	122 - 170 mg	1½ Madopark Quick
11.6 - 14 ml	172 - 220 mg	2 Madopark Quick mite
14.1 - 15.5 ml	222 - 250 mg	2½ Madopark Quick mite

Continuous maintenance dose/Infusion rate

Duodopa (20 mg/ml)	The equivalent dose of L-dopa	Madopark Quick mite (50 mg) / Madopark Quick (100 mg)
1.5 - 2.0 ml/hour	30 - 40 mg/hour	1½ Madopark Quick mite every 2 hrs
2.1 - 3.0 ml/hour	42 - 60 mg/hour	1 Madopark Quick every 2 hrs
3.1 - 4.0 ml/hour	62 - 80 mg/hour	1½ Madopark Quick every 2 hrs
4.1 - 5.5 ml/hour	82 - 110 mg/hour	2 Madopark Quick every 2 hrs
5.6 - 7.0 ml/hour	112 - 140 mg/hour	2½ Madopark Quick every 2 hrs

3.3 Consumption

Calculate daily consumption

Daily consumption is the sum of the following:

- Morning dose [ml]
- Continuous maintenance dose/infusion rate [ml/hour] multiplied by the time in hours
- Extra doses [ml]

Example

- *The example below illustrates the calculation of daily consumption*
- *Morning dose = 5 ml*
- *Continuous maintenance dose = 3.5 ml/hour*
- *Pump attached at 06:00 am - 10:00 pm = 16 hours*
- *=> Continuous consumption = 3.5 ml/hours x 16 hours = 56 ml*

Total daily consumption:

$$5 \text{ ml} + 56 \text{ ml} = 61 \text{ ml/day}$$

If the strength is 20 mg/ml:

$$20 \text{ mg/ml} \times 61 \text{ ml} = 1220 \text{ mg/day}$$

Note: Remember to include any extra dose. If the continuous maintenance dose exceeds 4.5 ml/h, 2 cassettes/day are probably needed.

Note: 1 mg Apomorphin is corresponding to approx. 10 mg Levodopa.

4. Measuring mobility

This chapter contains an overview of how to measure mobility for Parkinson's disease and an ON-OFF diagram for assessing mobility.

4.1 Measuring mobility with Parkinson's disease

It may be complicated to measure mobility with Parkinson's disease since the patient may often experience akinesia and dyskinesia at the same time. It is recommendable to find out what is most uncomfortable motor symptom for the patient and to focus on that for the measurements.

To get the best possible understanding of the patient's condition an ON-OFF diagram should be filled out by the patient and staff. The staff may mark their opinion with an "x" and the patient with an "o". Depending on the progress of the disease, the patients may assess their mobility differently from the staff, they will often say they are very akinetic, even though they are walking upright. Therefore, it is important to test the patient during assessment, by asking him/her to stand up, play with the fingers and take a little walk. Ask the patient what problems he/she experiences regarding mobility and take this into consideration.

Degrees of mobility

Very dyskinetic

A very dyskinetic patient is characterized by large uncontrolled movements, often throughout the body. The patient is unable to stay still. The extent of the movements may be 20–100 cm or more.

The risk of falling out of a bed or a chair is high. the patient cannot perform precision motor tasks. Difficulty for drinking a glass of water without spilling or knocking the glass into something. Problems with balance because the body and the legs are not coordinated. Often gets out of breath or sweaty due to the exertion. May be nauseous due to high concentrations of L-dopa in serum. The blood pressure may also be low (nausea and low blood pressure do not however have to mean the patient is hyperkinetic).

Moderately dyskinetic

Uncontrolled movements throughout the body or in certain extremities only. The extent of the movements is appr. 10–30 cm.

Cannot stay still. Can drink a glass of water relatively stably. Often relatively well balanced.

Slightly dyskinesic

Extra movements in one or a few extremities. The extent of the movements is appr. 5-15 cm.

Can be still for about 5-15 seconds. Can drink water without problems. No balance problems. The patient often finds this level optimal.

Normal mobility

No extra movements. No stiffness. No Parkinson symptoms.

Slightly akinetic

Gets up and walks around without problems. Turns without notically stopping. Standing up and walking are often somewhat slowed down. Often experiences "slight stiffness" finger play (air piano) may feel a bit slow. However the observer often considers the patient's movements normal.

Moderately akinetic

Has problems getting started. May need help getting up from a sitting/horizontal position. May "get stuck" and need help getting going. Stops when turning. Risk of falling.

Very akinetic

Incapable of moving. Cannot get up from a sitting/horizontal position, hardly even when being helped, and often has trouble swallowing.

4.2 On-Off diagram for Duodopa

ON-OFF schedule for Parkinson’s disease

Date

Bed

ID number

Name

Time	06	07	08	09	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	01	02	03	04	05
Mobility																								
Very dyskinetic*																								
Moderately dyskinetic*																								
Slightly dyskinetic*																								
Normal																								
Slightly akinetic																								
Moderately akinetic																								
Very akinetic																								
Comments																								
Shaking																								
None																								
Slight																								
Much																								
Duodopa																								
Morning dose ml																								
Maintenance dose ml/hour																								
Extra dose ml																								
<small>*L-dopa induced hyperkinesia</small>																								

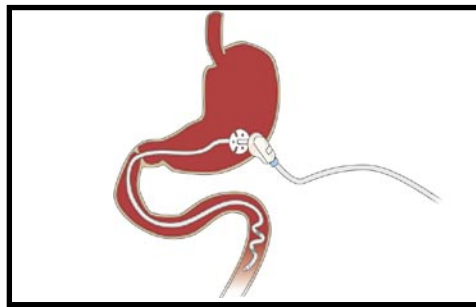
5. PEG operation

This chapter contains guidelines for the operation of the PEG (percutaneous endoscopic gastrostomy) with intestinal tube.

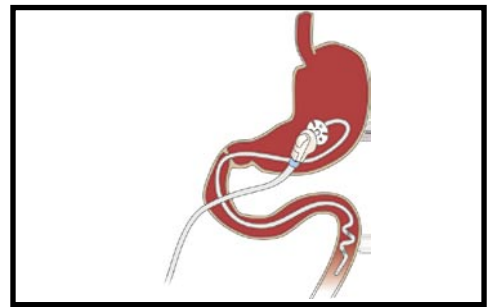
5.1 Guidelines for PEG operation

Operation

The patient is prepared the same way as for endoscopy and a mild sedation is usually recommended. Administration of a prophylactic antibiotic should be considered. Once the patient is in supine position, the endoscope is placed in the stomach and the stomach must be inflated. With the lights dimmed, the surgeon locates the appropriate puncture site in the left upper quadrant of the stomach, by placing a finger at the point of maximum transillumination by the endoscope light. The entire abdominal wall must be cleaned with a colourless disinfectant and sterile drapes must be put around the puncture site. The instruction how to manage all tubes and conexions are clear and simple and must be consulted by the surgeon. The PEG must be located at the level of the pylorus. See figures below.



Optimal PEG Position



Avoid this PEG position

Note: Unfortunately in some patients the PEG still twists away from the pylorus after the operation. This complicates the positioning of the inner tube, but is still acceptable.

During gastroscopy the stomach is filled with approximately 1 liter of air. This air often makes some hydrochloric acid leak out, causing mild peritonitis. The peritonitis causes the fistula to grow/heal and strengthen. If the skin cut is too tight, the hydrochloric acid may not be able to get out, and may then aggravate the peritonitis. A larger cut makes it possible for any fluids to leak through instead of irritating the peritoneum. If the tension applied to the PEG during or after the operation is too strong it may cause tissue damage to the stomach canal and possibly peritonitis.

Placement of the intestinal tube

During the PEG operation it is recommended that the surgeon places the inner tube in the small bowel with the help of the gastroscope.

Note: It may be difficult to pull back the gastroscope without bringing along the tube. If this happens the most important thing is to place the tip of the tube well past the pylorus.

Optimal tube position

Optimal tube position is when:

- No loop is present in the ventricle
- The tip of the tube is well inside the duodenum. It is recommended to place the tip in the distal part of the duodenum near the Treitz ligament to reduce the risk of dislocation to the stomach.
- The experience has shown that the tip could also be placed just beyond the ligament of Treitz, in the proximal jejunum, so that the tube will better stay in place. Available knowledge indicates that the absorption of levodopa does not differ at any site in the upper small intestine, including duodenum and the upper part of jejunum.



The inner tube should be cut off when the tip of the tube is in upper part of the small intestine and the tube is as little in the ventricle as possible.

The outer tube may well be as long as possible to contribute to the comfort of the patient.

The connections must always be firmly tightened, or the inner tube may lose its position in the small bowel or move all the way into the intestinal canal.

Checking the tube position

X-ray referral, abdominal

Questions: Is the tip of the tube well into the duodenum, near the Treitz ligament? Is there any loop in the ventricle?

If only the “tube position” is asked for, the answer is usually too vague. Explain that there is a PEG with duodenal tube and that the tip of the tube should be well inside the duodenum, **ideally in the distal part of the duodenum** near the Treitz ligament to ensure that the tube stays in place. If needed take help from gastroenterologist.

Contrast may be injected into the tube to help determining its position.

See also example of referral 7.4 X-ray referral – Abdominal overview on page 58.

A three-way tap is screwed onto the connection instead of the cassette. Please note that the patient receives approximately 60 mg of L-dopa upon flushing the tube.

If the tube is not in the duodenum.

Complication	Action
The inner tube has not been placed in the duodenum during the operation. The X-ray shows that the tip of the tube is in the ventricle.	<p>The tube must be placed in the duodenum, IDEALLY IN THE DISTAL PART NEAR THE TREITZ LIGAMENT TO REDUCE THE RISK OF DISLOCATION.</p> <p>There are three alternatives</p> <ul style="list-style-type: none">• Gastroscopy. It may be difficult to pull back the scope without bringing the tube along, and if this happens it is important to try to place the tip of the tube well past the pylorus.• “External” tube adjustment with fluoroscopy. Using steel guides the tube is placed in the duodenum. The most difficult part is to pass the pylorus, but by injecting contrast the pylorus is clearly visible and small amounts of water or air may distend the bulb. It may help if the patient is lying slightly on his/her right side.• Put about 70 cm of the inner tube blindly into the PEG, and it may find its own way in.

Equipment for tube adjustment

- Fluoroscopy
- Guides for the tube
- Contrast, syringe, three-way tap (Luer lock)

6. Check list for leaving the hospital

This chapter contains a check list to be used when the patient is leaving the ward, as well as information about the handling of Duodopa by the pharmacy and the patient.

6.1 Ordering Duodopa

It is important to make sure that the pharmacy gets the correct information about ordering Duodopa, in order to assure that the patient will receive properly it when he/she returns home.

Duodopa is usually delivered every other week to the patient. The Duodopa prescription is sent to the pharmacy of the patient's choice.

There is usually no Duodopa in stock at the pharmacy. To avoid a gap in the patient's medication intake due to delayed deliveries, the pharmacy needs a recurrent ordering schedule.

The prescription is only needed for new patients. However, the prescription must be renewed every 12 months.

See examples: 7.5 Prescription - Duodopa on page 59.

When the patient is admitted to the hospital or is discharged, the pharmacy should be informed so that the Duodopa delivery is sent to the patient's current location. If the patient is going to travel he/she should call the hospital or the pharmacy to determine where the medication should be delivered.

6.2 Check list

Step	Action
1	Supply the patient with enough medicine to last until his/her first delivery to the pharmacy.
2	Supply accessories: <ul style="list-style-type: none">• Syringes 10-20 ml (to clean the tube when detaching it).• Adapter for the syringe (three-way tap or female-female connection).
3	Check that the patient can handle the Duodopa system on his/her own What if the district nurse is not informed? <i>See 2.14 Training program for using the pump on page 39.</i>
4	Send along wound dressing instructions (for the patient to hand to the district nurse). <i>See 1.4.3 Dressing stoma on page 15.</i>
5	A certificate for travel abroad is needed. <i>See 7.6 Certificate for travel abroad on page 60.</i>
6	Remind the patient to store Duodopa in the refrigerator.

7. Templates

This chapter contains templates and examples of referrals and prescriptions.

7.1 X-ray referral – Inserting nasointestinal tube

Example of referral for inserting nasointestinal tube:

Examination	Question
X-ray control of ventricle - duodenum/jejunum	Positioning of nasointestinal tube
Case History	
<p>Patient with advanced Parkinson's disease. To test infusion via nasointestinal probe. (Tube sent along with patient)</p> <p>Positioning of Bengmark tube should ideally be with the tip in the upper part of the small intestine, preferably near the Treitz ligament and with its length so that it reaches the distal part of the duodenum to ensure that the tube stays in place and to reduce the risk of dislocation. Use contrast to verify the position of the tip.</p>	

7.2 Hospital requisition

Example of hospital requisition of Duodopa:

DRUG	VOLUME	AMOUNT
Duodopa	100 ml/cassette	7

7.3 Consultation referral for the PEG

Example of referral for the PEG:

Diagnosis

Parkinson's disease. PEG with intestinal tube required.

Case History

Parkinson's disease. Experiences motor fluctuations. Has tried nasointestinal L-dopa infusion with positive results. Wishes to have permanent infusion system. - PEG inner tube.

Positioning of Bengmark tube should ideally be with the **tip in the upper part of the small intestine, preferably near the Treitz ligament** and with its length so it reaches the **distal part of the duodenum** to ensure that the tube stays in place **and to reduce the risk of dislocation**. Use contrast to verify the position of the tip.

7.4 X-ray referral – Abdominal overview

Example of referral for checking PEG tube:

Examination Abdominal overview	Question Position of tube tip? (Suspicion of displacement). Possibly tube adjustment.
Case History Patient with advanced Parkinson's disease treated with intestinal L-dopa infusion. Has PEG with inner tube. The tip of the tube should ideally be positioned distally preferably near the Treitz ligament. Adjust position to optimal if the tube has been displaced to the ventricle.	

7.5 Prescription – Duodopa

Example of Duodopa prescription:

Drug		
Duodopa		
Strength	Amount	
20 mg/ml	1 month	
Dose		
1 cassette/day ie 4 boxes of 7 cassettes		


7.6 Certificate for travel abroad

The pocket-sized certificate below for pump and levodopa can be ordered from Solvay Pharma.

Product information

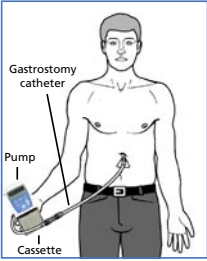
Each cassette (100 ml) contains:

- Levodopa 20 mg/ml
- Carbidopa 5mg/ml
- Cellulose (thickening agent)
- Water



Certificate

Medication with continuous intestinal infusion of levodopa by pump



The catheter, connectors, pump, and cassette contains metal parts that may cause indication on a metal detector.

This is to certify that:

Name: _____

Date of birth: _____

Sex: _____

Passport No.: _____

Date: _____

Name of issued clinic: _____

Phone: _____

is medicated with continuous intestinal infusion of levodopa by pump.

The patient needs one cassette of medication per day.

Approved stamp

Name of Physician

Signature

8. Contact information

Introduction

This chapter contains telephone numbers and other information.

8.1 Phone and address

Solvay Pharma

Hans-Böckler-Allee 20

30173 Hannover

Germany

Tel: + 49 (0)511 8570

Fax: + 49 (0)511 8573120

e-mail: info@duodopa.com

A. Information for the patient

Introduction

This chapter contains information about Duodopa to hand out to the patient.

A.1 Information for the patient before testing Duodopa

Information about the medication

Duodopa is an L-dopa medicine in liquid form, administered directly into the duodenum through a tube. The purpose is to even out the distribution of L-dopa in the body and thereby achieve a more stable mobility.

Duodopa contains:

- L-dopa: The active substance, which is part of Madopark and Sinemet
- Carbidopa: degradation inhibitor. Is an ingredient in Sinemet
- Cellulose: Thickening agent
- Water

Introduction

The medication is administered directly into the duodenum through a tube. At first a test period is used to set the appropriate dosage and for you to experience how the treatment works. All L-dopa medication is aborted and replaced by Duodopa. Other medications are removed on a per case basis. Changing medication can be difficult during the first few days.

The test period usually lasts one to two weeks. During this period, a tube is inserted through the nose, and can easily be removed after the test period. If you will be continuing Duodopa medication, a permanent tube is then inserted through the abdominal wall. It is set in place with the help of a gastroscope.

Nasointestinal tube

The nasointestinal tube is set in place with the help of X-ray. It is inserted through the nose down to the stomach and into the small bowel. When the tube passes through the nose and throat, you may experience “tickling” and possibly nausea. As soon as the tip has passed these areas, however, the discomfort will subside. The tube may feel hard and unpleasant as it is inserted, but it will soften as soon as it is in place in the small intestine and the steel guide inside the tube is pulled out. The guide makes the tube stiffer and easier to steer into the intestine. The nose and throat may feel irritated for a day after the procedure, but the tube rarely causes discomfort after that.

Starting treatment

When the tube is in place it is ready for use. An extension tube is then attached to the tube so that you can carry the pump on the hip or wherever you wish. The pump is connected to the extension tube and started. It is important to assess mobility approximately once every hour in order to set the correct dosage.

The morning dose and the continuous dose will now be set. The morning dose is administered in the morning to “start you up” and result in “optimal” condition after about 30-60 minutes. The continuous dose is meant to keep you on that optimal level during the entire day. If the continuous dose is too low you will experience stiffness. If it is too high on the other hand, you will become hyperactive. Morning dose and continuous dose should therefore be set individually.

Daily routines

In the morning the pump is connected to the tube system. The pump is started and the morning dose is administered to get your mobility going. Then the pump will administer a small continuous dose during the day to maintain mobility. There is also a possibility to add extra doses using the pump. In the evening the pump is disconnected, the extension tube is removed and put in the fridge (the Bengmark tube should not be rinsed). During the night or at other times when the pump is disconnected extra doses in tablet form may be taken if necessary. Please note that this must be discussed with your doctor.

Read through the instructions and decide whether you are able to start the treatment in the morning and stop it in the evening by yourself, or if someone close to you should learn how to do it for you.

PEG operation

If it is decided that you should continue on this medication, a permanent tube is inserted with the help of a gastroscope. This is done with a local anesthetic and sometimes tranquilizers. The permanent tube is inserted in the abdominal wall and into the stomach.

On the day of the operation you must not eat or drink. Usually you can take your morning medicines with some water.

Problems

The first few days of setting the medicine dosage may be problematic. You will usually start off with a low dose and give extra doses, instead of starting on a high dosage and risk side-effects (usually hyperactivity). The PEG operation may cause tenderness in the operated area for a few days. Major problems are rare. Some infections in the tube wound may occur. In such cases it is important to clean and change compresses more often, and sometimes treat with antibiotics.

Once you come home your dosage may have to be adjusted. This is probably due to the fact that you will be more active in your home environment, and thereby have a greater need for medicine. 1 to 6 months after the start of the treatment the dose can usually be decreased.

The dose can be adjusted after talking to the personnel who have been treating you at your hospital.



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