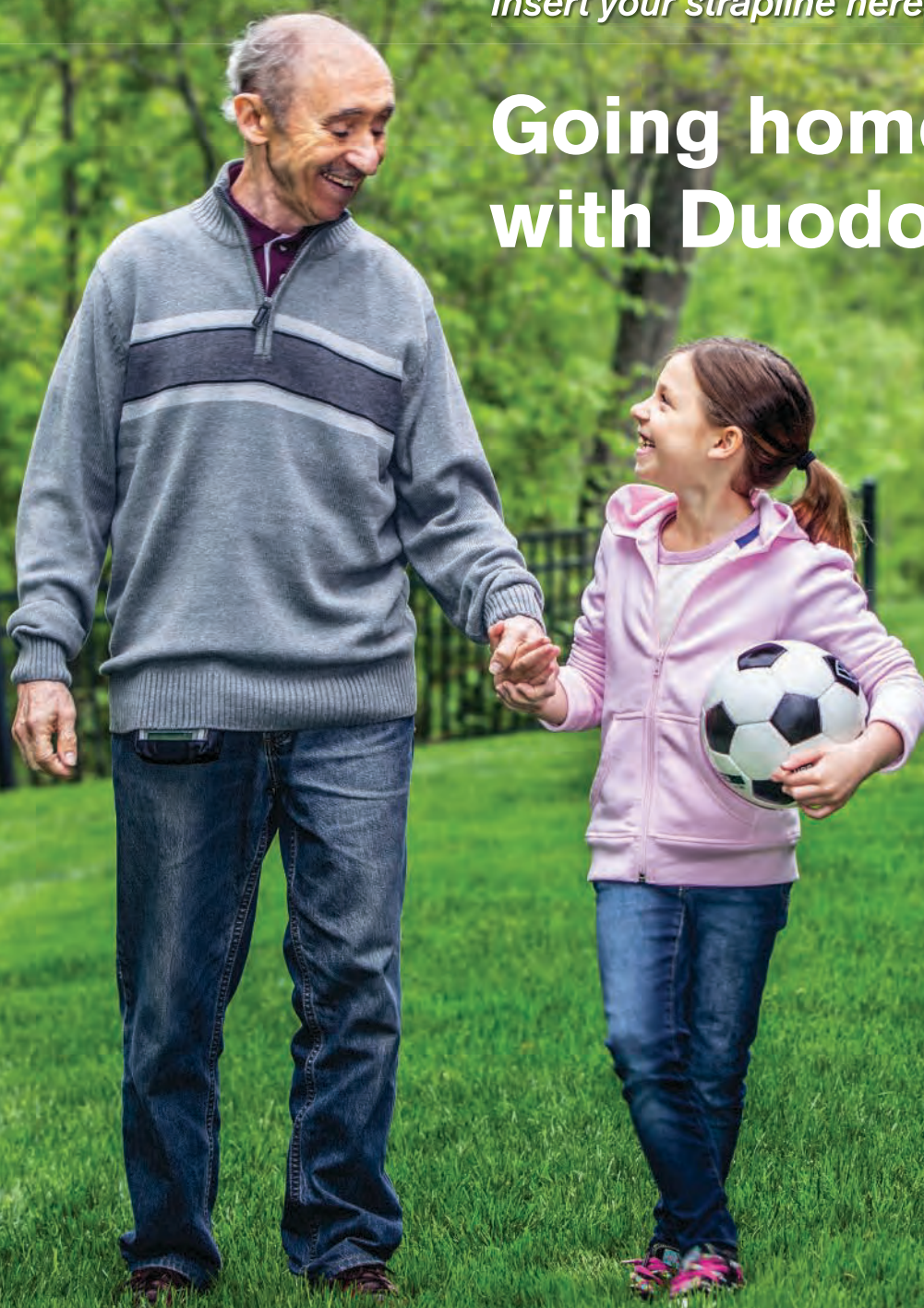


Insert your strapline here

Going home with Duodopa[®]



Placeholder for local Duodopa indication

Duodopa[®]
LEVODOPA/CARBIDOPA INTESTINAL GEL

Duodopa and you

Now that you have had your procedure, your healthcare team and caregivers will continue to support you and help you integrate Duodopa treatment into your daily routine.

Your healthcare provider is giving you this booklet so that you have information on what to expect next, how to administer and maintain your Duodopa tubing and pump, taking care of your stoma, how to get into a routine with Duodopa, and how to perform everyday tasks with Duodopa.

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Next steps

You have now had your **percutaneous endoscopic gastrostomy/jejunal (PEG/J) tube** inserted and, with the help of your healthcare team, should be getting familiar with your new Duodopa treatment.

You have come so far, and you will already have received information on Duodopa. Your dose will have been adjusted by your doctor, and the pump programmed to deliver your daily treatment.

It is important that at this next step in your treatment journey you are confident managing your treatment and you feel supported by those around you.

What does it mean?

PEG/J tube – The tube that carries your Duodopa medicine from the cassette directly into your intestine.

Next steps

You are supported

As you begin treatment with Duodopa, the level of support you need from your caregiver and healthcare team may change. However, you should realise that support is always there when you need it.

- Your family members and caregivers will support you every step of the way, and letting them know you appreciate their help will go a long way
- Discuss with those close to you how much you want to manage your day-to-day treatment yourself
- Don't be afraid to ask for help
- Be positive – as you get used to your new treatment, things that seem difficult at the beginning will become easier

Placeholder for local contact information

Duodopa

Looking after Duodopa

Your healthcare team will have discussed possible problems you may encounter with your new treatment.

By taking a few preventative steps, you can help decrease the chance of developing some of these problems:

- Wash your hands before connecting or disconnecting the pump
- Inspect your stoma daily for redness, tenderness or drainage; these could be signs of an infection
- Follow your healthcare provider's instructions on how to clean and care for your stoma
- Mobilise your tube as instructed by your healthcare provider
- Flush your tubing to prevent clogging
- Inspect your tubing daily for kinks and twisting, being careful not to turn or twist the PEG/J tube
- Inspect your pump for damage

Duodopa

Stoma care

Follow the instructions provided by your healthcare team on how to clean your stoma.

The stoma is the opening in your stomach that was made during the PEG procedure. Once the wound has healed (after about 1–2 weeks), the tube should be carefully moved in and out slightly in the stoma every day, according to the following steps or your doctor's instructions.

1. Release the external retention plate to allow free movement of the PEG/J tube
2. Carefully push the tube 3–4 cm into the stomach and gently pull back until you feel resistance from the internal retention plate; **do not twist the tube** (Figure 1)
3. Inspect your stoma for any signs of redness, swelling, or pain. Inform your doctor of any signs of complications; **do not apply any ointment to the stoma**
4. Put the external retention plate back to its original position (approximately 1 cm away from your skin; Figure 2)

It is important that your external retention plate is not too tight or too loose. If you feel that it is, contact your healthcare team for their guidance.

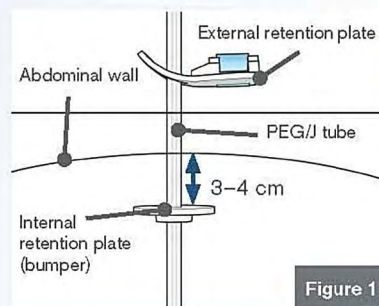


Figure 1

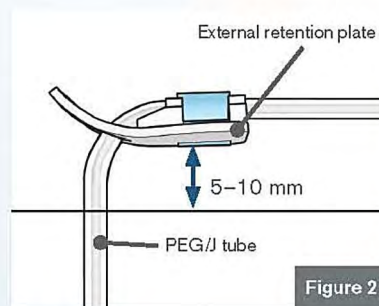


Figure 2

Please ensure that the tubing pictures are appropriate for the tubing being used in your country.

Please ensure that the instructions provided above follow the NJ tubing Information for Users, PEG Information for Users, and appropriate labelling for your country.

Duodopa

Caring for the tubing – every evening

STEP ONE Stop pump



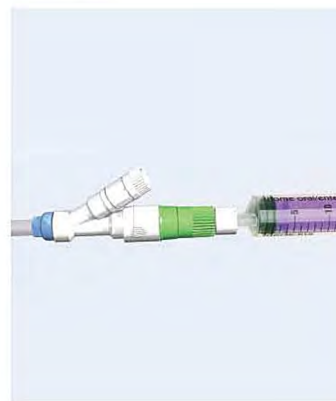
- Press and hold the **STOP/START** button for 3 seconds to stop infusion
- Press and hold the **ON/OFF** button for 3 seconds to turn off pump

STEP TWO Disconnect tube



- Disconnect the cassette tube from the intestinal port of the PEG/J tube (twist the cassette tube, **NOT** the PEG/J tube)

STEP THREE Flush



- Use a syringe to flush the intestinal tube with room temperature drinking water according to your doctor's instructions; please contact your doctor if you have any questions
- When internal and external tubing has been in place for more than a year, your doctor should assess its functioning regularly
- **Do not administer any substances other than Duodopa into your PEG/J tube without consulting your doctor**
- The extension tube should not be flushed; remove it, cap it, and place it in the refrigerator each night
- The external PEG/J tubing and connectors should be cleaned regularly with warm, soapy water

Please ensure that the tubing pictures are appropriate for the tubing being used in your country.

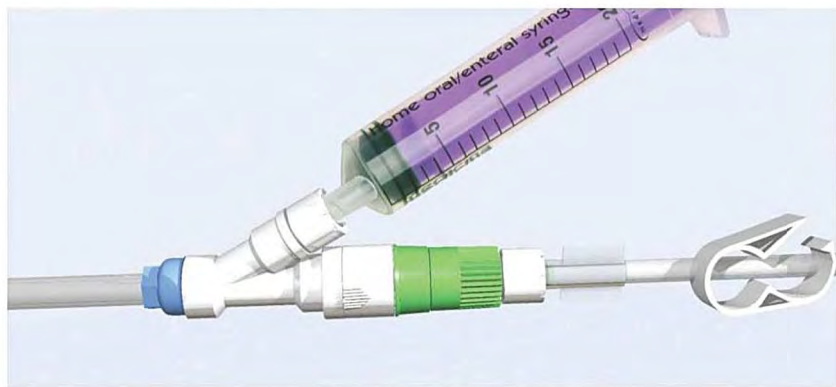
Duodopa

Caring for the tubing

Flush the space between the intestinal and PEG/J tube every day.

Use a syringe to flush the Y-connection with room temperature drinking water according to your doctor's instructions.

Flush the Y-connection



To ensure that the tubing is working normally, the external and internal tubing should be assessed by your doctor at least once a year.

If it is difficult to flush your tube, do not force water into your tube. Call your healthcare provider.

Please ensure that the tubing pictures are appropriate for the tubing being used in your country.

Getting into a routine

Your Duodopa treatment will be part of your day-to-day life. Creating a routine may help you manage this and allow you to concentrate on living your life.

Every morning

Below are instructions for administering your morning dose of Duodopa, or see your CADD-Legacy Pump Manual for detailed instructions on using the pump. Before use, Duodopa cassettes should always be stored in the refrigerator (2–8°C). For more information about storage, see page 16.

1. Remove a new Duodopa cassette from the refrigerator; do not re-use an opened cassette
2. Allow the cassette to reach room temperature
3. Wash your hands
4. Attach a new Duodopa cassette to the pump. To do this, you or your caregiver should:
 - a. Insert cassette hooks into the hinge pins on the pump
 - b. Place the pump upright on a flat surface
 - c. Press down so that the cassette fits tightly against the pump
 - d. Insert a coin into the latch and turn counter clockwise until you feel the latch click into place (the line on the latch will line up with the arrow on the pump)
 - e. Ensure the cassette is firmly attached



Getting into a routine

Every morning

5. Place the pump in your carrying case before you put it on (see page 14 for tips on carrying your pump)
6. Remove the red protective cap from the cassette tube
7. Connect the cassette tube to the intestinal port of the PEG/J tube (twist the cassette tube and **NOT** the PEG/J tube)



8. Press and hold **ON/OFF** for 3 seconds to turn on the pump. Press and hold **STOP/START** for 3 seconds to start the infusion
9. Press **MORNING DOSE TWICE** to administer the morning dose

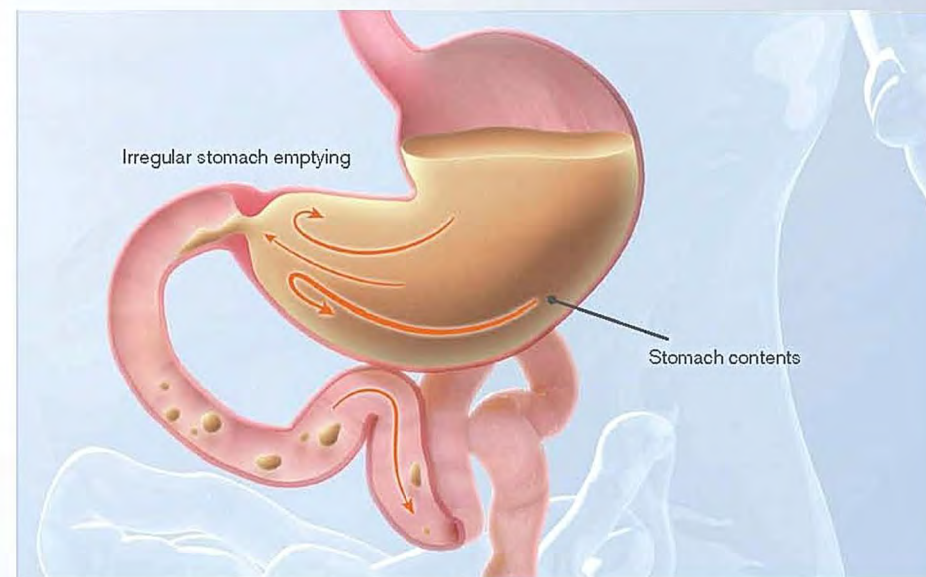
Getting into a routine

Throughout the day

Once you have received your morning dose, a lower maintenance dose, called the **continuous maintenance dose**, is given throughout the day by the pump until bedtime.

This continuous maintenance dose is **automatically** delivered by the pump after your morning dose.

You do not have to press additional buttons on your pump.



Extra doses

Throughout the day, the **EXTRA DOSE** feature allows you to administer an extra dose as needed, and as instructed by your doctor.

To administer an extra dose, press the **EXTRA DOSE** button on the pump and the pump will administer the extra dose followed by the continuous dose.

Getting into a routine

Every evening

Duodopa is used throughout the day, and treatment is stopped in the evening when you go to bed.

Follow these instructions:

1. Wash your hands
2. Press and hold **STOP/START** for 3 seconds to stop the infusion
3. Press and hold **ON/OFF** for 3 seconds to turn the pump off
4. Disconnect the cassette tube from the intestinal port of the PEG/J tube (twist the cassette tube and **NOT** the PEG/J tube)
5. Once the pump has been stopped and disconnected from the intestinal port of your PEG/J tube, remember to care for your tube as described on pages 7 and 8
6. Put the white cap back on the PEG/J tube and the red cap onto the cassette tube
7. Discard the used Duodopa cassette
8. Use a syringe to flush your tubing as described on pages 7 and 8
9. Clean your stoma as instructed by your healthcare team



Leftover gel in your Duodopa cassette

It is normal that some gel remains in the cassette after the 16-hour infusion. This should be discarded according to the instructions received from your healthcare team.

It is important to never re-use leftover gel.

Getting into a routine



Consider these tips

- Obtain a pump carrying accessory that is comfortable and enables the pump to be close to your body so that the tubing remains intact (see page 14)
- Throughout the day be careful not to dislodge the tubing
- The pump is not waterproof, so please be mindful of keeping the pump dry at all times
- If you plan to go shopping, plan on going when it is likely to be less crowded
- Money and credit cards should be arranged so you can get to them without interfering with your tubing
- Talk with your caregiver so they know when you need help
- Ask for help when you need it

Taking an active role in planning your activities will help you get the most out of your day. Getting used to your new routine will naturally take time for you and your caregiver. Be patient and remain positive.

Daily activities

There are a number of accessories designed to help you carry the Duodopa pump. These are designed to ensure the pump can be held close to your body, so that the tubing does not get easily dislodged and stays in place.

Your healthcare team may have other suggestions to make it easier to carry the pump and tubing.



- **Hip bag:**
can be worn over your left or right hip, or at the back of your waist



- **Vest/waistcoat:**
pockets help keep the pump close to your body



- **Handbag:**
the waist belt helps take pressure off the shoulder



- **Pump holster:**
designed to conceal the pump beneath your normal clothing

Please ensure that the images reflect clothing available in your country.

Daily activities

Washing and swimming

Once the stoma has healed you may wash or shower.

Your Duodopa pump is **not waterproof**, so you should always **disconnect it** before taking a shower or going swimming.

The area around the stoma should be gently dried before reconnecting your Duodopa pump.

You will not receive medication during the period you are disconnected from the pump. This may mean that your symptoms suddenly or slowly worsen. If this occurs, please ask your doctor what to do.

Useful information: Duodopa storage

This section gives you more information about Duodopa and pump care. Duodopa is sensitive to light and heat and therefore it is important that it is stored correctly.

- The carton containing the Duodopa cassettes should remain closed to protect it from the light except when removing a new cassette
- The Duodopa carton should be stored in the refrigerator (2–8°C)
- When you get a new carton of Duodopa, place it behind older cartons in the fridge. This ensures that the oldest carton is used first
- The cassettes should be used before their expiry date, which is printed on the carton
- The gel inside the Duodopa cassettes may become slightly yellow. This is normal and does not affect the use of the medication



Useful information: pump care

Consult your doctor immediately if you think there is a problem with your pump. The following procedures will help maintain the pump in good working order.

Cleaning the pump

The pump should be cleaned regularly with a soft, lint-free cloth.

1. Dampen the cloth in soapy water and wipe the external surface of the pump
2. Dry the surface of the pump with another soft, lint-free cloth
3. Always allow the pump to dry completely before using it again
4. It is important never to immerse the pump in water or any type of cleaning fluid



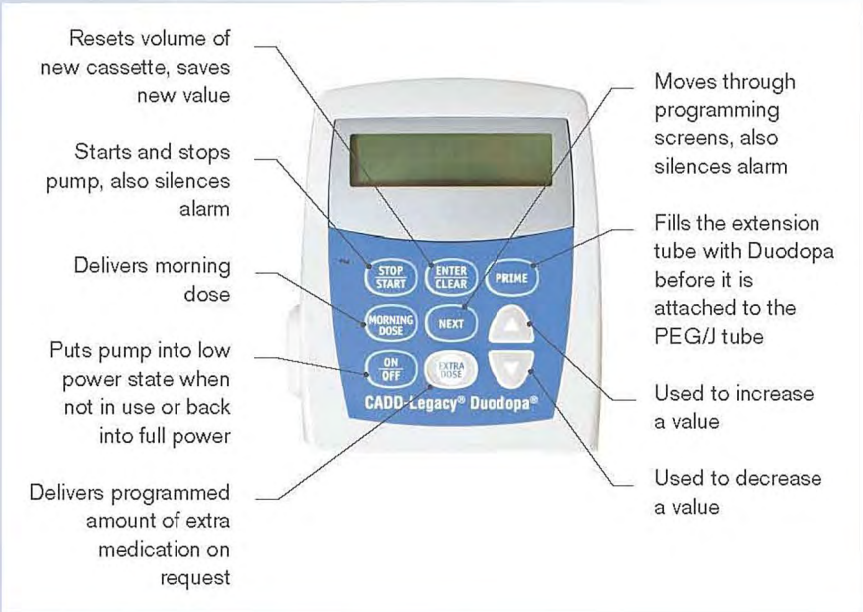
Do not operate the pump at temperatures below 2°C or above 40°C
Do not store the pump at temperatures below -20°C or above 60°C

Useful information: pump buttons

Know your buttons

Here's a quick reference of the buttons you will use to control your dose delivery.

Refer to the individual instructions on pages 10–12 for sequences and the number of times to press each button.



Useful information: pump alarms

Message	What you hear	Cause	Action
Battery Depleted	Two-tone alarm	Battery power too low, pump is now stopped.	Install new batteries then restart pump.
Battery Removed Pump won't run	Two-tone alarm	Batteries were removed while pump was running, or battery power is too low.	Press STOP/START or NEXT to silence alarm. Reinstall batteries or install new batteries.
Error	Two-tone alarm	Pump needs repair.	Close tubing clamp and stop using pump. Contact your doctor.
High Pressure	Two-tone alarm	High pressure in system due to kink in tubing or closed tubing clamp.	Press STOP/START or NEXT to stop pump and silence alarm for 2 minutes. Remove obstruction and restart pump. If alarm continues, contact your doctor.
Key pressed, Please release	Two-tone alarm	A key (button) is being pressed.	Stop pressing the key (button). If alarm persists, close tubing clamp and stop using pump. Contact your doctor.
LowBat	Three two-tone beeps every 2 minutes	Battery power is low but pump still operable.	Change batteries soon.
Motor Locked, remove all power	Two-tone alarm	Batteries are depleted and pump was powered by AC adapter.	Install new batteries, re-connect AC adapter and restart pump.
No Disposable Clamp Tubing	Two-tone alarm	Pump is not sensing a cassette.	Press STOP/START or NEXT to silence alarm. Clamp tubing or disconnect tubing from your PEG/J port. Reattach cassette.
No Disposable, Pump won't run	Two-tone alarm	You tried to start pump without inserting a cassette.	Press STOP/START or NEXT to silence alarm. Insert cassette and restart pump.
(No message)	Two-tone alarm	Batteries have been removed while pump was running and no AC adapter is attached. Pump is stopped.	Install batteries.

Useful information: pump alarms

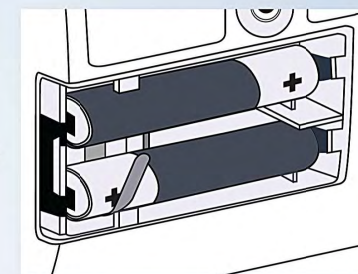
Message	What you hear	Cause	Action
Power lost while pump was on	Two-tone alarm	Pump was running when power failed.	Press STOP/START or NEXT to silence alarm. Stop pump and change batteries or remove power source.
Remote Dose Cord Removed	Two single-tone beeps, if pump is stopped. Two-tone alarm, if pump is on	Remote dose cord was removed.	Reattach remote dose cord or press NEXT to silence alarm.
Reservoir Volume Empty	Two-tone alarm	There was no medication left in cassette.	Press STOP/START or NEXT to silence alarm. Insert new cassette and reset reservoir volume.
RUN ResVol Low	Three single beeps	Volume in cassette is 5 ml.	Change cassette before it is empty.
(Screen displays current pump status)	Two beeps (long short)	Duodopa cassette is not aligned with pump or medication is not flowing from medication bag to pump, medication is too cold.	Press STOP/START or NEXT to silence alarm. Ensure cassette is aligned with pump and allow medication to reach room temperature before attaching to pump.
Service Due See manual	Two-tone alarm	Pump is scheduled for service.	Press STOP/START or NEXT to silence alarm. Pump is still functional but contact your doctor for further instructions.
Upstream Occlusion	Two-tone alarm	Upstream occlusion sensor is set to 'dry' and occlusion is detected.	Press STOP/START or NEXT to stop pump and silence alarm for 2 minutes. Remove obstruction or reattach cassette to the pump. Restart pump if alarm continues, contact your doctor.

Useful information: replacing pump batteries

How to replace pump 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.

1. Stop the pump
2. Open the battery compartment by pressing the arrow button while sliding off the cover
3. Remove the used batteries by pulling the end of the battery strap
4. Insert the new batteries on top of the battery strap ensuring the battery positive (+) and negative (-) ends are correctly aligned with the symbols in the battery compartment
5. The pump will automatically switch on
6. Replace the battery cover
7. Start the pump if required



Caution!

Do not use rechargeable batteries. They do not provide sufficient power for the pump to operate properly.



Frequently asked questions

Is there something very important I should know about Duodopa?

Duodopa can cause side effects. However, many of them can be managed by having your dose adjusted. Contact your doctor to discuss any questions about side effects. If you experience any side effects, contact your doctor as soon as possible.

How long do I take Duodopa?

You may take Duodopa for up to 16 hours every day, but always follow your clinician's instructions.

What happens if I feel my symptoms suddenly or slowly becoming worse?

It is possible that the tube in your small intestine is blocked, disconnected or has moved. Contact your doctor right away if this happens. Your doctor may also check to see if your dose needs adjustment. Always use Duodopa exactly as your doctor has instructed you.

How many cassettes will I use?

That depends on your individual dosing needs as determined by your doctor. Patients may require more than one cassette per day.

Why is there leftover gel in the cassette?

You may find leftover gel in your cassette at the end of the day. This is normal and nothing to worry about. It is important never to re-use a cassette with leftover gel. Always discard each cassette you use at the end of the day according to the instructions given by your healthcare team.

Frequently asked questions

Can any drugs interact with Duodopa?

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines. This includes medicines obtained without a prescription, including herbal medicines.

In particular, talk to your doctor or pharmacist before starting Duodopa if you are taking other medicines for:

- Parkinson's disease, severe allergic reactions, asthma, chronic bronchitis, heart diseases and low blood pressure
- Fits or epilepsy
- High blood pressure
- Mental problems
- Depression
- Tuberculosis
- Anxiety
- Anaemia
- Sickness
- Spasms in the blood vessels

Can food interact with Duodopa?

Duodopa may be taken with or without food. For some patients, Duodopa may not be well absorbed if it is taken with, or shortly after eating protein-rich food (such as meats, fish, dairy products, seeds and nuts). You should consult your doctor if this applies to you.



Important information about Duodopa

Common side effects of levodopa (the active ingredient in Duodopa) include (but are not limited to):

- Uncontrolled movements (dyskinesia); worsening of Parkinson's disease
- Feeling sick; constipation
- Decreased weight
- Anxiety; depression; insomnia
- Feeling dizzy, especially when you stand up due to low blood pressure
- Falls

Common side effects from the intestinal tube include (but are not limited to):

- Infection in the wound from the surgery
- Stomach pain
- Thickened scarring after surgery
- Complications of device insertion like pain in the mouth and throat; swollen stomach; stomach discomfort; pain; throat irritation; injury to the digestive tract; internal bleeding; anxiety; difficulty in swallowing; vomiting; wind; or gas
- Redness of incision site; post-procedural discharge; procedural pain; procedural site reaction

If you have taken too much Duodopa, always contact your doctor or trained healthcare practitioner, or go to your nearest hospital.

The above information does not contain everything there is to know about Duodopa. Please refer to the consumer leaflet that comes with Duodopa for complete product information.

What does it mean?

Levodopa – The active ingredient in many medicines used to treat Parkinson's disease. It is used at all stages of the condition and can relieve many of the symptoms of Parkinson's disease.

Questions?

If you have any questions about your Duodopa treatment, or about topics not covered in this booklet, please contact your healthcare team.

Asking questions may help you get the most out of the Duodopa treatment experience.



Important treatment considerations

To report any side effects for Duodopa please contact AbbVie Biopharmaceuticals GmbH

Riyadh: 00966112180011

Jeddah: 00966126573044

National Pharmacovigilance center – Saudi food and drug authority.

Fax: +966-11-205-7662

Tel: +966-11-2038222

Ext.: 2340-2317-2356-2353-2354-2334

Toll free No.: 8002490000

E.mail: npc.drug@sfda.gov.sa

Website: www.sfda.gov.sa/npc