Duodopa Everyday

The Treatment. The Pump. The Lifestyle.

Abbott
A Promise for Life

Index

Welcome to Your New Life with Duodopa

As you begin to grow accustomed to your Duodopa treatment, you may find yourself encountering a number of practical questions regarding how the medication works, how to operate the pump and what day-to-day procedures you should keep in mind. The following information aims to answer these questions.

To best understand your treatment, however, it is important that you also review the Patient Information leaflet that accompanies your medication, which will provide you with additional useful information regarding:

– What Duodopa is and what it is used for
– Considerations before you take Duodopa
– How to take Duodopa
– Possible side effects
– How to store Duodopa
– Further information

If you have any questions or concerns regarding Duodopa, please contact your physician.

Parkinson's Disease and Duodopa

Getting acquainted with Duodopa and Parkinson's disease is the first step toward returning to a more natural, active lifestyle. When beginning any new medical treatment, it is especially important to refresh your understanding of the disease, its symptoms and various treatment methods.

In this section you'll learn the basic facts about Parkinson's disease and Duodopa. This will help you to understand the fundamentals of how Duodopa works. The more you know, the more comfortable you will feel.

About Parkinson's Disease

Parkinson's disease is a chronic, progressive disorder of the central nervous system that belongs to a group of conditions called motor system disorders. Parkinson's is the direct result of the loss of cells in a section of the brain called substantia nigra, where cells produce dopamine, a chemical messenger responsible for transmitting signals within the brain. Dopamine allows for smooth, coordinated function of the body's muscles and movement. Loss of dopamine causes neurons to fire out of control, leaving patients unable to direct or control their movement in a normal manner. Symptoms usually appear when between 50% and 80% of the dopamine-producing cells are damaged.

The symptoms of Parkinson's, which often appear gradually and increase in severity over time, may include:

- Trembling of hands, arms, legs, jaw and face
- Stiffness of the arms, legs and trunk
- Slowness of movement
- Poor balance and coordination

As symptoms worsen, people with the disease may have trouble walking, talking or performing simple tasks. They are often isolated at home due to unpredictable ON/OFF symptoms, thus leading to a poorer quality of life. They may also have non-motor symptoms such as depression, anxiety, pain, sleep problems or trouble chewing, swallowing or speaking. Parkinson's disease is a progressive disorder, meaning that it tends to worsen with time. Despite extensive research, there is currently no cure for the disease.

The course of Parkinson's varies substantially. Some patients have relatively few troublesome symptoms for many years, while others have especially severe cases that leave them with little or no mobility within just a few years. Scientists have not yet found the exact cause of Parkinson's disease. Most believe

that it is a combination of genetic and environmental factors, but no definitive data exists.

Parkinson's disease affects both men and women in almost equal numbers. There are no significant social, ethnic, economic or geographic variations in prevalence. The average age at onset is 60, although 15% of those diagnosed are under age 50 and in about five to ten percent of patients, the disease starts at age 40. People as young as 30 can also be affected.

Parkinson's disease primarily affects individuals over the age of 50. According to a 2005 estimate, between 4.1 and 4.6 million individuals suffer from the disease worldwide. This number is likely to double by 2030.

Is Parkinson's Disease Hereditary?

Generally, Parkinson's disease is not hereditary. However, a genetic predisposition for a familial form of Parkinson's disease has been established[1]. There have been a small number of cases in which mutations in particular genes have caused Parkinson's disease[2].

Treatment Methods

Most medications used to treat Parkinson's disease can help patients manage many of the symptoms, but they do not stop the disease from progressing. Because each patient reacts differently to each treatment, doctors and patients must work closely together to find a tolerable balance between the drug's benefits and side effects. Medication selection is individualised, taking into consideration the severity of symptoms, age and presence of the other medical conditions. As the disease progresses, drug dosages may need to be modified, medications may need to be changed, and/or medications may be used in combination.

Levodopa was the first drug introduced specifically for Parkinson's disease in 1967. Levodopa, which is converted by the body into dopamine, is still the most commonly administered Parkinson's medication. Carbidopa, which inhibits the enzyme responsible for breakdown of levodopa to dopamine, does not cross the blood-brain barrier. When levodopa is given together with carbidopa, the extracerebral breakdown of levodopa is diminished. This reduces the daily amount of levodopa required for beneficial effects, and thus lowers the incidence of side effects.

Most levodopa therapies are administered through oral medications, which may become less effective over time due to variability in blood levels. In these cases Duodopa and its unique, continuous delivery system may offer improvements in the reduction of some motor side effects.

1. Jain S, Wood NW, Healy DG, Molecular genetic pathways in Parkinson's disease: a review. Clinical Science, 109(4): 355-64, 2005
2. Schapira AHV: Etiology of Parkinson's disease. Neurology 66: 10-23, 2006

What is Duodopa and How Does it Work?

Duodopa is a gel for continuous intestinal administration. It is administered through the use of a special ambulatory pump device. The gel is administered with a pump directly into the duodenum or upper jejunum through a permanent tube via PEG. This tube has an outer transabdominal tube and an inner intestinal tube. An alternative method for inserting the tube is a radiological gastrojejunostomy, which may be considered if percutaneous endoscopic gastrostomy is not suitable for any reason.

After the tube is placed, watch carefully for signs of infection. Complications of tube placement may include abdominal pain and tenderness. Tell your physician if your pain or tenderness worsens, if you develop a fever, chills, nausea and vomiting, have difficulty urinating or develop signs of local infection around the tube.

Mode of Action

Duodopa comprises a concentrated levodopa/carbidopa gel formulation. Levodopa is converted into dopamine in the brain, thereby treating the symptoms associated with Parkinson's. Carbidopa is added to improve the effect of levodopa and reduce its undesirable side effects.

The levodopa/carbidopa gel formulation is administered into the small intestine via a tube from an ambulatory pump fitted with a small cassette containing the gel. As Duodopa infusion is continuous, patients carry the pump with them during waking hours.

The drug cassettes must be kept cold and stored at +2°C to +8°C. They are for single use only and should not be used for longer than one day (up to 16 hours), even if some intestinal gel remains. Please note that in some cases, if medically justified Duodopa may be administered during the night. Please speak to your physician who will be able to advise you.


CADD-Legacy® Duodopa
ON OFF
STOP START
ENTER CLEAR

The Treatment

Duodopa is a levodopa solution in gel form that is administered directly into the duodenum. Because Duodopa is designed to be delivered through a programmable pump, patients can receive a steady and individually adjusted dose.

In this section, you will learn more about the technical and physiological aspects of the Duodopa infusion system, its construction, functions and daily routines.

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

The Principles of Continuous Infusion

The traditional Parkinson's treatment methods when patients are first diagnosed involve pills. At first the pills are taken a few times during the day at scheduled times. As their disease progresses, patients begin to take more pills and take them more frequently, including rescue doses if they have an "off" episode. The progression of Parkinson's disease also affects how the body functions. One affect is the slowing of the digestive tract and erratic emptying of the stomach contents. Because the pills are absorbed in the intestine, the erratic emptying of the stomach can affect the absorption of the pills causing fluctuations of dopamine in the blood. This can result in unpredictable motor function.

Duodopa is designed as a continuous infusion into the intestine for patients with advanced Parkinson's disease. Since Duodopa is infused directly into the intestine, it can be absorbed without the delay of erratic stomach emptying. It is given as a small dose continuously during the day. This means the level of dopamine in the blood is more constant and some of the movement side effects are lower. However, patients taking Duodopa still have good days and bad days; they still have periods of "off" time, and absorption can still be affected by the slowing of the digestive tract.

Duodopa is not a cure for Parkinson's disease. It helps control symptoms, dyskinesias and motor fluctuations, of the disease. Each person has a different response to Duodopa. Some common side effects of Duodopa include involuntary movements and muscle cramps (dyskinesias and dystonias), slow movement, feeling dizzy when you stand up or feeling like you might faint, depression, hallucinations, fatigue, confusion, sleepiness, nightmares, euphoria, loss of memory and other mental problems such as psychotic episodes or elevated mood.

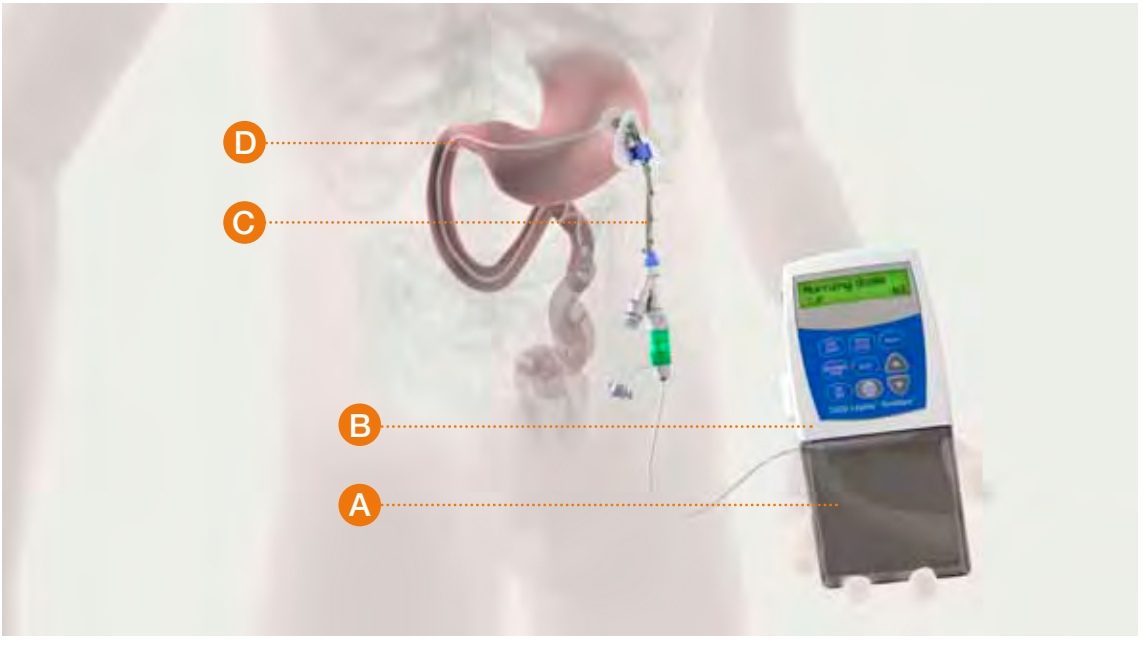
It is possible to take too much medicine. If you have received more Duodopa than you should, speak with your physician or go directly to a hospital. Symptoms of too much

medicine may include: problems opening your eyes, uncontrolled muscle spasms of your eyes, head, neck and body, involuntary movements, and unusually fast, slow or uneven heartbeat. It is also important that you do not completely stop receiving Duodopa or lower your dose until told to do so by your physician, as this could cause serious complications. Your physician will provide instructions regarding any adjustments to your dose and how to administer extra doses at the appropriate time.

The Duodopa Infusion System

The main components of the Duodopa system are the pump, the medication cassette (containing active ingredients), the PEG (outer) tube, the intestinal (inner) tube, and various connections (see image). The PEG tube passes through the wall of the abdomen, while the inner stopper of the PEG tube is attached within the stomach. The inner tube is inserted through the PEG tube, past the pylorus (strong ring of smooth muscle connecting the stomach to the duodenum), and into the small intestine. Duodopa is infused from the cassette, through the intestinal (inner) tube, directly to the small intestine, where absorption is optimal. Some patients using the tube delivery system have reported leaks at the connections and leakage of gastric fluid.

Duodopa System
A. Cassette
B. Pump
C. PEG tube
D. Intestinal tube



Daytime Treatment

The following is a short daily guide explaining how to use, connect, disconnect and clean the pump and tubes. Please note that the pump should run throughout the day, for approximately 16 hours. Since it is not water-proof, however, you will have to disconnect the pump when bathing, swimming or showering. Use care during activity and ensure the pump is secure to prevent dislocation of the tube.

Pump malfunction alarms can result from occlusion, kinking and knotting of the tube.

For further instructions please read the Duodopa patient information leaflet as well as the manual for your particular device. The devices in the following instructions are common examples, however other devices may be used.

Morning Procedure

Getting started

1. Attach a new cassette to the pump and place the pump in your carrying accessory before you put it on.
2. Remove the red protective cap from the cassette tube and open any tube clamps.
3. Connect the cassette tube to the intestinal port on PEG/J.
4. Press and hold the ON/OFF button for 3 seconds to start the pump.
5. Press and hold the STOP/START button for 3 seconds to start the continuous infusion.

Administering a morning dose

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

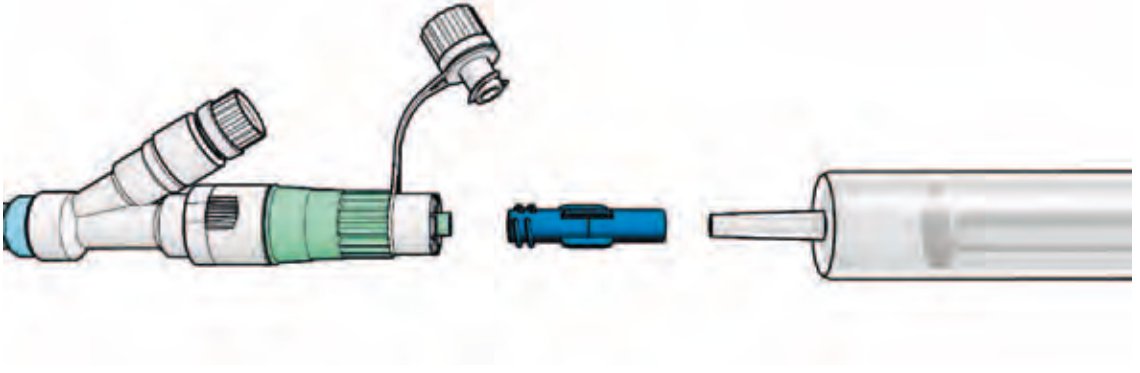
Daily Procedure

Keep the pump running throughout the day. When symptoms of Parkinson's appear administer an extra dose by pressing the EXTRA DOSE button (one touch). Watch for signs of infection, such as redness, tenderness and yellow drainage around the tube insertion site in your abdomen. If you think your tube site is infected, call your physician.

Evening Procedure

Discontinuing the infusion and flushing the intestinal tube

1. Press and hold the STOP/START button for 3 seconds to stop the infusion.
2. Press and hold the ON/OFF button for 3 seconds to turn off the pump.
3. Disconnect the cassette tube from the intestinal port on the PEG/J.
4. Disconnect the cassette from the pump.
5. Use a syringe to flush the intestinal tube with at least 40 ml of drinking water. (Picture)



Stoma Care

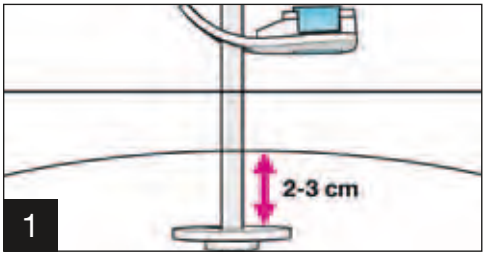
Tube Mobilisation

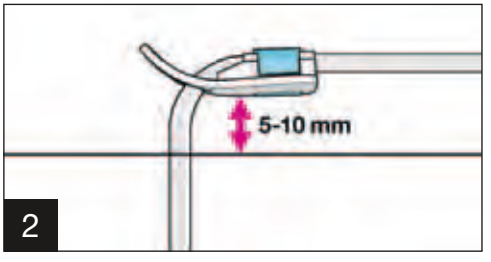
Once the initial wound has healed, this procedure should be performed every 2–3 days. Daily dressing is no longer necessary at this point.

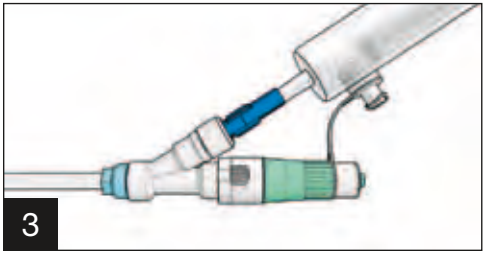
1. If dressing is used, remove the dressing and release the external retention plate to allow free movement of the PEG/J tube.
2. Carefully push the tube 2–3 cm into the stomach and gently pull back until you feel resistance from the internal retention plate. Do not twist the tube. (Picture 1)
3. Inform your physician if there are any signs of complications.
4. Replace the retention plate allowing free movement of 5–10 mm. Apply a Y-dressing if needed. A plaster fixation is recommended for patients experiencing skin or stoma irritation. (Picture 2)

Weekly Procedure

Flush the space between the intestinal tube and PEG tube at least once a week with 40 ml of drinking water. It is preferable to do this every day. (Picture 3)







Pump Alarms

Display	Alarm	Cause	Action
Error	Two-tone alarm signal	An error has occurred.	Contact the hospital/clinical department; the pump needs to be returned to Solvay for service.
No message	Two-tone alarm signal	The batteries have been removed while the pump is running. The pump is now stopped and unpowered. Or the batteries were removed within approximately 15 seconds after stopping the pump.	Install the batteries to silence the alarm.
High pressure	Two-tone alarm signal	The pump has detected high pressure, which may be resulting from a downstream blockage, kink in the tube or a closed tubing clamp.	Remove the obstruction to resume operation. Or press Next or STOP/START to stop the pump and silence the alarm for 2 minutes. Remove the occlusion and restart the pump.
RunResVol Low	Three single signals	The reservoir volume is low.	Change the cassette without delay.

Display	Alarm	Cause	Action
No disposable, Pump will not run	Two-tone alarm signal	You tried to start the pump without a properly connected cassette. A cassette must be properly attached in order for the pump to run.	Press STOP/START or NEXT to stop the alarm signal. Attach the cassette properly and press STOP/START to restart the pump.
Reservoir Volume Empty	Two-tone alarm signal	The reservoir volume has reached 0,0 ml.	Press STOP/START or NEXT to silence the alarm. Change to a new cassette if necessary and reset the reservoir volume.
LowBat	Three two-tone alarm signals every five minutes	The battery power is low but the pump is still operating.	Change the batteries without delay. Press and hold STOP/START button to restart the pump.
Value not saved	No alarm	The input value was not saved, i.e. the key ENTER/CLEAR was not pressed.	Press NEXT to resume programming. Save the value before moving on to the next program window or before starting the pump.

Life with Duodopa

After beginning treatment with Duodopa, many patients find that their lifestyles have changed significantly. Even a partial reduction of motor-related symptoms can lead to a more active life, whether involving work, leisure or simple everyday activities.

However, as with any treatment method, Duodopa is not entirely free of complications. PEG operations, for example, involve invasive surgery, which is a decision that needs careful consideration. In other cases, handling the pump itself may seem frustrating, particularly when inserting new cartridges in the morning, bathing or being seen in public. By discussing your concerns openly with your physician it will become easier to adjust to these changes in lifestyle.

Live an Active Life

As you become familiar with how Duodopa affects you and grow comfortable with the system, you may be able to resume some of the activities you enjoy most. Certain activities away from home, for example, may become possible again. In the beginning, you may want to have a friend accompany you, but over time you'll discover the potential for new challenges that awaits. Do not be discouraged from trying out new activities as you learn and work with your physician and nurse to discover the best dosage for you. Keep safety in mind with new activities and communicate your responses with your physician and nurse.

Sex Life

As with any chronic condition, Parkinson's disease can affect a person's relationship both emotionally and physically. The first and most important step is to try to overcome any anxieties in order to speak openly and honestly with your partner, physician or counsellor. Whether it's a feeling of unattractiveness due to occasional shaking and rigidity, or a partner's concern about causing pain during sex, an open dialogue will go a long way towards reducing unnecessary distress.

It is important to understand the potential medical problems that could impact your sexual relationship. Make a list of questions or concerns you have about having sex with a G-tube and with the pump. Bring this list with you when you see your physician or nurse and discuss with them. Questions may include: Will sex dislodge or cause complications with my tube? Can I stop my infusion to have sex? Is there another Duodopa patient I can talk to about how they have coped with the tube and/or pump? Some patients, for example, use a G-tube holder to hide the tube, while others are more comfortable with the tube as it is. Levodopa can have the side effect of increasing the desire to have sex. It can also have other side effects, such as decreasing the desire to have sex. Depression, which affects a third of all people with Parkinson's, can decrease the libido, as can some antidepressants used to treat depression, This is all the more reason to speak openly with your doctor about any concerns that you believe may be related to Parkinson's or its treatments.

Extra Dose

Initially, you may find yourself wondering about the purpose of the extra dose button on the Duodopa delivery system. If the dosage is continuous, you might ask, then why would I ever need an extra dose? There are several reasons for this. Some, such as before the pump needs to be disconnected, are more obvious. In other cases, such as prior to eating a protein-rich meal or before engaging physical activities, you may also need an extra dose.

Your nurse or physician will work with you to help you understand your Duodopa needs and to assess if an extra dose is needed or if your maintenance dose needs to be adjusted. Too much levodopa can have undesired effects, such as hallucinations. Never change any settings on your pump without being directed by your physician. Duodopa treats the symptoms of Parkinson's and is not a cure. Your disease will progress over time, thus requiring the need for more medication.

Back to Work

As the symptoms of Parkinson's are reduced, you may find that you are better able to manage your work life. For some, this may mean just a partial return of physical capabilities. For others, it could mean a return to full-time work. At first this may be intimidating, so don't be afraid to discuss your challenges with your workmates and colleagues. A bit of assistance and understanding can have long-lasting benefits.

Duodopa and Water

It is critical to remember that the pump is not waterproof, and that you should always disconnect it before taking a shower or going for a swim. An increase from normal daily activity, especially while you are disconnected from the pump, can cause your Parkinson's symptoms to unexpectedly occur. Talk with your physician or nurse on how to manage your dose and symptoms when you need to disconnect the pump. You may need an extra dose before a swim or shower, since some of the symptoms, such as rigidity, can have serious consequences if you are in water.

You may be able to participate in new activities while on treatment with Duodopa. However, it is also important to remember that unexpected symptoms can occur while on or off the treatment. Understanding your disease, how you respond to stress and to Duodopa can help you plan ahead and remain safe.

Showering

Washing or showering with regular soap and water will become possible again two weeks after insertion of the PEG tube. To reduce the risk of stoma infection, it is very important to leave the area clean and dry.

Early in the morning you may find that you feel stiffer than normal. At this point you should connect the tube, take your morning dose and wait approximately 30 minutes until normal mobility returns. Before taking a shower, you may then take an extra dose before disconnecting the pump.

Together with your physician, you will learn over time how long you can stop the pump. This period varies from individual to individual.

Showering Procedure:

1. Press the STOP/START button and then turn off the pump with the ON/OFF button.

2. Disconnect the cassette tube.

3. Put the cap on the PEG tube.

4. Put the cap on the cassette tube.

5. Once the cap is in place,
the tube may hang freely.

6. After showering, be very careful to ensure that the area around the stoma is kept clean and dry.

7. Reconnect the cassette tube and turn on the pump to start the infusion.

Travelling

As you discover how you respond to Duodopa, you may find a greater ability to travel or a greater confindence to do so. It might be a day out with the grandchildren, a weekend visit to old friends or a short business trip. For longer journeys, special assistance may reduce stress when checking in and passing security control at airports.

Be Prepared – Plan Ahead

Naturally, proper travel preparation is important. For example, you should always have levodopa tablets with you. You should also request an extra pump from your local support provider when travelling abroad, to eliminate the risk of malfunction. If you plan to be away for more than one day, be sure to bring extra gel cassettes. Also make sure that you have adequate cool packaging for the journey, and that you have access to refrigeration for the Duodopa cassettes at your destination. The cassettes should always be stored at a temperature of 2–8 degrees Celsius.

If you are travelling abroad, you will need a certificate stating in English that you are on medication and receiving continuous duodenal infusion with Duodopa via the pump. A special certificate for carrying the pump onboard a plane can also be issued if necessary. Note that the pump can be used on airplanes, however it can also be helpful to contact your airline or charter flight provider to inform them of your treatment in advance in order to ensure that your travels go smoothly.

Special Assistance

Most major airports provide a special check-in service to avoid long waits in a queue, as well as help when passing through security control with the pump. Arrive early to the airport, and never hesitate to ask for advice or assistance.

Pack List

- A copy of your Duodopa prescription
- Sufficient Duodopa medication
- Treatment certificate – issued by your doctor
- Patient's pump manual
- Extra tablet medication
- Reserve pump – if travelling abroad
- Adaptors
- Syringes, 20 ml
- Reserve batteries, size AA
- Wound dressing material

Food and Meals

If dining in restaurants has made you feel uncomfortable, you're not alone. When your symptoms are reduced, it can help make the experience of a night out more enjoyable.

Can Food Interact with Duodopa?

Since levodopa is an amino acid (a small protein), absorption into the blood and transport to the brain may be inhibited by the presence of similar amino acids in food. This explains why protein-rich food may reduce the therapeutic effect of Duodopa, making symptoms unexpectedly occur. Not everyone experiences the reduced effect, but some experience considerable difficulties. You may require more Duodopa with a protein-rich meal. Talk to your physician or nurse on how to manage your diet and Duodopa.

How to Store Duodopa

Store in a refrigerator at +2°C to +8°C. Keep the cassettes in the outer carton in order to protect them from light. The drug cassettes are for single use only and should not be used for longer than one day (up to 16 hours), even if some intestinal gel remains. By the end of the storage time the gel might become slightly yellow. This does not influence the effectiveness of Duodopa.

Support 24–7

Local support is available for immediate assistance with problems or issues related to your treatment with Duodopa. For technical questions regarding your Duodopa pump or tubes, related stoma problems or questions related to the medication or dosage, please contact your local Duodopa representative.

Carrying the Pump

At first, you may have a number of questions about handling the pump and PEG tube in your daily life. How do I carry the pump? What does it feel like? Won't people see it? Do I need special clothes? This section offers advice and tips to help answer all of these questions.

The Duodopa pump is designed to provide a steady and continuous dose of Duodopa throughout the day. Although it may take some getting use to, don't be discouraged. Experiment with different carriers and clothing to find the best fit for you.

Stylish Yet Comfortable

At first glance, the infusion pump and its holder may appear cumbersome, so it's natural that such issues crop up. Wearing the pump, however, presents relatively few real drawbacks.

To begin with, the carrying accessories have been tested and refined so that the pump and related items (e.g. spare batteries) are comfortable to wear. Several designs are also available, such as shoulder holsters or hip bags.

Dress Naturally and Attractively

Of course, you can still wear the clothes you feel comfortable in today, but there are some issues that might be worth considering. For example, hanging the pump holster over a cotton vest or top noticeably reduces the pressure felt from the shoulder straps. You may also find your own ways to make the PEG tube less visible to others.

Similarly, jackets or unbuttoned shirts sit casually yet still conceal the presence of the pump. A knitted cardigan can achieve a similar result. Try out a number of garment combinations to find out what feels best.

Wearing the Pump with Style

A few simple tricks can help you find a style that suits both your personality and your daily routines.

Tailoring Proportions

Thinking 'light' and 'dark' can help change the perception of a body's proportions. Darker colours tend to reduce contours while lighter colours do the opposite. If you have lost upper-body weight, light-coloured fabrics will help add bulk. In contrast, a dark skirt or pair of trousers will help slim down broad hips. Patterns function in the much same way as colours, and both provide plenty of opportunity to develop an individual style.

Choose Natural Fabrics

You should look for natural fabrics that are light and comfortable to wear, both next to the skin and combined with other layers of clothing. In order to stay cool, it is important to choose fabrics that are breathable. Unfortunately, many of today's fabrics often comprise cotton mixed with elastane. Elastane doesn't breathe in the same way as cotton, so it tends to make you feel too warm. Synthetics like polyester, rayon and lycra also have this problem.

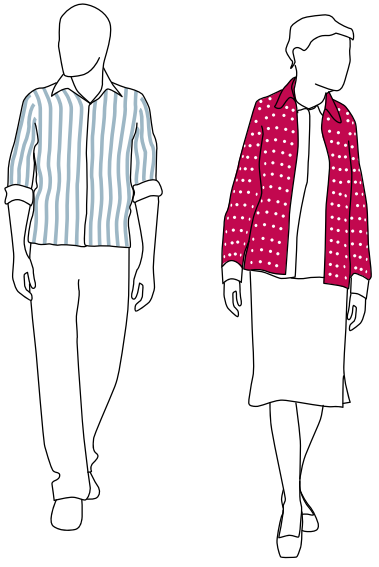
Pure cotton, linen or silk are much better. Most well stocked stores will have a good range of functional yet attractive items to choose from.

Small Adjustments can Make a Large Impact

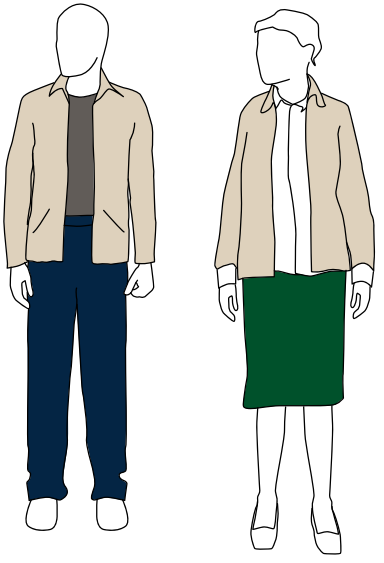
At some stage, you may want to make an adjustment or two. For example, if you have bought a larger-sized jacket or shirt to provide extra room for the pump, you may find the arms too long and the underarm space too large. A skilled tailor will help you solve this.

Bring a Friend

Be sure to take your time and get used to going out shopping. Bring a friend, and with a little help and encouragement you will soon feel comfortable with how you look and how you wear the infusion pump.



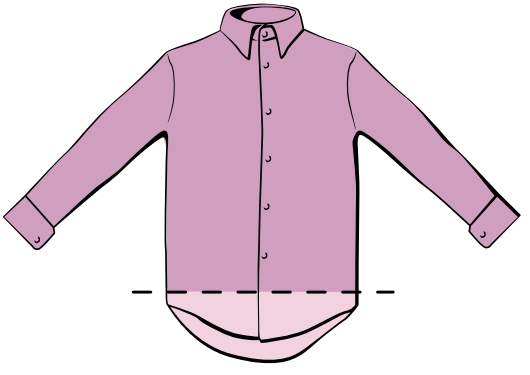
Vertical stripes and discrete patterns promote a slimmer look. Horizontal lines or large, bold patterns broaden and accentuate.



Light-coloured fabrics enhance the body's contours. A beige jacket will 'add weight' to the upper body. A dark skirt will slim down wide hips.

Instead of shortening a large-sized shirt or jacket's sleeves at the bottom, unpick the shoulders, shorten them at the top, and take in the extra space. Lift the bottom hem to complete the job.

A straight-hanging vest or shirt falls naturally along the body's contours, and in an extra-large size will also diminish the presence of both pump and holder. Raising the hemline a few centimetres is a simple yet effective adjustment.



Carrying Accessories

Parkinson's patients have carried the Duodopa pump on a daily basis since duodenal infusion was first prescribed as a routine treatment. Early carrying system designs have proven safe and reliable. Now, as more and more patients gain experience with the pump, new designs with greater comfort and improved ergonomics are being introduced.

When trying out any carrying accessories, place the pump in your carrying accessory before turning it on. Likewise, you must disconnect the pump from the tube before removing the device from its carrying case. Be sure to ensure that the full range of carrying accessories are demonstrated and fitted to you, so that the most suitable options can be provided.

Designed Together with Patients

All Duodopa carrying accessories, including a new waistcoat and a new singlet, are developed together with patients. Based on user trials and feedback from designers, they are crafted to help patients handle the pump with ease and confidence.

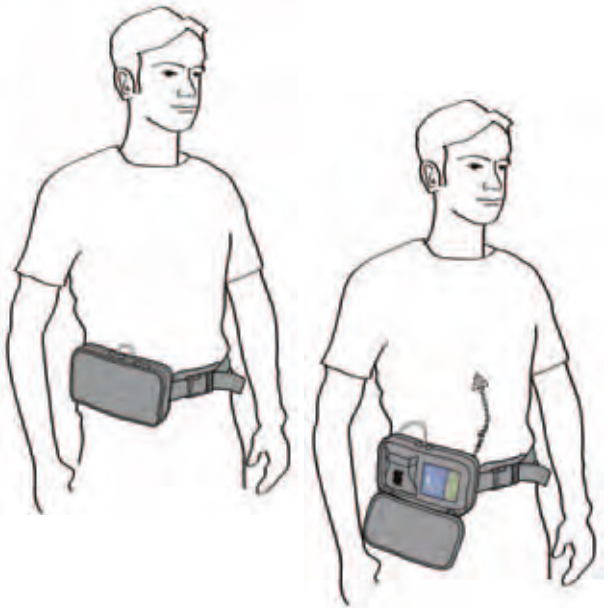
The basic hip bag design is shown to the right. Note the window for the pump control panel, holders for an extra gel cassette and spare batteries, and the easy-to-grip zippers. Soft yet durable materials are used, while sharp seams and edges have been avoided.

One-handed Operation
When fully unzipped, the hip bag pocket opens at just the right angle to allow easy viewing without bending down. The pump can be positioned with its control panel facing you when the pocket is opened – which facilitates one-handed operation – or against the waist with the panel facing outwards.

Easy-to-use Zips
The hip bag's zippers have specially-designed extra-large grips.

Built-in Flexibility
Easy-to-use clasps are fitted to both sides of the hip bag so that you can open or close them on whatever side feels most convenient. The sliding mechanism adjusts smoothly, making it easy to attain the right tension on the belt.

Hip Bag
The hip bag can easily be worn on your left or right hip, or even at the back of your waist, according to what is most comfortable and as much as the length of the tube allows. The hip bag is made from easy-to-clean synthetic leather and is available in black or red.



Waistcoat
The waistcoat is made from high-quality, breathable cotton and is washable at 40 degrees Celsius. Several pockets make it highly versatile for daily activities. The waistcoat's neutral brown colour also makes it easy to combine with other clothing.

Handbag
For a more stylish alternative, female patients may choose the handbag, in black or brown leather. Perfect for a special night out, it is not suitable for daily use. In order to take pressure off the shoulder, be sure the waist belt is fastened securely.

Singlet
The singlet keeps the pump held closely to the body, making it especially well suited for nighttime use or sports activities. It includes many pockets, is made from high-quality bamboo pigue, and can be washed at 40 degrees Celsius.

Pump Holster
The pump holster is ideal for concealing your pump beneath your normal jacket. The bag can also be removed and attached to your normal belt.

Information for the User

Duodopa®, 20 mg/ml + 5 mg/ml, intestinal gel
Levodopa and carbidopa monohydrate

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

If you have any further questions, ask your doctor or pharmacist.

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

If any of the side effects gets serious, or if you notice any side effects not listed in this guide, please tell your doctor or pharmacist.

Index

1. What Duodopa® is and What it is Used for

What Duodopa® is Used for

Duodopa® belongs to a group of medicines for treatment of Parkinsons'disease. Duodopa® contains two medicines in a gel: levodopa and carbidopa monohydrate.

How Duodopa® Works

Levodopa is made into dopamine in the body. Dopamine is present in your brain and in your spinal cord. It helps transfer signals between nerve cells. Too little dopamine causes Parkinson's disease signs like tremor, feeling rigid, slow movements, and problems keeping your balance.

Treatment with levodopa increases the amount of dopamine in your body and so reduces these signs

Carbidopa monohydrate is added to improve the effect and reduce the undesirable effects of levodopa.

2. Before You Take Duodopa®

Do not Take Duodopa® if:

- You are allergic (hypersensitive) to levodopa, carbidopa monohydrate or any of the other ingredients of Duodopa® (listed in Section 6)
- You have an eye problem called 'narrow-angle glaucoma'
- You have severe liver or kidney problems
- You have severe heart disease
- You have a severe irregular heart beat (arrhythmia)
- You have an acute stroke

- You have depression and have recently (within the previous two weeks) been treated with either a medicine called a 'non-selective MAO inhibitor' or a 'selective MAO A inhibitor
- You have a growth in your adrenal gland (adrenocortical tumour)
- You have hormonal problems (such as over-production of adrenocortical or thyroid hormones)

Take Special Care with Duodopa®:

Check with your doctor before or while taking Duodopa® if:

- You have a severe heart disease or have had a heart attack
- You have a lung problem (such as bronchial asthma)
- You have a hormonal problem
- You have depression with suicidal tendencies or any mental problem
- You are taking medicines used to treat depression or other mental disorders (antipsychotics)
- You have an eye problem called 'wide-angle glaucoma'
- You have ever had a stomach ulcer
- You have fits (convulsions)
- You experience failure to resist gambling impulses (pathological gambling), altered sexual interest and behaviour (increased sex drive and hyper-sexuality)
- You have had previous upper abdominal surgery
- You experience a reduced ability to handle the device system (pump or tube connections)
- You experience worsening of execution of movements (bradykinesia) which may indicate a malfunction of the device system

Duodopa® should not be given to children or adolescents under the age of 18 years.

Duodopa® contains a substance called hydrazine, a breakdown product of one of the ingredients (carbidopa). This substance can cause damage to the genetic material which could theoretically lead to cancer. The risk for humans when exposed to hydrazine at recommended doses of Duodopa® is not known.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking Duodopa®.

Taking Other Medicines

Please tell your doctor or pharmacist if you are taking or have recently taken 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 (such as Anticholinergics and Sympathicomimentics)
- Fits (convulsions) or epilepsy
- High blood pressure
- Mental problems
- Depression (such as 'tricyclic antidepressants' or 'non-selective monoamine oxidase inhibitors')
- Tuberculosis (such as isoniazide)
- Anxiety (such as benzodiazepines)
- Anaemia (such as iron tablets)
- Sickness (such as metoclopramide)
- Spasms in the blood vessels (such as papaverine).

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking Duodopa®.

Pregnancy and Breast-feeding

Do not use Duodopa® if:

- You are pregnant or are planning to become pregnant while taking Duodopa®. Unless you have discussed it with your doctor and he or she has clearly told you to do so.
- You are breast-feeding.

Ask your doctor or pharmacist for advice before taking any medicine, if you are pregnant or breast-feeding.

Driving and Using Machines

Duodopa® may cause you to feel dizzy, sleepy or to fall asleep suddenly. Do not drive or use any tools or machines until you are sure how the medicine affects you.

3. How to Take Duodopa®

Always take Duodopa® exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

How Duodopa® is Given

- Duodopa® is a gel which comes in a plastic cassette. These are connected to a pump.
- The pump is connected to a tube which is placed into the small intestine.
- You are given a small dose continuously during day-time. This means that the level of the medicines in your blood is more constant and also some of the movement side effects are lower.

How Much Duodopa® is Given

- Your doctor will decide how much Duodopa® you should be given and for how long
- Usually, a larger morning dose is given using the pump (bolus dose) to quickly reach the correct blood level. After that dose, a continuous (maintenance) dose is given
- If needed, extra doses may be given.

If You Have More Duodopa® than You Should

If you have had more Duodopa® than you should, talk to your doctor or go to a hospital straight away. Take the medicine pack with you. The following effects may happen: problems opening your eye (blepharospasm), uncontrollable muscle spasms affecting your eyes, head, neck and body (dystonia),involuntary movements (dyskinesia),unusual fast, slow or uneven heart beats (arrhythmia).

If You Stop or Lower Your Dose of Duodopa®

It is important that you do not stop having Duodopa® or lower your dose until told to do so by your doctor.

Suddenly stopping or lowering your Duodopa® dose may result in a serious problem called ‘Neuroleptic Malignant Syndrome’. The signs may include:

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

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

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

4. Possible Side Effects

Like all medicines, Duodopa® can cause side effects, although not everybody gets them.

Stop taking Duodopa® and tell your doctor straight away if you notice any of the following side effects – you may need urgent medical treatment:

- Swelling of the face, tongue or throat which may make it difficult to swallow or breathe; nettle type skin rash. These may be signs of an allergic type reaction called 'angioedema'
- Fever, sore throat or mouth or trouble passing water. These may be signs of a white blood cell problem called 'agranulocytosis'. Your doctor will take a blood sample to check the levels of your white blood cells.

The following side effects have also been observed with drugs containing levodopa and carbidopa monohydrate:

Common (affects 1 to 10 users in 100)

- Loss of appetite
- Seeing, hearing or feeling things that are not there (hallucinations), confusion, nightmares, feeling sleepy, fatigue, sleeplessness, euphoria (abnormal elation), loss of memory, and other mental problems such as psychotic episodes or elevated mood
- Depression with very rare thoughts of suicide
- Involuntary movements and muscle cramps (dyskinesias and dystonias), slow movement
- Increased, rapid or irregular heart beat (palpitations)
- Feeling dizzy, especially when you stand up (orthostatic hypotension)
- Feeling like you want to faint and fainting (syncope)
- Feeling sick (nausea), being sick (vomiting), dry mouth, taste disturbance (bitter taste).

Uncommon (affects 1 to 10 users in 1,000)

- Loss of weight, increased weight
- Difficulty in controlling movements, increased tremor of the hands
- High blood pressure
- Hoarseness, chest pain
- Constipation, diarrhoea, increased saliva, difficulty swallowing, wind (flatulence)
- Swelling caused by excess fluid (oedema)
- Muscle spasms
- Dark urine
- Feeling weak, feeling tired or generally unwell.

Rare/Very Rare (affects 1 to 10 users in 10,000)

- Agitation, fear, reduced thinking capacity, being disorientated, increased sex drive, headache
- Numbness, pins and needles, neuroleptic malignant syndrome (see 'If you stop taking Duodopa®' in Section 3 for signs of this effect)
- Change in blood values (shown in blood tests) including agranulocytosis
- Swelling in the vein (phlebitis) or inflammation of the blood vessels

- Feeling very sleepy, falling asleep suddenly. If this happens, you should not drive or operate machinery.
- Blurred vision, double vision or other eye problems
- Shortness of breath, abnormal breathing pattern
- Indigestion (dyspepsia), abdominal pain, dark saliva, hiccups, perforation or bleeding of the stomach or bowel, burning sensation of the tongue, lockjaw, grinding of the teeth
- Skin problems such as itching, rash, facial redness, bleeding, hair loss, dark sweat, increased sweating, tumour of the skin (malignant melanoma)
- Difficulty urinating, urinary incontinence, prolonged and painful erection
- Falling or problems walking
- Fits (convulsions).

Other Possible Side Effects (not known: frequency cannot be estimated from the available data)

Other side-effects that have been reported are pathological gambling (failure to resist gambling impulses despite serious personal or family consequences), increased sex drive and hypersexuality (altered sexual interest and behaviour of significant concern to the patient or to others) These side effects are generally reversible upon reduction of the dose or treatment discontinuation.

The Following Very Common Complications Have Been Reported for the 'Tube Delivery System':

- Leaks at the connections and leakage of gastric fluid
- Blockade of flow of Duodopa® due to occlusion, kinking and knotting of the tubing
- Dislocation of the tube e.g. to the stomach (resulting in decreased treatment response)
- Local infection around the site of tube entering the stomach area (stoma), inflammation of the abdominal cavity (peritonitis), and perforation of adjacent organs, bleeding and abdominal pain, especially during tube placement.

If any of the side effects gets serious, or if you notice any side effects not listed here, please tell your doctor or pharmacist.

5. How to Store Duodopa®

Keep the cassettes with gel out of the reach and sight of children.

Do not use Duodopa® after the expiry date which is stated on the carton label after EXP.

Store in a refrigerator (2°C-8°C).

Keep the cassettes in the outer carton in order to protect from light.

The drug cassettes are for single use only and should not be used for longer than one day (up to 16 hours) even if some intestinal gel remains. By the end of the storage time the gel might become slightly yellow. This does not influence the treatment with Duodopa®.

Do not re-use an opened cassette.

Medicines should not be disposed of via waste-water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Used cassettes should not be re-used but returned to your nearest pharmacy.

6. Further Information

What Duodopa® Contains

- The active substances are levodopa and carbidopa monohydrate. 1 ml of gel contains 20 mg levodopa and 5 mg carbidopa monohydrate.
- The other ingredients are carmellose sodium and purified water.

What Duodopa® Looks Like and Contents of the Pack

Duodopa® is available in cassettes (bags of PVC with a protective hard plastic cover) containing 100 ml with 7 cassettes in each pack. The gel is white to slightly yellow.

Marketing Authorisation Holder

Abbott Products GmbH
Hans-Boeckler-Allee 20
D-30173 Hannover
Germany

Manufacturer

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

This user information was last approved 28th May 2010.

Produced by Animech AB 2011

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Hegenheimermattweg 65, 4123 Allschwil, Switzerland
Duodopa® Homepackage – Everyday. Version no: EN-C02-111027.

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