PART III: CONSUMER INFORMATION

Pr DUODOPA®
levodopa/carbidopa intestinal gel

This leaflet is PART III of a three-part Product Monograph published when DUODOPA was approved for sale in Canada and is designed specifically for consumers. This leaflet is a summary and will not tell you everything about DUODOPA. Contact your doctor or pharmacist if you have any questions about the drug.

Please read this information before you start to take your medication, even if you have taken this drug before. Keep this leaflet with your medication in case you need to refer to it again.

ABOUT THIS MEDICATION

What the medication is used for:

DUODOPA is used to treat patients with advanced Parkinson's disease who are responsive to levodopa treatment.

DUODOPA is a levodopa and carbidopa combination in the form of a gel that is delivered directly into the small intestine. This type of treatment is for use in patients with advanced Parkinson's disease who have severe and disabling motor symptoms that cannot be well controlled with available combinations of medications for Parkinson's disease.

What it does:

DUODOPA helps to reduce disabling motor symptoms of Parkinson's disease and improve the ability to perform activities of daily living.

Levodopa is made into dopamine in the body. Dopamine is naturally present in the brain and spinal cord. In Parkinson's disease there is too little dopamine in the brain, and this can cause symptoms of the disease such as tremor, rigidity/muscle stiffness, slow movements, difficulty keeping one's balance. Treatment with levodopa increases the amount of dopamine in the brain and reduces these and other symptoms of Parkinson's disease.

Carbidopa is used together with levodopa to improve the effect of levodopa and reduce unwanted effects of levodopa, such as upset stomach.

DUODOPA is a gel that is delivered continuously throughout the day with a pump via a tube, directly into the small intestine to provide more constant amounts of levodopa and carbidopa in the body throughout the day.

When it should not be used:

DUODOPA should not be used if you:

- **have a history of complications or problems with your stomach and/or intestines (such as swelling or obstruction) or with your pancreas that prevents placement of the delivery tube (a Percutaneous Endoscopic Gastrostomy [PEG] tube) through the stomach and into the small intestine**
- are allergic to levodopa, carbidopa or any of the other ingredients of DUODOPA
- have narrow-angle glaucoma
- have untreated heart, liver, kidney, lung, blood, or hormonal disease
- have had an acute stroke in the last 6 months
- have been treated during the last two weeks with certain monoamine oxidase (MAO) inhibitor drugs for depression or Parkinson's disease
- have been told you should not take sympathomimetic drugs such as isoproterenol, amphetamines, epinephrine or cough and cold medications containing drugs related to epinephrine
- have suspicious, undiagnosed skin lesions or a history of skin cancer (melanoma)

Be sure to tell your doctor if you have had any of the above.

What the medicinal ingredients are:

levodopa and carbidopa

What the non-medicinal ingredients are:

DUODOPA also contains carmellose sodium and purified water.

What dosage forms it comes in:

DUODOPA is available as a ready-to-use intestinal gel contained in a reservoir bag inside a hard plastic cassette. Each cassette contains 100 mL of DUODOPA. Each 1 mL of DUODOPA contains 20 mg levodopa and 5 mg carbidopa monohydrate.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

Serious and/or life-threatening complications can occur with the surgical procedure that is done to create the small opening in the stomach wall for the intestinal tube and with the long-term use of the intestinal tube. You and your doctor should discuss and weigh these potential harms against the expected benefits of using DUODOPA.

Some people feel sleepy, drowsy, or, rarely, may suddenly fall asleep without warning (i.e., without feeling sleepy or drowsy) when taking levodopa. During treatment with DUODOPA take special care when you drive or operate a machine. If you experience excessive drowsiness or a sudden sleep onset episode, refrain from driving and operating machines, and contact your physician.

Studies of people with Parkinson's disease show that they may be at an increased risk of developing melanoma, a form of skin cancer, when compared to people without Parkinson's disease. It is not known if this problem is associated with Parkinson's disease or the drugs used to treat Parkinson's disease. Therefore, your doctor should perform periodic skin examinations.

Your doctor will need to carefully examine your overall condition to determine if DUODOPA treatment will be suitable for you.

Before treatment with DUODOPA is started, talk to your doctor or pharmacist if you have or have had other medical problems including:

- severe heart disease, irregular heart rhythm or history of heart attack
- severe lung problems, asthma, chronic bronchitis
- glaucoma
- hormonal disturbances
- severe liver or kidney disease
- depression, suicidal tendencies or any mental disorder
- gastric ulcer or previous surgery in the upper part of your abdomen
- a history of convulsions
- allergies to any other medicines, foods, dyes or preservatives

It is also important to tell your doctor before beginning treatment if:

- you drive or operate machinery.
- you or your family member/caregiver notices you are developing urges to gamble, increased sexual urges, excessive eating or spending, and/or other intense urges that could harm yourself or others. These behaviors are called impulse control disorders. Your doctor may need to review your treatments.

Use in children

DUODOPA should not be given to children or people under 18 years.

Pregnancy

If you are pregnant or think you may be pregnant, do not use DUODOPA before consulting your doctor.

Breastfeeding

You should not breastfeed while under treatment with DUODOPA.

INTERACTIONS WITH THIS MEDICATION

Inform your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes prescription drugs and drugs that you can buy without a prescription, including herbal medicines.

In particular, if you are already taking or have recently taken medicines for:

- Parkinson's disease
- severe allergic reactions, asthma, chronic bronchitis, such as sympathomimetics
- heart disease
- anemia, such as iron tablets or multivitamins containing iron
- anxiety, such as benzodiazepines
- depression, such as certain monoamine oxidase inhibitors or tricyclic antidepressants
- fits (convulsions) or epilepsy
- high blood pressure or low blood pressure
- nausea or vomiting, such as metoclopramide
- schizophrenia
- spasms in the blood vessels, such as papaverine
- tuberculosis, such as isoniazid
- cough and cold, such as certain medications that contain epinephrine

Protein rich diets (for example, a lot of meat, poultry or fish) may reduce the beneficial effects of levodopa.

PROPER USE OF THIS MEDICATION

DUODOPA should only be prescribed by a doctor who is experienced in treating patients with Parkinson's disease. Your doctor or trained healthcare professional will guide you on the proper use and administration of DUODOPA.

DUODOPA is delivered into your small intestine by a pump through a tube (called percutaneous endoscopic gastrostomy jejunal tube or PEG-J tube). To use DUODOPA, a surgical procedure is required to create a small opening (called a "stoma") in your stomach wall for the tube to go through. The stoma will heal over time, but will remain open since the tube goes through it. The surgical procedure to insert the tube is performed by a gastroenterologist or other healthcare provider experienced in this procedure.

Before you have surgery, your doctor will usually first insert a temporary tube through the nose into the small intestine for at least a few days, to see if you respond well to DUODOPA treatment and to adjust the dose.

Only the CADD-Legacy DUODOPA pump should be used for administration of DUODOPA.

Usual dose:

Always use DUODOPA exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are not sure. The dose of DUODOPA is different for each patient and may need regular small adjustments, to reach the best dose for your symptoms. Your prescription is programmed into your pump by your doctor/nurse and should only be adjusted by your doctor/nurse if your medication needs change.

Once your pump has been programmed, you will learn how to administer your various doses throughout the day (up to 16 hours). Usually, a larger morning dose is administered with the pump (bolus dose) to quickly reach the correct blood level of levodopa. After that, a lower maintenance dose is given continuously throughout the day until bedtime. If needed, you may give yourself extra doses throughout the day (e.g., prior to eating a protein-rich meal or performing physical activity), following your doctor's recommendations. The pump allows you to independently control drug delivery to meet your actual needs for managing your symptoms.

The tube should be disconnected from the pump at bedtime and flushed daily with room temperature tap water to prevent the tube from becoming blocked.

You should take your usual night-time dose of levodopa/carbidopa tablets (or antiparkinson medication) as prescribed by your doctor.

If medically justified, your doctor may have you use DUODOPA during the night.

It is normal that some gel may remain in your cassette after the 16-hour period. You should never reuse any leftover gel after the 16-hour period. Based on individualized doses and extra dose needs, some patients may require more than one cassette over the 16-hour period.

Use of the CADD-Legacy DUODOPA Pump

Before starting medication delivery, carefully inspect the tubing and connections for kinks or other blockages. An undetected kink or blockage may result in too little or no medication delivery and/or nuisance alarms from the pump, and a return of your Parkinson's disease symptoms.

Prior to attaching the cassette to the pump, inspect the cassette tube. If the tube contents appear milky white, or slightly yellow, the cassette may be used. If the tube contents appear discoloured, other than milky white or slightly yellow, or the container is leaking, do not use the product.

To attach the cassette to the pump:

1. Insert the cassette hooks into the hinge pins on the pump.
2. Place the pump and cassette upright on a firm, flat surface. Press down so the cassette fits tightly against the pump.
3. Insert a coin into the latch, push in, and turn counterclockwise until the line on the latch lines up with the arrow on the side of the pump and you feel the latch click into place.
4. Gently twist, push and pull on the cassette to make sure it is firmly attached. If the cassette is not secure, repeat the procedure.

An improperly attached cassette could result in an error in your dosing.

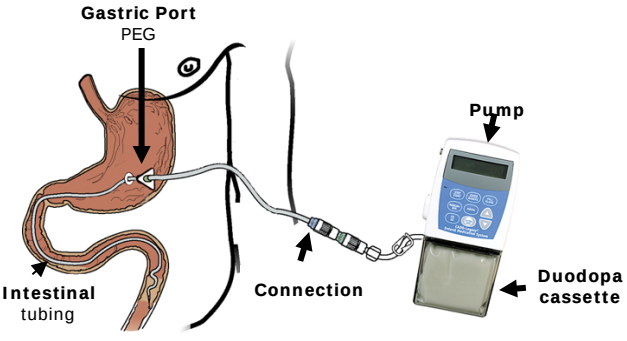
For more details on how to handle the pump, an Instruction Manual is provided with the pump.

To attach the cassette to the PEG-J tube:

1. Remove red protective cap from the cassette tube and open any tube clamps.

2. Connect the cassette tube to the intestinal port of the PEG-J tube. Make sure to twist the cassette tube and not the PEG-J tube.

The following diagram shows how all the components of the DUODOPA system should look when in use.



Abrupt or unintentional stopping of treatment:

Do not change the dosage or stop DUODOPA treatment without talking to your doctor.

- It is important that you do not stop taking DUODOPA or lower your dose until you are told to do so by your healthcare provider. Suddenly stopping or lowering DUODOPA dose may result in a serious, life-threatening problem called Neuroleptic Malignant Syndrome.
- If your symptoms suddenly or slowly become worse, it is possible that the tube in the small intestine is blocked, disconnected or has moved. If this happens, call your doctor immediately.

Intentional stopping of treatment:

If you wish to stop treatment with DUODOPA, talk to your doctor. Your doctor will remove the tube to allow the wound to heal. Treatment will continue with levodopa tablets taken by mouth.

Overdose:

If you have taken more medication than what has been prescribed, contact a hospital emergency department, the nearest Poison Control Centre or your doctor immediately. You may require medical attention even if there are no symptoms.

Care of the CADD-Legacy DUODOPA pump

To clean the pump and accessories, dampen a soft, lint-free cloth with soapy water and wipe the exterior surface of the pump. Do not immerse the pump in water or cleaning fluid. Do not use acetone, solvents or abrasive cleaners. Wipe the surface dry with another soft, lint-free cloth. Allow the pump to dry completely before use.

Maintenance and care of the intestinal tubing:

The external PEG tubing and connectors should be cleaned regularly with warm, soapy water.

The intestinal tube should be flushed with tap water **every night** to prevent blockages.

Do not use your PEG tube to take any substances other than DUODOPA without consulting your doctor.

During the initial test phase DO NOT flush the nasojejunal tube as this can result in too much medication entering your body at one time. If using an extension tube, the extension tube should be removed, capped and placed in the refrigerator each night. The extension tube should not be flushed.

During treatment with DUODOPA, the internal and external tubing will periodically require replacement. Your doctor should regularly assess its functioning.

Maintenance and care of the surgical wound:

The surgical wound should be cleaned and disinfected daily for the first 10 days after surgery. The dressing on your surgical wound should be changed daily for the first three weeks.

After the initial wound healing, the tube opening should be cleaned with soap and water during showers and baths, or every 2 to 3 days. Always make sure that the skin is properly dried afterwards.

Close attention to keeping the wound clean and daily careful inspection of the wound are important for reducing problems. If the tube wound becomes red and swollen or infected, contact your doctor.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, DUODOPA can cause side effects. You may not experience any of them. If you experience any of these side effects, contact your doctor as soon as you can. Many of the side effects can be relieved by adjusting the dose.

Side effects of the medication

Very common side effects (affecting more than 1 user in 10)

- upset stomach, vomiting
- involuntary movements (dyskinesia)
- constipation
- decrease in weight
- falls

Common side effects (affecting 1 to 10 users in 100)

- dizzy spell
- feeling lightheaded or faint after standing
- decreased appetite
- involuntary movements, muscle cramps
- cold, burning, tingling, prickling sensations in the hands, feet, arms or legs
- hallucinations (seeing or hearing things that are not there)
- depression
- anxiety
- diarrhea

Problems related to the surgical procedure

Very common problems

- pain in the abdomen
- redness and swelling around the surgical wound
- excessive tissue growing around the surgical wound
- infection around the tube
- leakage of stomach fluid around the surgical wound

Common problems

- infection and/or irritation in your abdomen
- air or gas in your abdomen
- pain when breathing, feeling short of breath, chest infections (pneumonia)

Uncommon problems

- damage to nearby organs or the intestine
- ulcers or bleeding in your intestine

Pain in the abdomen can be a sign of a serious problem. Pneumonia can become severe or lead to complications that are more serious. Contact your healthcare provider right away if you experience pain in the abdomen, or respiratory problems, or any of the other symptoms described above.

Problems related to the tubing

The tube going to your stomach or intestine can move out of place and possibly damage your intestine. This may cause stomach pain and/or worsening slowness of movement (return of Parkinson's symptoms). If this happens your healthcare provider will have to find the end of the tube and put it back in place. Sometimes this can be serious and may require surgery.

You may develop a blockage in your intestine if the food you eat gets stuck around or at the tip of the tube. The tubing may also cause one part of the intestine to slide into a neighbouring part of the intestine. Both of these tubing problems may cause stomach pain, nausea and vomiting. These problems can be life-threatening, and will require urgent medical treatment (including surgery). Contact your healthcare provider right away if you experience stomach pain, nausea and vomiting.

The most common side effect of problems related to the tubing is worsening or slowness in movement (return of Parkinson's symptoms). Contact your healthcare provider if you experience worsening or slowness in movement.

If any problem occurs with the pump or the tube system, contact your doctor immediately.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom/effect		Talk with your doctor or pharmacist		Stop taking drug and seek immediate medical help
		Only if severe	In all cases	
Common	Changes in mental condition such as hallucinations, depression or worsening of depression	✓		
	A sudden return of your Parkinson's disease symptoms, as this may represent a blockage of the intestinal tube	✓		
	Irregular heartbeat, feeling dizzy or faint when standing up, fainting		✓	
	Pain when breathing, difficult breathing, cough, fever		✓	
Rare	Allergic reaction such as: redness, itching or swelling of your skin, hives; swelling around eyes or lips, swelling of hands, feet or throat; any trouble with breathing not present before using this medicine			✓
	Severe abdominal pain, which may be associated with fever, vomiting, abdominal tenderness, or swelling of the abdomen			✓
	Signs of skin cancer – irregular or new skin lesions		✓	

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom/effect		Talk with your doctor or pharmacist		Stop taking drug and seek immediate medical help
		Only if severe	In all cases	
	Developing urges to gamble, increased sexual urges, excessive eating or spending, and/or other intense urges that could harm yourself or others		✓	
Very Rare	Falling asleep without warning		✓	
	Vomiting blood or notice blood in your stool			✓
	When lowering or stopping medication, you may develop high fever, neurological findings including muscle rigidity, involuntary movements, altered consciousness, mental status changes; more frequent breathing, sweating or dizziness (signs of Neuroleptic Malignant Syndrome)			✓

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

This is not a complete list of side effects. For any unexpected effects while taking DUODOPA, contact your doctor or pharmacist.

HOW TO STORE IT

Store at 2 to 8ºC (in a refrigerator).

Close the carton carefully. DUODOPA is sensitive to light.

Keep out of reach and sight of children.

Use before the expiry date printed on the carton. Cassettes with left-over gel should never be reused.

By the end of the storage time, the gel might become slightly yellow. This does not affect the amount of the drug or the treatment.

REPORTING SIDE EFFECTS

You can report any suspected side effects associated with the use of health products to Health Canada by:

- **Visiting the Web page on Adverse Reaction Reporting (**https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html**) for information on how to report online, by mail or by fax; or**
- **Calling toll-free at 1-866-234-2345.**

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

The most recent version of this document plus the full Product Monograph, prepared for healthcare professionals, can be found at:

www.abbvie.ca

or by contacting the sponsor, AbbVie Corporation, Saint-Laurent, QC H4S 1Z1 at:
1-888-704-8271

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