

## PART III: CONSUMER INFORMATION

### Pr<sup>r</sup>DUODOPA™ (levodopa/carbidopa intestinal gel)

*DUODOPA, for use in the treatment of advanced levodopa-responsive Parkinson's disease -when satisfactory control of severe, disabling motor symptoms cannot be achieved with available combinations of Parkinson medications has been approved with conditions, pending the results of studies to verify its clinical benefit. For more information, contact your healthcare provider.*

#### **What is a Notice of Compliance with Conditions (NOC/c)?**

An NOC/c is a form of market approval granted to a product on the basis of **promising** evidence of clinical effectiveness following review of the submission by Health Canada.

Products approved under Health Canada's NOC/c policy are intended for the treatment, prevention or diagnosis of a serious, life-threatening or severely debilitating illness. They have demonstrated promising benefit, are of high quality and possess an acceptable safety profile based on a benefit/risk assessment. In addition, they either respond to a serious unmet medical need in Canada or have demonstrated a significant improvement in the benefit/risk profile over existing therapies. Health Canada has provided access to this product on the condition that sponsors carry out additional clinical trials to verify the anticipated benefit within an agreed upon time frame.

**Information in this leaflet is intended for patients and/or caregivers. "You" refers to the patient or someone in your care.**

**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 contains a combination of levodopa and carbidopa, which is used to treat the signs and symptoms of Parkinson's disease.

DUODOPA is a levodopa and carbidopa combination in the form of a gel that is administered directly into the small intestine. This type of treatment is mainly for use in patients with advanced Parkinson's disease who do not have satisfactory control of severe, disabling motor symptoms with available combinations of medications for Parkinson's disease.

### **What DUODOPA does:**

Levodopa is transformed in the body to dopamine, a substance that is naturally present in the brain and spinal cord. Dopamine helps nerve cells in the brain that control movement to function properly. Too little dopamine can cause symptoms like those seen in Parkinson's disease, e.g. tremor, rigidity/muscular stiffness, slow movements, difficulty keeping one's balance. Treatment with levodopa increases the amount of dopamine in the brain and reduces these symptoms.

Carbidopa is used in combination with levodopa to ensure that enough levodopa gets to the brain where it is needed. This improves the effect and reduces the undesirable effects of levodopa, such as upset stomach.

DUODOPA is a gel that is administered throughout the day with a pump via a tube, directly into the duodenum (the beginning portion of the small intestine). This means that the two active ingredients are received continuously over the day. Consequently, the amount of drug in the blood becomes more constant and the risk of symptoms such as movement disorders is reduced.

### **When 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 a PEG tube.**
- if you are hypersensitive (allergic) to levodopa, carbidopa or any of the other ingredients of DUODOPA.
- if you have narrow-angle glaucoma
- if you have kidney disease.
- if you have severe heart disease
- if you have severe cardiac arrhythmia (irregular heartbeat)
- if you have had an acute stroke
- if you have been treated during the last two weeks with a MAO-inhibitor, such as for depression or Parkinson's disease
- if you have a tumour of the adrenal gland
- if you have hormonal problems (over-production of the adrenal or thyroid hormones)

- if you have been told you should not take sympathomimetic drugs such as isoproterenol, amphetamines, epinephrine or cough and cold medications containing drugs related to epinephrine

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

**What the medicinal ingredient is:**

The active substances are levodopa and carbidopa.

**What the important nonmedicinal ingredients are:**

Other ingredients are carmellose sodium and purified water.

**What dosage forms DUODOPA comes in:**

Intestinal gel (1 mL DUODOPA contains 20 mg levodopa and 5 mg carbidopa, monohydrate).

100 mL of DUODOPA is contained in a PVC bag, which is kept inside a hard plastic cassette while connected to the portable pump.

**WARNINGS AND PRECAUTIONS**

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 beginning treatment with DUODOPA it is important that you tell your doctor about any other medical problems that you have or have had including:**

- irregular heart rhythm or history of heart attack
- severe lung problems, asthmatic bronchitis
- glaucoma
- hormonal disturbances
- severe liver or kidney disease
- depression or any mental disorder
- gastric ulcer or previous surgery in the upper part of your abdomen
- a history of convulsions
- skin cancer or suspicious skin cancer
- 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
- if you are going to have an operation that requires general anesthesia

**Use in Children**

DUODOPA has not been studied in and should not be given to children or young people under 18 years (due to lack of clinical experience).

**Pregnancy**

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

**Breast-feeding**

You should not breast-feed while under treatment with DUODOPA.

**INTERACTIONS WITH THIS MEDICATION**

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, including drugs that you can buy without a prescription.

It is important to tell your doctor if you are already taking or have recently taken:

- drugs used for the treatment of depression, such as MAO inhibitors or tricyclic antidepressants
- drugs used for the treatment of schizophrenia, tuberculosis, high blood pressure, muscle twitches or epileptic convulsions
- sympathomimetic drugs, such as isoproterenol, amphetamines, or cough and cold medications containing epinephrine
- iron tablets or multivitamin tablets containing iron

You should also tell your doctor about all medications that you are taking for Parkinson’s disease.

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 and who has completed the DUODOPA Education Program. The DUODOPA Education Program provides training to doctors and nurses for the safe and effective use of this treatment. Your doctor or trained health care professional will guide you on the proper use and administration of DUODOPA. Only the CADD-Legacy DUODOPA pump should be used for administration of DUODOPA. The FLOCARE PEG Tube is one of the PEG tubes that may be used with the CADD-Legacy DUODOPA pump. Please see information below for care and maintenance of these components.

Before you have surgery to insert a tube directly into the upper small intestine, 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.

### 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.

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, extra doses may be given, following your doctor's recommendations.

### 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.

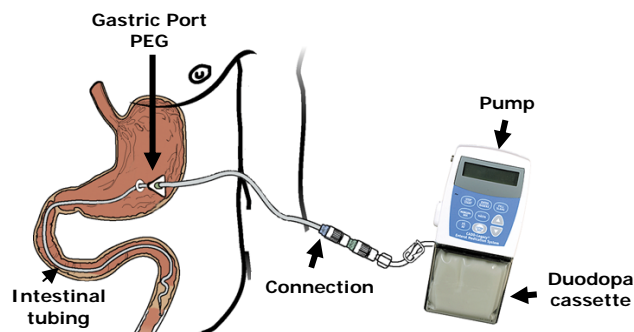
To attach the cassette to the pump:

1. Clamp the tubing.
2. Insert the cassette hooks into the hinge pins on the pump.
3. Place the pump upright on a firm, flat surface. Press down so the cassette fits tightly against the pump.
4. 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.
5. 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.

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.**

- Abrupt interruption of treatment may result in complications.
- 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 too large a dose of the drug always contact your doctor or trained health practitioner, or go to your nearest hospital.

### 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. **During the initial test phase DO NOT flush the naso-intestinal tube as this can result in too much medication entering your body at one time.**

The extension tube should be removed, capped and placed in the refrigerator each night. The extension tube should not be flushed.

When internal and external tubing has been in place for more than a year, your doctor should assess its functioning regularly.

### **Maintenance and Care of the Surgical wound:**

The dressing on your surgical wound should be changed daily for the first three weeks.

The tube opening should be cleaned with soap and water during showers and baths. Make sure that the skin is properly dried afterwards.

If the tube wound becomes red and swollen, or infected, contact your doctor.

**Do not administer any substances other than DUODOPA into your PEG tube without consulting 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 that can be caused by levodopa**

#### Common:

- loss of appetite, upset stomach, vomiting, dry mouth, bitter taste
- hallucinations, confusion, nightmares, sleepiness, fatigue, sleeplessness, feeling sad, exaggerated feeling of happiness, delusions, loss of concentration and memory, agitation
- involuntary movements (dyskinesias), muscle cramps,
- dizziness
- heart palpitations, irregular heartbeat, fainting

#### Uncommon:

- loss of weight, increased weight
- walking disturbances, tremor of the hands
- high blood pressure
- hoarseness, chest pain
- constipation, diarrhea, increased salivation, difficulty swallowing, flatulence
- swelling (edema)
- muscle spasms
- dark-colored urine
- weakness, feeling of discomfort (malaise)

#### Rare:

- fear, reduced thinking, disorientation, increased sexual desire, numbness
- drowsiness and sleepiness (somnia),
- burning/prickling sensation of skin, falling, walking defects, spasm of jaw muscles, headache and convulsions.
- blurred vision, involuntary winking (contraction of eyelid muscle), double vision
- inflammation of veins (phlebitis)
- shortness of breath, abnormal breathing pattern
- indigestion, abdominal pain, dark-colored saliva, teeth grinding, hiccups, burning sensation of the tongue, duodenal (beginning portion of the small intestine) ulceration
- itching, rash, flushing, hair loss, increased sweating, dark colored sweating
- difficulty urinating, inability to control urinating, prolonged and painful erection

#### Very rare:

- falling asleep without warning
- changes in behavior, such as compulsive gambling

### **Side effects caused from the intestinal tube**

The following common complications have been reported for the tube system:

- dislocation of the intestinal tube to the stomach, knot in tube, blockage of tube (which leads to decrease in treatment response)
- local infection around the tube through the abdominal wall
- secretion/leakage or swollen flesh around tube through abdominal wall
- stomach pain

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

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

Symptom/effect	Talk to your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
	Only if severe	In all cases	
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		✓	
Common Irregular heartbeat, feeling dizzy or faint when standing up, fainting		✓	
Common Changes in mental condition such as hallucinations, depression	✓		
Rare Inability to urinate		✓	
Very rare Falling asleep without warning		✓	

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°C-8°C (in a refrigerator).

Close the carton carefully. DUODOPA is sensitive to light.

The cassettes with intestinal gel should be kept out of reach and sight of children.

The drug cassettes are for one time use only and should not be used for longer than one day (up to 16 hours) even if some intestinal gel remains. Use before the expiry date printed on the carton. Used cassettes should not be reused but returned to a designated pharmacy.

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 SUSPECTED SIDE EFFECTS**

To monitor drug safety, Health Canada collects information on serious and unexpected effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug you may notify Health Canada by:

**Toll-free telephone:** 866-234-2345  
**Toll-free fax:** 866-678-6789  
**By email:** [cadtmp@hc-sc.gc.ca](mailto:cadtmp@hc-sc.gc.ca)

**By regular mail:**  
**National AR Centre**  
**Marketed Health Products Safety and Effectiveness Information Division**  
**Marketed Health Products Directorate**  
**Tunney's Pasture, AL 0701C**  
**Ottawa ON K1A 0K9**

*NOTE: Before contacting Health Canada, you should contact your physician or pharmacist.*

**MORE INFORMATION**

This document plus the full product monograph, prepared for health professionals can be found at:

<http://www.hc-sc.gc.ca> (Drug Product Database) or by contacting the sponsor, Abbott Laboratories, Limited, at: 1-800-699-9948

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