What is DUODOPA and what is it used for?
DUODOPA is a combination of levodopa and carbidopa in the form of a gel that is administered directly into the small intestine through a surgically placed tube. This treatment is for use in patients with advanced Parkinson’s disease who do not have satisfactory control of severe, disabling motor symptoms when using available combinations of other medications for Parkinson’s disease.

Health Canada has approved DUODOPA with conditions, under the Notice of Compliance with Conditions (NOC/c) policy. This authorization reflects the promising nature of the clinical evidence, which must be confirmed with further studies. Products approved under Health Canada’s NOC/c policy, have demonstrated promising benefit, are of high quality and possess an acceptable safety profile based on a benefit/risk assessment.

What is Parkinson’s Disease?
Parkinson’s disease is a progressive disease which results from the loss of cells in the brain which produce dopamine. Dopamine is a substance that is naturally present in the brain and spinal cord. Dopamine helps the nerve cells in the brain that control movement to function properly. As levels of dopamine in the brain get lower, the symptoms of Parkinson’s disease appear for example, tremor, muscle stiffness, slow movements and difficulty keeping one’s balance.

How does DUODOPA work?
Levodopa is transformed in the body to dopamine. Treatment with levodopa increases the amount of dopamine in the brain and reduces the symptoms of Parkinson’s disease.

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 upper small intestine. This means that the two active ingredients, levodopa and carbidopa, are received continuously over the day. This allows the amount of drug in the blood to be more constant and the risk of symptoms such as movement disorders is reduced.
What other treatments have been used to treat Parkinson’s disease?
As Parkinson’s disease progresses to more advanced stages, medicines used to treat the early stages of Parkinson’s disease, such as dopamine receptor agonists, may no longer be able to provide satisfactory control of motor symptoms. At this advanced stage there are limited treatment options. The treatments offered will depend on your general health and may include therapy with DUODOPA, brain surgery, or supportive care.

What are the advantages of DUODOPA over oral therapies?
By providing a continuous flow of medication directly to the intestines, where it is absorbed, DUODOPA can help maintain a constant level of levodopa in the blood. Maintaining a constant level of levodopa in the blood may decrease the number of times a patient alternates between stiffness and uncontrolled movements.

Who can be treated with DUODOPA?
DUODOPA is for use in patients with advanced Parkinson’s disease, when treatment with other medicines for Parkinson’s disease no longer provides adequate control of the severe, disabling motor symptoms. The doctor will need to carefully examine your overall condition to determine if DUODOPA treatment will be a suitable treatment for you.

Who should not be treated with DUODOPA?
If you cannot take levodopa/carbidopa (for example, as tablets), because you are hypersensitive (allergic) to levodopa or carbidopa, or because you have certain other medical conditions, 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, DUODOPA should not be used.

What are the side effects and how serious are they?
Side effects that can be caused by the drug
The side effects of DUODOPA are similar to the side effects experienced with tablets of levodopa/carbidopa. The most common serious effects of levodopa include irregular heartbeat and changes in mental condition. Rare cases of allergic reaction or inability to urinate may occur and very rarely patients have been reported to fall asleep without warning.

If you experience any of the following, while using DUODOPA, you should notify your doctor:
- Allergic reaction
- Irregular heartbeat, feeling dizzy or faint when standing up
- Changes in mental condition such as hallucinations or depression
- Inability to urinate
- Falling asleep without warning
**Side effects caused by the intestinal tubing**
The long-term use of DUODOPA requires that a tube be surgically placed into your intestine. Side effects related to the tube and the surgery include movement of the tube back into the stomach, knots or blockages in the tube, infection of the surgical opening, leakage or swollen flesh around the surgical opening, and stomach pain.

It is important to note that in very rare cases, serious complications may occur such as bleeding and damage to the lining of the digestive tract, associated with the surgical procedure. Leakage of fluids from the stomach through the surgical opening can result in inflammation of the lining of the abdomen (peritonitis). Pneumonia may also occur.

One of the most important things for you to do to minimize the risks from side effects, while being treated with DUODOPA, is to contact your doctor or nurse if you notice any symptom that worries you, even if you think it is not connected with this treatment or is not described in any of the information provided to you for DUODOPA.

**What do patients need to know about taking DUODOPA?**
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 on how to use DUODOPA and what information is necessary for you to use this treatment safely and effectively. For patients who will be treated with DUODOPA or who have discussed DUODOPA treatment with their doctor, detailed educational material about DUODOPA will be provided for you and your caregiver.

Because DUODOPA may interact with other medications, including over-the-counter medications, natural health products and multivitamins containing iron, you should inform your doctors about all medications you are taking. You should also inform your doctor about any medical problems you have or have had or if you are going to have an operation that requires general anesthesia.

Because some patients treated with levodopa/carbidopa have been reported to fall asleep without warning, special care should be taken when driving or operating machinery during DUODOPA treatment.

You should not change the dosage or stop DUODOPA treatment without first talking to your doctor. Abrupt interruption of treatment may result in complications.
How is DUODOPA taken?
DUODOPA is available in 100mL cassettes for use with the CADD-Legacy DUODOPA pump. It is administered with the pump, through a tube directly into the upper intestine as shown in the diagram below.

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.

The dose of DUODOPA is different for each patient. The doctor/nurse will determine the best dosing regimen for you and program it into the pump. You will be able to make regular, small adjustments to the dose, as required, to maintain the best control. If bigger dose adjustments are required you should consult with your doctor/nurse.

Where can I learn more about DUODOPA?
For more information about DUODOPA please contact Abbott Products Inc. Medical Information at: 1-800-268-4276.

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