



# Duopa (carbidopa and levodopa) enteral suspension Approved by FDA

Duopa (carbidopa and levodopa) enteral suspension was approved by the U.S. Food and Drug Administration (FDA) in January 2015 as a new treatment option for motor fluctuations for people with advanced Parkinson's disease. Duopa uses a portable infusion pump that delivers carbidopa and levodopa directly into the intestine via a procedurally-placed tube for up to 16 continuous hours.

Do not use DUOPA if you take or have taken a nonselective monoamine oxidase (MAO) inhibitor within the last 2 weeks. Serious side effects include suddenly falling asleep during activities without warning; low blood pressure; hallucinations; unusual urges such as gambling, compulsive eating, compulsive shopping, and increased sex drive; depression and suicide; dyskinesia; progressive weakness, numbness, or loss of sensation in the fingers or feet; heart attack or heart problems; melanoma; and worsening of glaucoma. Suddenly stopping DUOPA can cause serious side effects. Do not stop DUOPA without directions from your healthcare provider. Risks associated with the PEG-J tube include blockage or stopping movement of your stomach or intestines; infection and/or pain in your stomach; stomach or intestine ulcers or bleeding; inflammation of your pancreas; air in your stomach; infection around the tube or in your blood or abdomen; or worsening of Parkinson's symptoms that may be caused by problems with the tube. Tell your healthcare provider right away if you have stomach pain, constipation, nausea or vomiting, fever, or blood in your stool. The most common side effects of DUOPA include swelling of legs and feet, nausea, high blood pressure, depression, and mouth and throat pain.

## Challenges Associated with Advanced Parkinson's Disease

As Parkinson's disease progresses to advanced stages due to loss of dopamine-producing neurons, patients may begin to have "off" episodes.

Additionally, some orally-administered tablets may remain in the stomach too long due to slow, inconsistent emptying of its contents. This can result in a delay in the absorption of the tablet and delayed response to the treatment.<sup>1</sup>

## Another Option for Managing Motor Fluctuations in Advanced Stage Parkinson's Disease

Duopa provides the same active ingredients as oral carbidopa and levodopa, but it is administered uniquely - a suspension that bypasses the stomach and goes directly into the small intestine.

- Duopa is administered directly into the small intestine through a procedurally-placed tube connected to a portable infusion pump, which delivers a 16-hour continuous dose of Duopa.
- A physician will customize the carbidopa and levodopa dose to each individual patient.



Please see accompanying full prescribing information at  
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**Duopa**  
carbidopa/levodopa  
enteral suspension

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The efficacy of Duopa was established in a Phase 3, 12-week, randomized, double-blind, double-dummy, active-controlled, parallel group, multi-center trial. The study was conducted with patients with advanced Parkinson's disease who were levodopa-responsive and had persistent motor fluctuations. A total of 71 patients were enrolled, 33 were randomized to Duopa and 31 to carbidopa and levodopa immediate release tablets.

The improvement in "off" time at week 12 for Duopa was significantly greater ( $p=0.0015$ ) than for oral carbidopa and levodopa immediate release tablets. Additionally, the improvement in "on" time without troublesome dyskinesia was significantly greater ( $p=0.0059$ ) for Duopa than oral carbidopa and levodopa immediate release tablets. The treatment difference for decrease in "off" time was approximately 1.9 hrs. and the treatment in "on" time was approximately 1.9 hrs.

*"Off" time refers to a return of Parkinson's motor symptoms such as rigidity, stiffness, slowness of movement and poor mobility. "On" time refers to periods of motor fluctuation control while on treatment. Patients with advanced Parkinson's disease may fluctuate between periods of "off" and "on" time.<sup>2</sup>*

The most common adverse reactions for DUOPA (incidence at least 7% greater than oral immediate-release carbidopa-levodopa) were: complication of device insertion, nausea, depression, peripheral edema, hypertension, upper respiratory tract infection, oropharyngeal pain, and incision site erythema.

## Important Safety Information <sup>3</sup>

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### Use

DUOPA is a prescription medicine used for treatment of advanced Parkinson's disease. DUOPA contains two medicines: carbidopa and levodopa.

### Important Safety Information about DUOPA (carbidopa and levodopa) enteral suspension

#### What is the most important information I should know about DUOPA?

**Stomach and intestine (gastrointestinal) problems and problems from the procedure you will need to have to receive DUOPA (gastrointestinal procedure-related problems).** Some of these problems may require surgery and may lead to death.

- a blockage of your stomach or intestines (bezoar)
- stopping movement through intestines (ileus)
- drainage, redness, swelling, pain, feeling of warmth around the small hole in your stomach wall (stoma)
- bleeding from stomach ulcers or your intestines
- inflammation of your pancreas (pancreatitis)
- air or gas in your abdomen
- skin infection around the intestinal tube, infection in your blood or abdominal cavity may occur after surgery
- stomach pain, nausea, or vomiting

#### **Tell your healthcare provider right away if you have any of the following symptoms of stomach and intestine problems and gastrointestinal procedure-related problems:**

- stomach (abdominal) pain
- constipation that does not go away
- nausea or vomiting
- fever
- blood in your stool or a dark tarry stool (melanotic stool)

You will need to have a procedure to make a small hole (called a "stoma") in your stomach wall to place a tube in an area of your small intestine. DUOPA is continuously delivered through the tube over 16 hours by a small pump (CADD-Legacy 1400). Before the stoma procedure, tell your healthcare provider if you have ever had a surgery or problems with your stomach.

Talk to your healthcare provider about what you need to do to care for your stoma. After the procedure, you and your healthcare provider will regularly check the stoma for any signs of infection.

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If your tube becomes kinked, knotted, or blocked, this may cause you to have worsening of your Parkinson's symptoms or recurring movement problems (motor fluctuations). Call your healthcare provider if your Parkinson's symptoms get worse or you have slow movement while you are treated with DUOPA.

**Do not take DUOPA if you:**

- are currently taking or have recently taken (within 2 weeks) a medicine called a nonselective monoamine oxidase (MAO) inhibitor. Ask your healthcare provider or pharmacist if you are not sure if you take an MAO inhibitor.

**Before taking DUOPA or before surgery, tell your healthcare provider if you have any medical conditions or have:**

- stomach ulcers or stomach surgery
- low blood pressure (hypotension) or high blood pressure (hypertension); if you feel dizzy or faint (syncope); any heart problems
- feel sleepy, have fallen asleep suddenly during the day (or without warning), or drink alcohol as it may make these problems worse
- depression (feelings of hopelessness or sadness) or any mental problems
- trouble controlling your muscles (dyskinesia)
- nerve problems (peripheral neuropathy)
- skin cancer called melanoma
- increased pressure in your eye (glaucoma)
- are pregnant or planning to become pregnant or are breastfeeding

**Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, herbal supplements.** Using DUOPA with certain other medicines may affect each other and cause serious side effects, including medications for hypertension, MAO inhibitors, antipsychotics, metoclopramide, isoniazid, and iron or vitamin supplements.

Eating high protein foods may affect how DUOPA works. Tell your healthcare provider if you change your diet. Ask your healthcare provider or pharmacist for a list of these medicines or foods if you are not sure.

**How should I use DUOPA?**

**Always take your medicine as directed.** Your healthcare provider will program and show you how to use your pump. Contact your healthcare provider if you are stopping your pump for more than 2 hours outside of your normal daily routine. Always have oral carbidopa-levodopa immediate release (IR) tablets available in case you are unable to take DUOPA.

- **Do not** stop using DUOPA or change your dose unless you are told to do so by your healthcare provider. Tell your healthcare provider if you develop withdrawal symptoms such as fever, confusion, or severe muscle stiffness.
- The DUOPA dose is given continuously over 16 hours in three parts: a morning, a continuous, and extra doses.
- DUOPA comes in a small plastic container (cassette) that you connect to the CADD-Legacy 1400 Pump. Each cassette can only be used **1** time for up to **16** hours. Discard after use.
- Disconnect the pump after the 16 hour dose as directed. Follow your healthcare provider's instructions, including those for the nighttime routine and also refer to the **Patient Instructions for Use**.
- If you stop DUOPA for more than 2 hours during your 16 hour dosing time for any reason, call your healthcare provider and take oral carbidopa-levodopa as prescribed until you are able to restart your DUOPA.
- If you stop DUOPA for less than 2 hours, you do not need to take oral carbidopa-levodopa, but your healthcare provider may tell you to take an extra dose of DUOPA.

**What should I avoid while using DUOPA?**

Do not drive, operate machinery, or do other activities until you know how DUOPA affects you. DUOPA can cause sleepiness and falling asleep suddenly that can happen as late as 1 year after you start your treatment.

**What are the possible side effects of DUOPA?**

**DUOPA may cause serious side effects, including:**

**See "What is the most important information I should know about DUOPA?"**

- **Falling asleep during normal daily activities without warning.** DUOPA may cause you to fall asleep while you are doing daily activities such as driving, which may result in an accident.  
Tell your healthcare provider if you take other medicines that can make you sleepy such as sleep medicines, antidepressants, or antipsychotics.

- **Low blood pressure when you sit or stand up quickly.** Until you know how DUOPA affects you, stand up slowly to help reduce dizziness, nausea, sweating, or fainting.
- **Seeing things, hearing sounds, or feeling sensations that are not real (hallucinations).** Tell your healthcare provider if you have hallucinations.
- **Unusual urges.** Some people taking certain medicines to treat Parkinson's disease, including DUOPA, have reported problems, such as gambling, compulsive eating, compulsive shopping, and increased sex drive. If you or your family members notice that you are having unusual urges or behaviors, talk to your healthcare provider.
- **Depression and suicide.** DUOPA can cause or worsen depression. Pay close attention to sudden changes in your mood, behavior, thoughts, or feelings. Call your healthcare provider right away if you feel depressed or have thoughts of suicide.
- **Uncontrolled sudden movements (dyskinesia).** If you have new dyskinesia, or your dyskinesia gets worse, tell your healthcare provider.
- **Progressive weakness or numbness or loss of sensation in the fingers or feet (neuropathy)**
- **Heart attack or other heart problems. Tell your healthcare provider if you have experienced increased blood pressure, a fast or irregular heartbeat, or chest pain.**
- **Skin cancer (melanoma).** Parkinson's disease may be associated with a higher chance of having melanoma than people who do not have Parkinson's disease. People who use DUOPA should have their skin checked regularly for melanoma by a qualified healthcare professional.
- **Worsening of the increased pressure in your eyes (glaucoma).** The pressure in your eyes should be checked after starting DUOPA.
- **The most common side effects of DUOPA include:** swelling of legs and feet, nausea, high blood pressure (hypertension), depression, and mouth and throat pain.

**Call your healthcare provider or get medical care right away if you have any of the above symptoms. Your healthcare provider will tell you if you should stop treatment with DUOPA and if needed, tell you how to discontinue DUOPA.**

Tell your healthcare provider if you have any side effect that bothers you or does not go away.

These are not all of the possible side effects of DUOPA. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

#### **How should I store DUOPA?**

- Store DUOPA carton in the refrigerator between 36°F to 46°F (2°C to 8°C) and protect from light. Do not freeze.
- Use at room temperature. Take one DUOPA cassette out of the carton and out of the refrigerator 20 minutes prior to use. Use DUOPA before the expiration date printed on the cassette.

To report SUSPECTED ADVERSE REACTIONS, contact AbbVie Inc. at 1-800-633-9110 or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

Please see the [Full Prescribing Information](#), including [Medication Guide](#), for Duopa.

## References

- 1 Gastrointestinal and Urinary Dysfunction. Parkinson's Disease Foundation. 2014. Accessed January 21, 2014 from [http://www.pdf.org/en/spring07\\_gastrointestinal\\_and\\_urinary\\_dysfunction\\_in\\_pd](http://www.pdf.org/en/spring07_gastrointestinal_and_urinary_dysfunction_in_pd)
- 2 Parkinson's Disease: Hope Through Research. National Institute of Neurological Disorders and Stroke. 2014. Accessed January 22, 2014 from [http://www.ninds.nih.gov/disorders/parkinsons\\_disease/detail\\_parkinsons\\_disease.htm](http://www.ninds.nih.gov/disorders/parkinsons_disease/detail_parkinsons_disease.htm).
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