About Advanced Parkinson's Disease and Duopa (carbidopa and levodopa) enteral suspension 4.63 mg/20 mg per mL

What is Parkinson's disease?

- Parkinson's disease is a progressive disease that results from the loss of cells in the brain; these cells produce dopamine, a substance that is naturally present in the brain and helps the nerve cells in the brain that control movement to function properly.[1]
- As levels of dopamine in the brain get lower, motor symptoms of Parkinson's may include tremors, muscle stiffness, slow movements and difficulty maintaining balance.[2]
- An estimated 1 million people in the United States and 7-10 million worldwide live with Parkinson's disease.[3]

What is advanced Parkinson's disease?

- As Parkinson's disease progresses, the amount of dopamine produced and stored in the brain decreases, resulting in motor symptoms, including resting tremor, slowness of movement, postural instability (balance problems) and rigidity.[2]
- As Parkinson's disease progresses to advanced stages, patients may begin to have "off" episodes that may not adequately be controlled with oral medications, making motor symptom control challenging.

What is Duopa (carbidopa and levodopa) enteral suspension?

Duopa is a prescription medicine used for the treatment of motor fluctuations in advanced Parkinson's disease. Duopa contains two medicines: carbidopa and levodopa.

Duopa is not a pill. It's a suspension form of carbidopa and levodopa. Duopa is delivered continuously by a pump through a tube into your intestine for up to 16 hours.

How does Duopa work?

- Duopa provides patients with the same active ingredient as oral carbidopa and levodopa, but in suspension form. It is administered directly into the small intestine, bypassing the stomach, through a procedurally-placed tube connected to a portable infusion pump, which delivers a 16-hour, continuous dose of carbidopa and levodopa.
- By providing a 16-hour, continuous flow of medication directly to the intestines, where it is absorbed, Duopa may help maintain a continuous supply of carbidopa and levodopa.
- A physician must program the pump to customize the dose to each individual patient.

Who should not take Duopa?

- Patients who take a medicine for depression called a nonselective monoamine oxidase (MAO) inhibitor or have taken a nonselective MAO inhibitor within the last 14 days. Ask your doctor or pharmacist if you do not know if you take an MAO inhibitor.

Please see accompanying full prescribing information at
http://www.rxabbvie.com/pdf/duopa_pi.pdf

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Important Safety Information[3]

Use

DUOPA (carbidopa and levodopa) enteral suspension is a prescription medicine used for treatment of advanced Parkinson's disease. DUOPA contains 2 medicines: carbidopa and levodopa.

Important Safety Information

DUOPA is given over a period of 16 hours by a portable pump through a tube that requires a small hole (stoma) be made into the stomach. **Because DUOPA is administered using a PEG-J or naso-jejunal tube**, gastrointestinal complications can occur, some can be serious and require surgery, or be fatal, including blockage of the stomach or intestines, stopping movement through the intestines, infection, inflammation of the pancreas, stomach pain, gas, stomach and intestinal ulcers or bleeding, nausea, and blocking of the tube.

- Patients and healthcare providers need to check the stoma for signs of infection including: drainage, redness, swelling, pain, or feeling of warmth around the small hole in the stomach wall (stoma).

Before the PEG-J procedure, a discussion with the healthcare provider about any previous procedures or problems with the stomach area is required.

DUOPA should not be taken by people who currently take, or have taken within 2 weeks, a medicine for depression called a nonselective monoamine oxidase (MAO) inhibitor.

Suddenly falling asleep without warning during daily activities can occur with medicines containing levodopa, including DUOPA. Prescribers should reassess patients for drowsiness or sleepiness, especially since some of the events occur well after the start of treatment. Patients should not drive or operate heavy machinery until they are sure how DUOPA affects them.

Patients taking DUOPA can experience **low blood pressure when standing or sitting up quickly; fast irregular heartbeat or chest pain; dizziness or fainting.**

Hallucinations (seeing, hearing, or feeling things that are not there) can occur with DUOPA. Patients with a major psychotic disorder should not be treated with DUOPA.

Patients may experience **unusual urges** such as excessive gambling, compulsive eating, compulsive shopping, or increased sexual urges while on DUOPA. Because patients may not recognize these urges as abnormal, it is important for prescribers to ask patients or their caregivers about the development these behaviors.

DUOPA can **cause or worsen depression**. Patients should be counseled to report symptoms of depression or thoughts of suicide.

DUOPA can cause or worsen **uncontrolled sudden movements** (dyskinesia).

Avoid sudden discontinuation or rapid dose reduction of DUOPA, as this may result in a serious, life-threatening condition. Patients should be monitored for these symptoms when DUOPA is discontinued or the dose is lowered.

Neuropathy, a progressive weakness or loss of sensation in the fingers or feet, can occur with DUOPA.

DUOPA can cause **changes in some blood tests**, including certain hormone and kidney blood tests.

People with Parkinson's disease have a **greater risk of melanoma** than the general population. Patients should be monitored for melanoma while on DUOPA.

Worsening of glaucoma may occur.

The **most common adverse events** for DUOPA, with an incidence at least 7% greater than oral carbidopa-levodopa immediate release (CLIR), were (DUOPA vs. CLIR): complication of device insertion (57% vs 44%), nausea (30% vs 21%), depression (11% vs 3%), peripheral edema (8% vs 0%), hypertension (8% vs 0%), upper respiratory tract infection (8% vs 0%), oropharyngeal pain (8% vs 0%), atelectasis (8% vs 0%), and incision site erythema (19% vs 12%).

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

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http://www.rxabbvie.com/pdf/duopa_pi.pdf

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References

1 Parkinson's Diagnosis Questions. The Michael J. Fox Foundation for Parkinson's Research. 2014. Accessed January 31, 2014 from https://www.michaeljfox.org/understanding-parkinsons/i-have-got-what.php#q2.

2 What is Parkinson's disease? Parkinson's Disease Foundation. 2014. Accessed January 31, 2014 from http://www.pdf.org/en/about_pd.

3 Coping with a Diagnosis. Parkinson's Disease Foundation. 2014. Accessed January 20, 2014 from http://www.pdf.org/en/newly_diagnosed_pd.

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