MEDICATION GUIDE
DUOPA (Do-oh-pa)
(carbidopa and levodopa) enteral suspension

Read this Medication Guide before you start using DUOPA and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or treatment.

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

DUOPA can cause serious side effects, including:
• 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 abdominal cavity
  ◦ 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 gastro-jejunostomy tube (called a PEG-J tube) in an area of your small intestine called the jejunum. DUOPA is delivered directly to your small intestine through this tube. Your healthcare provider will talk to you about the stoma procedure. 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 need to regularly check the stoma for any signs of infection.

If your PEG-J 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.

What is DUOPA?
DUOPA is a prescription medicine used for treatment of advanced Parkinson's disease. DUOPA contains 2 medicines, carbidopa and levodopa.

DUOPA should not be given to children (younger than 18 years).

Who should not use DUOPA?
Do not use DUOPA if you:
• take a medicine called a nonselective Monoamine Oxidase (MAO) Inhibitor (such as phenelzine or tranylcypromine) or have taken a nonselective MAO Inhibitor within the last 14 days. Ask your healthcare provider or pharmacist if you are not sure if you take an MAO Inhibitor.

What should I tell my healthcare provider before using DUOPA?

Before you use DUOPA, tell your healthcare provider if you:
• have or have had stomach ulcers or stomach surgery
• have low blood pressure (hypotension) or if you feel dizzy or faint, especially when getting up from sitting or lying down
• have had problems with fainting (syncope)
• feel sleepy or have fallen asleep suddenly during the day
• have or have had depression (feelings of hopelessness or sadness) or any mental problems
• drink alcohol. Alcohol can increase the chance that DUOPA will make you feel sleepy or fall asleep when you should be awake
• have trouble controlling your muscles (dyskinesia)
• have nerve problems (peripheral neuropathy)
• have or have had heart problems, an abnormal heart rate or have had a heart attack in the past
• have or have had a type of skin cancer called melanoma
• have or have had high blood pressure (hypertension)
• have eye problems that cause increased pressure in your eye (glaucoma)
• have a history of attacks of suddenly falling asleep and without warning
• have any other medical conditions
• are pregnant or planning to become pregnant. It is not known if DUOPA will harm your unborn baby
• are breastfeeding or plan to breastfeed. DUOPA can pass into your milk and may harm your baby. Talk to your healthcare provider about the best way to feed your baby if you take DUOPA

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.

Especially tell your healthcare provider if you take:
• medicines used to treat high blood pressure (hypertension)
• medicines used to treat depression called nonselective Monoamine Oxidase (MAO) Inhibitor (such as phenelzine or tranylcypromine) or have taken one within the last 14 days
• dopamine D2 receptor antagonists (antipsychotics or metoclopramide), and isoniazid
• iron or multivitamins with iron

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.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I use DUOPA?
• Use DUOPA exactly as your healthcare provider tells you to use it.
• Your healthcare provider should show you how to use DUOPA before you use it for the first time. Ask your healthcare provider or pharmacist if you have any questions.
• Your prescribed dose of DUOPA will be programmed into your pump by a healthcare provider and should only be changed by your healthcare provider or while you are with your healthcare provider.
• **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.

• Keep a supply of oral carbidopa-levodopa immediate release (IR) tablets with you in case you are unable to give your DUOPA infusion.

• DUOPA is given continuously over 16 hours through a tube that is put into your stomach called a PEG-J. A small pump (CADD-Legacy 1400) is used to move DUOPA from the medication cassette through your PEG-J tube.

• Your DUOPA dose has three parts:
  ◦ a morning dose
  ◦ a continuous dose
  ◦ extra doses

• DUOPA can also be given for a short time (short-term) through a tube put into your nose called a naso-jejunal (NJ) tube.

• The CADD-Legacy 1400 portable infusion pump should be used to give DUOPA through your PEG-J tube. See the **Instructions for Use** that comes with your CADD-Legacy 1400 portable infusion pump for complete instructions on how to use the pump.

• DUOPA comes in a small plastic container (cassette) that you connect to the pump to get your medicine.
  ◦ Each cassette can only be used **1** time. An opened cassette should not be reused.
  ◦ The cassette should not be used for longer than **16** hours.
  ◦ The cassette should be thrown away at the end of the infusion, even if there is some medicine still in the cassette.

• Disconnect the pump from your PEG-J tube after the **16** hour dosing time is finished. Use a syringe filled with room temperature water to flush your PEG-J tube. See the “**Instructions for Use**” for more information about how to flush your PEG-J tube with a syringe.

• After your daily DUOPA infusion, you should take your usual night-time dose of oral carbidopa-levodopa tablets as prescribed.

• If you stop your DUOPA infusion 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 infusion.

• If you stop your DUOPA infusion 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. Sleepiness and falling asleep suddenly caused by DUOPA 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.** DUOPA may cause you to fall asleep while you are doing daily activities such as driving, talking with other people, or eating.
  ◦ You could fall asleep without any warning.
  ◦ Some people using DUOPA have had car accidents because they fell asleep while driving.
    **Do not** drive or operate machinery until you are sure how DUOPA affects you.
    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.** After you have been sitting or lying down, stand up slowly until you know how DUOPA affects you. This may help reduce the following symptoms while you are using DUOPA:
• Seeing things that are not there, hearing sounds or feeling sensations that are not real (hallucinations). Hallucinations can happen in people who use DUOPA. 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 depression or make your depression worse. 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. This may be a sign that your dose of DUOPA or other medicines to control your Parkinson’s disease may need to be adjusted.

• 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. It is not known if the chance of having melanoma is higher because of the medicines used to treat Parkinson’s disease, like DUOPA, or from the Parkinson’s disease. People who use DUOPA should have their skin checked regularly for melanoma by a qualified healthcare professional.

• Abnormal blood tests. DUOPA may cause changes in certain blood tests, especially certain hormone and kidney function blood tests.

• 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
  ◦ 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 in the refrigerator between 36ºF to 46ºF (2ºC to 8ºC). 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 the product at room temperature or you may not get the right amount of medication.

• Protect the cassette from light and keep it in the carton before using.
• Use DUOPA before the expiration date printed on the cassette.

Keep DUOPA and all medicines out of the reach of children.

General information about the safe and effective use of DUOPA.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use DUOPA for a condition for which it was not prescribed. Do not give DUOPA to other people, even if they have the same symptoms that you have. It may harm them.

This Medication Guide summarizes the most important information about DUOPA. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about DUOPA that was written for healthcare professionals.

For more information go to www.DUOPA.com or call 1-844-386-4968.

What are the ingredients in DUOPA?

Active ingredients: carbidopa and levodopa

Inactive ingredients: carmellose sodium and purified water

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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