

## INDICATION

RYTARY (rye-TAR-ee) is a prescription medication that contains carbidopa and levodopa for the treatment of Parkinson's disease, Parkinson's disease caused by infection or inflammation of the brain, or Parkinson's disease resulting from carbon monoxide or manganese poisoning.

### IMPORTANT SAFETY INFORMATION—*for patients*

Do not take RYTARY with an antidepressant medication class known as nonselective monoamine oxidase (MAO) inhibitors because high blood pressure can result.

Taking RYTARY may result in falling asleep while engaged in normal activities, even without warning and as late as one year after starting to take RYTARY. Other sedating medicines and alcohol taken together with RYTARY may have additional sedative effects. Tell your healthcare provider if you have any kind of sleep disorder or are experiencing drowsiness or sleepiness.

Some side effects of taking RYTARY including sleepiness and dizziness may affect your ability to drive or operate machinery. Do not drive a car, operate a machine, or do anything that requires you to be alert until you know how RYTARY affects you.

Do not quickly lower your dose or suddenly stop taking RYTARY without talking to your healthcare provider as this may result in developing serious side effects. Call your healthcare provider immediately if you develop withdrawal symptoms such as fever, confusion, or severe muscle stiffness.

Make sure to tell your healthcare provider if you have any heart conditions, especially if you have had a heart attack or experience irregular heartbeat. Some people with a history of or risk factors for heart disease have experienced heart problems while taking RYTARY.

Some patients taking RYTARY can experience hallucinations (unreal visions, sounds, or sensations) or abnormal thoughts and behaviors (such as excessive suspicion, believing things that are not real, confusion, agitation, aggressive behavior, and disorganized thinking). If you have hallucinations or abnormal thoughts or behaviors, talk with your healthcare provider.

Some patients taking certain medicines to treat Parkinson's disease have intense urges to gamble, increased sexual urges, other intense urges, and the inability to control those urges. If you or your family members notice that you are developing unusual urges or behaviors, talk to your healthcare provider.

Tell your healthcare provider if abnormal involuntary movements appear or get worse during treatment with RYTARY.

Tell your healthcare provider if you have ever had an ulcer, because RYTARY may increase your chances of having bleeding in your stomach.

Tell your healthcare provider if you have glaucoma, because RYTARY may increase the pressure in your eyes.

Parkinson's disease patients are at an increased risk of developing melanoma, a form of skin cancer. See your healthcare provider for regular skin examinations when taking RYTARY.

The most common side effects that may occur with RYTARY include nausea, dizziness, headache, sleeplessness, abnormal dreams, dry mouth, abnormal involuntary movements, anxiety, constipation, vomiting, and low blood pressure upon rising. Rise slowly after sitting or lying down for a prolonged period.

Tell your healthcare provider if you have any side effects while taking RYTARY. He or she can make adjustments that may reduce those effects.

Notify your healthcare provider if you become pregnant or intend to become pregnant during therapy or if you intend to breast-feed or are breast-feeding an infant.

Make sure you tell your healthcare provider about all of the prescription and non-prescription medications you take, including supplements, and especially those for Parkinson's disease, heart disease, blood pressure, abnormal thoughts, tuberculosis, and sleep problems, and supplements containing iron. Do not take other carbidopa-levodopa preparations with RYTARY without consulting your healthcare provider.

Be sure to take your medicine as instructed. You may take RYTARY with or without food. However, taking RYTARY with food may decrease or delay its effect. For this reason consider taking the first dose of the day about 1 to 2 hours before eating. Swallow RYTARY whole; do not chew, divide, or crush. If you have difficulty swallowing, the capsule may be carefully opened and the entire contents sprinkled on a small amount of applesauce (1 to 2 tablespoons) and taken immediately.

Note: The above information for patients being treated with RYTARY is intended to aid in the safe and effective use of this medication. It is not a disclosure of all possible adverse or intended effects. Please read the Full Prescribing Information and talk to your healthcare provider for more information concerning your treatment if you have questions.

**You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088. To report SUSPECTED ADVERSE REACTIONS contact Impax Laboratories, Inc. at 1-877-994-6729.**

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