



# Starting your patients on treatment

A digital educational tool to help you have more productive conversations with your patients.

Please see Important Safety Information throughout this presentation and [full Prescribing Information](#).

**RYTARY<sup>®</sup>**  
(carbidopa and levodopa)  
EXTENDED-RELEASE CAPSULES  
23.75 mg/95 mg • 36.25 mg/145 mg  
48.75 mg/195 mg • 61.25 mg/245 mg

# Starting your patients off right with RYTARY

HCP

This tool is designed to help you educate and support patients as they begin treatment with RYTARY and will answer the following questions:

- How does RYTARY work?
- What makes RYTARY different?
- How can RYTARY help?
- How is RYTARY taken?
- What support is available?

Inside, you'll also find talking points to guide your discussion. During these conversations, we suggest:

- Keeping the dialogue open and interactive
- Asking patients to repeat what they just learned for greater retention

## INDICATION

RYTARY is a combination of carbidopa and levodopa indicated for the treatment of Parkinson's disease, post-encephalitic parkinsonism, and parkinsonism that may follow carbon monoxide intoxication or manganese intoxication.

## IMPORTANT SAFETY INFORMATION

### CONTRAINDICATIONS

RYTARY is contraindicated in patients who are currently taking or have recently (within 2 weeks) taken a nonselective monoamine oxidase (MAO) inhibitor (e.g., phenelzine, tranylcypromine). Hypertension can occur if these drugs are used concurrently.

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# How does RYTARY work?

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- RYTARY contains a unique combination of time-released CD/LD beads
- Together, these beads allow RYTARY to work quickly and then keep working for up to 4 to 5 hours, which may reduce “off” time

Every RYTARY capsule contains a unique combination of time-released CD/LD beads

1/3 of the capsule contains IR beads that **start working quickly**

1/3  
IMMEDIATE  
RELEASE

2/3 of the capsule contains extended release beads that, when combined with the IR beads, **work up to 4 to 5 hours**

2/3  
EXTENDED  
RELEASE

## IMPORTANT SAFETY INFORMATION (continued)

### WARNINGS AND PRECAUTIONS

**Falling Asleep During Activities of Daily Living and Somnolence:** Patients treated with levodopa (a component of RYTARY) have reported falling asleep while engaged in activities of daily living, including the operation of motor vehicles, which sometimes resulted in accidents. Although many of these patients reported somnolence while on levodopa, some perceived that they had no warning signs (sleep attack), such as excessive drowsiness. Some of these events have been reported more than 1 year after initiation of treatment.

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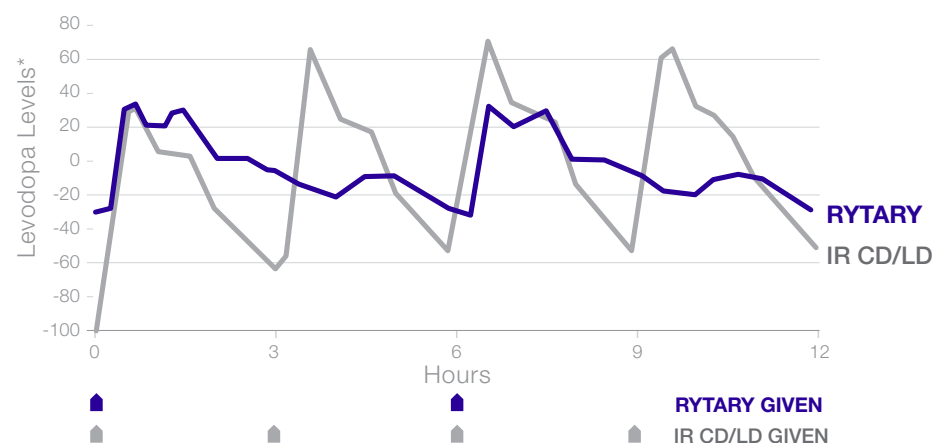
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# What makes RYTARY different?

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- This chart illustrates projected levodopa levels in healthy volunteers over the course of 12 hours
- With IR CD/LD, it looks like a series of peaks and troughs, because IR CD/LD only provides an immediate dose of medication
- With RYTARY, each dose of levodopa is delivered quickly, and then the levels are extended over a longer period of time

RYTARY can fill in the troughs and smooth out the peaks created by IR CD/LD



RYTARY was given every 6 hours while IR CD/LD was given every 3 hours.

This chart is based on a single-dose study of RYTARY in healthy volunteers; PK level was projected over 12 hours.

\*Percentage deviation from LD average concentration at steady state.

## IMPORTANT SAFETY INFORMATION (continued)

**Falling Asleep During Activities of Daily Living and Somnolence (continued):** Advise patients of the potential to develop drowsiness and specifically ask about factors that may increase the risk for somnolence with RYTARY, such as concomitant sedating medications or the presence of a sleep disorder. Consider discontinuing RYTARY in patients who report significant daytime sleepiness or episodes of falling asleep during activities that require active participation. If a decision is made to continue RYTARY, patients should be advised not to drive and to avoid other potentially dangerous activities that might result in harm if the patients become somnolent.

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# How can RYTARY help?

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- In a head-to-head study vs IR CD/LD, RYTARY demonstrated 2X the reduction in “off” time during waking hours

Taking RYTARY may result in:

**2X reduction**  
in “off” time  
compared with immediate-release carbidopa/levodopa (IR CD/LD)

In a clinical study, people with advanced Parkinson’s disease taking RYTARY experienced a 13.1% reduction in “off” time during waking hours (compared with only 6.2% for people taking IR CD/LD)\*;  $P < 0.0001$  vs IR CD/LD

- RYTARY at study start and study end†: 36.9% to 23.8%
- IR CD/LD at study start and study end†: 36.0% to 29.8%

\*“Waking hours” is a term used to describe the hours during a day in which you are awake. The primary measurement in this study was the percentage of “off” time during waking hours.

†Study end = Week 22 or early termination.

## IMPORTANT SAFETY INFORMATION (continued)

**Withdrawal-Emergent Hyperpyrexia and Confusion:** A symptom complex that resembles neuroleptic malignant syndrome (characterized by elevated temperature, muscular rigidity, altered consciousness, and autonomic instability), with no other obvious etiology, has been reported in association with rapid dose reduction of, withdrawal of, or changes in dopaminergic therapy. Avoid sudden discontinuation or rapid dose reduction in patients taking RYTARY.

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# How is RYTARY taken?

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- Your dose of RYTARY will be different than your dose of IR CD/LD
- Your dose of RYTARY may need to be adjusted
- Keep track of your progress and be open and honest about how you're doing, especially if you experience:
  - Too much “off” time
  - A delay in “on” time
  - Too much dyskinesia
- Never adjust your dose or stop taking RYTARY on your own

## RYTARY is not a one-dose-fits-all type of medication

As you begin your RYTARY treatment plan, here are some key points to keep in mind:



Your dose of RYTARY will not be the same as your dose of IR CD/LD



Your dose may need to be adjusted



Finding the right dose may take time

This is why it's important to be open and honest about your progress, especially if you're experiencing:

Too much “off” time

A delay in “on” time

Too much dyskinesia

## IMPORTANT SAFETY INFORMATION (continued)

**Cardiovascular Ischemic Events:** Cardiovascular ischemic events have occurred in patients taking RYTARY. In patients with a history of myocardial infarction who have residual atrial, nodal, or ventricular arrhythmias, cardiac function should be monitored in an intensive cardiac care facility during the period of initial dosage adjustment.

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# How is RYTARY taken?

- Take your doses of RYTARY with or without food, and consider taking your first dose of the day 1 to 2 hours before eating
- Swallow RYTARY capsules whole, or sprinkle the entire contents of both halves of the capsule on a small amount of applesauce (1 to 2 tablespoons) and consume the mixture immediately
- Don't chew, cut, or crush RYTARY capsules

Like with any medication, it's important that you understand how to take it. For example:

**DO**

Take your doses of RYTARY with or without food, and you may want to consider taking your first dose of the day 1 to 2 hours before eating.

**DO**

Swallow RYTARY capsules whole. Or, you may sprinkle the entire contents of both halves of the capsule on a small amount of applesauce (1 to 2 tablespoons) and consume the mixture immediately.

**DON'T**

Chew, cut, or crush RYTARY capsules.

You may also want to avoid eating foods that are high in fat, calories, and/or protein, because these types of foods may affect how your body absorbs RYTARY.

## IMPORTANT SAFETY INFORMATION (continued)

**Hallucinations/Psychosis:** There is an increased risk for hallucinations and psychosis in patients taking RYTARY. Because of the risk of exacerbating psychosis, patients with a major psychotic disorder should not be treated with RYTARY. In addition, medications that antagonize the effects of dopamine used to treat psychosis may exacerbate the symptoms of Parkinson's disease and may decrease the effectiveness of RYTARY.

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# What support is available?

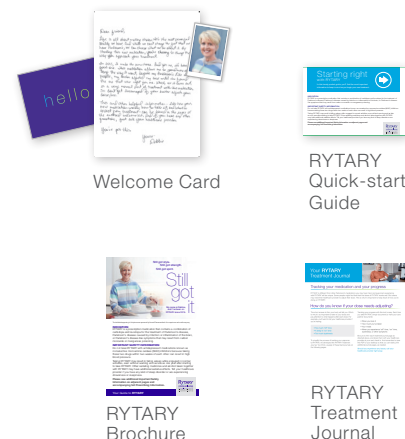
HCP

- The makers of RYTARY have developed a comprehensive Welcome Kit to help you learn about your new medication, how to track your response to treatment, and how to stay on top of your dosing schedule
- Remember, you're not alone in this journey, and I encourage you to reach out to me with any questions or concerns you might have

## The RYTARY Welcome Kit

**A collection of resources designed to support you in your journey**

The Welcome Kit contains the following materials:



## IMPORTANT SAFETY INFORMATION (continued)

**Impulse Control/Compulsive Behaviors:** Case reports suggest that patients can experience intense urges to gamble, increased sexual urges, intense urges to spend money, binge eating, and/or other intense urges, and the inability to control these urges while taking one or more of the medications, including RYTARY, that increase central dopaminergic tone and that are generally used for the treatment of Parkinson's disease. Because patients may not recognize these behaviors as abnormal, specifically ask patients or their caregivers about the development of new or increased urges and consider a dose reduction or stopping the medication if a patient develops such urges while taking RYTARY.

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## IMPORTANT SAFETY INFORMATION (continued)

**Drug Interactions:** Monitor patients taking selective MAO-B inhibitors and RYTARY. The combination may be associated with orthostatic hypotension. Dopamine D2 receptor antagonists (e.g., phenothiazines, butyrophenones, risperidone, metoclopramide), isoniazid, and iron salts or multivitamins containing iron salts may reduce the effectiveness of RYTARY.

The most common adverse reactions (incidence  $\geq$  5% and greater than placebo) in early Parkinson's disease are nausea, dizziness, headache, insomnia, abnormal dreams, dry mouth, dyskinesia, anxiety, constipation, vomiting, and orthostatic hypotension; and in advanced Parkinson's disease are nausea and headache. Reported adverse reactions identified during post approval use of RYTARY include suicide attempt and ideation.

### OVERDOSAGE:

The acute symptoms of levodopa/dopa decarboxylase inhibitor overdose can be expected to arise from dopaminergic overstimulation. Doses of a few grams may result in CNS disturbances, with an increasing likelihood of cardiovascular disturbance (e.g., hypotension, tachycardia) and more severe psychiatric problems at higher doses.

## GENERAL DOSING AND ADMINISTRATION INFORMATION:

See Full Prescribing Information for instructions for starting levodopa-naïve patients on RYTARY and converting patients from immediate-release carbidopa and levodopa to RYTARY (Table 1).

Avoid sudden discontinuation or rapid dose reduction of RYTARY.

The dosages of other carbidopa and levodopa products are not interchangeable on a 1:1 basis with the dosages of RYTARY.

RYTARY should not be chewed, divided, or crushed and should be swallowed whole with or without food. For patients who have difficulty swallowing, the capsule can be opened and the entire contents can be sprinkled on a small amount of applesauce and consumed immediately.

***To report SUSPECTED ADVERSE REACTIONS, contact Amneal Specialty, a division of Amneal Pharmaceuticals LLC at 1-877-835-5472 or the FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).***

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