myRytary®

Fax to 1-844-IMPAX08 (467-2908)
Questions? Call our toll-free hotline
1-844-IMPAX2U (467-2928)
MONDAY-FRIDAY, 8AM-8PM EST

Rytary®
(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

MyRYTARY is a personalized program helping patients connect to access support, affordability support, case management, and educational resources. Here's how to get started.

PATIENT

- ❑ Complete all fields on the **green form (p. 2)** either electronically or by hand (using black ink).
- ❑ **Don't forget to sign** where indicated:
- ❑ Return the form to your prescriber. He or she will take care of the rest.

PRESCRIBER

- ❑ Complete all fields on the **blue form (p. 4)** either electronically or by hand (using black ink). Then sign it.
- ❑ Ask your patient to complete and sign the **green form** either electronically or by hand (using black ink).
- ❑ Collect all necessary clinical documentation.
- ❑ **Fax both forms to 1-844-IMPAX08 (467-2908)**.

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WHAT HAPPENS NEXT?
A MyRYTARY Case Manager will call you soon to:

- Help you navigate and understand the Payer Approval process
- Suggest options that may make RYTARY more affordable
- Answer questions about RYTARY
- Provide ongoing support throughout your treatment journey

These calls will appear on Caller ID as 1-844-IMPAX2U (467-2928).

WHAT HAPPENS NEXT?
We will begin a benefits investigation as soon as we receive your fax of the completed green and blue forms. We may contact your office via phone or fax to:

- Obtain any missing and/or incomplete information
- Request additional information for prior authorization, if necessary
- Clarify the prescription

Let your patient know that a MyRYTARY Case Manager will be calling them soon to:

- Help in navigating and understanding the Payer Approval process
- Suggest options that may make RYTARY more affordable
- Answer questions about RYTARY
- Provide ongoing support throughout their treatment journey

These calls will appear on Caller ID as 1-844-IMPAX2U (467-2928).

Mail us at
Patient Support
2250 Perimeter Park Drive
Suite 300
Morrisville, NC 27560

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PATIENT INFORMATION

Name: (First) _____ (Last) _____

DOB: (mm/dd/yyyy) _____ Gender: ☐ Male ☐ Female

Address: _____

City: _____ State: _____ ZIP Code: _____

Home Phone: _____ Mobile Phone: _____

Email: _____

Preferred Pharmacy: _____

Preferred Pharmacy Phone Number: _____

Preferred Language: ☐ English ☐ Spanish ☐ Other: _____

Preferred Contact Method (If Available): ☐ Phone ☐ Email ☐ Text Message

If you are unavailable when we call, may we leave a message including the prescription name? ☐ Yes ☐ No

Are you a United States resident? ☐ Yes ☐ No

PATIENT AUTHORIZATION FOR USE/DISCLOSURE OF HEALTH INFORMATION

I understand that I am submitting this Patient Enrollment Form to Impax Laboratories, Inc. and to Impax Agents, or my doctor's office is submitting it on my behalf, to see if I qualify for financial assistance and other services to help me find possible sources of financial assistance, or to assess whether I have insurance coverage for RYTARY®. I understand that before you can assist me, you may need to collect, use, and disclose information about me that is requested on this application, including my Protected Health Information ("PHI" as defined by the Health Insurance Portability and Accountability Act of 1996 as amended ("HIPAA")), my financial information and other personal information about me (collectively "My Personal Information"). PHI that will be disclosed includes any information related to my healthcare insurance or plan benefits, including coverage limits and other information related to my health.

I understand that by signing this form, I am permitting my doctor's office, my healthcare plan or insurance company, my pharmacies, as well as other entities that may hold my PHI, to release My Personal Information, including my PHI, to Impax and to Impax Agents who may be assisting with the administration of the patient assistance programs. I understand that to provide the services for the patient assistance programs, Impax and the Impax Agents may need to further disclose My Personal Information to and communicate with other Impax Agents involved with patient assistance programs, my doctor's office or other health care providers, including my insurance company or health plan or pharmacies.

I further understand that Impax and the Impax Agents will use My Personal Information in the following manner: (1) to review my application for patient assistance programs; (2) to help determine my healthcare plan coverage for RYTARY and other procedures as part of my therapy by conducting reimbursement verification and obtaining payment from my Health Plan(s); (3) to contact me or my doctor's office or other of my health care providers, as necessary, to conduct such services; and (4) providing me with educational support services by mail, text, messaging, email and/or telephone and (5) referring me to, or determining my eligibility for, other programs, foundations or alternative sources of funding or coverage to help me with the cost of RYTARY®.

I understand that I do not have to sign this consent, but if I do not, the MyRYTARY® Patient Support Program cannot provide the described services. I understand that I might need to pay for RYTARY® on my own, whether I sign this form or not. I understand that once my doctors, healthcare plan, pharmacies, or others who have my Protected Health Information release it, my information may no longer be covered by Federal Privacy Law (for example, HIPAA).

This authorization allows those who rely on it to release my Protected Health Information for 10 years from the date I have signed it. I understand that I can withdraw it at any time by sending a written request to the mailing address below. My withdrawal goes into effect once it is received by the program. I also understand that by withdrawing, I may not receive or I may stop receiving the services provided under this program.

SIGN HERE Patient's Signature: _____ Date of Signature: _____

Printed Name: _____

Parent/Guardian/Legal Representative's Signature: _____ Date of Signature: _____

Printed Name: _____ Relationship to Patient: _____

PATIENT AUTHORIZATION TO DISCLOSE TO OTHERS

In order to protect your privacy we will not share your information with anyone you do not authorize. Please list names of anyone you would like to have access to your medical information. Only the names listed below will be given any information regarding your medical condition.

I hereby authorize TrialCard, its staff and providers to disclose my protected health information to the following representative:

Name: _____ Phone Number: _____

Relationship to Patient: _____

Patient's Signature: _____ Date of Signature: _____

Please see Important Safety Information on following page, and Full Prescribing Information at http://documents.impaxlabs.com/rytary/pi.pdf.
For more information, visit RYTARY.COM and/or talk to your healthcare provider.

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INDICATION

RYTARY is a prescription medication that contains a combination of 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

Do not take RYTARY with antidepressant medications known as nonselective monoamine oxidase (MAO) inhibitors because taking these two drugs within two weeks of each other can result in high blood pressure.

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.

Talk to your healthcare provider before you lower the dose or stop taking RYTARY, as this may result in 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.

In post-marketing use, some patients taking RYTARY have experienced suicidal thoughts or have attempted suicide. A causal relationship has not been established. Tell your healthcare provider if you have thoughts of suicide or have attempted suicide.

Tell your healthcare provider if you have any side effects while taking RYTARY. He or she can make adjustments that may reduce these 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, twist apart both halves and sprinkle the entire contents of both halves of the capsule on a small amount of applesauce (1 to 2 tablespoons). Consume the mixture immediately. Do not store the drug/food mixture for future use.

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.

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. To report SUSPECTED ADVERSE REACTIONS, contact Impax Laboratories, Inc. at 1-877-994-6729.

Please read the Full Prescribing Information. For more information, go to RYTARY.com and/or talk to your healthcare provider.

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PRESCRIBER INFORMATION

Prescriber Name: (First) _____ (Last) _____

State License #: _____ NPI # : _____

Prescriber Phone: _____

Name of Facility: _____

Facility Street Address: _____

City: _____ State: _____ ZIP Code: _____

Office Contact Name: (First) _____ (Last) _____

Title/Position: _____

Office Contact Phone: _____ Fax: _____

Preferred Contact Method (If Available): ☐ Phone ☐ Fax ☐ Email

Email: _____

PATIENT INSURANCE INFORMATION

Fax a copy of the front and back of insurance card(s) OR fill in the patient information below.

If the patient has Medicare, please check all that apply: ☐ Part A ☐ Part B ☐ Part D ☐ Medicare Advantage

☐ Secondary/Supplemental ☐ Veterans Affairs Benefits ☐ State Pharmaceutical Assistance Program ☐ Uninsured

Medical Insurance Company: _____

Name of Insured (Cardholder): _____

Policy #: _____ Group #: _____

Member ID #: _____

Plan Phone: _____

Prescription Drug Plan Name: _____

Name of Insured (Cardholder): _____

BIN #: _____ PCN #: _____

Policy #: _____ Group #: _____

Plan Phone: _____

PATIENT DIAGNOSIS INFORMATION

ICD-10-CM ☐ G 20 ☐ G 21.2 ☐ G 21.3 ☐ Other: _____

PARKINSON'S DISEASE MEDICATIONS

Please indicate current or previous Parkinson's disease medications:

☐ MAO-B:
- ☐ Selegiline ☐ Current ☐ Previous
- ☐ Rasagiline ☐ Current ☐ Previous

☐ Dopamine Agonist:
- ☐ Apomorphine (Apokyn) ☐ Current ☐ Previous
- ☐ Rotigotine (Neupro) ☐ Current ☐ Previous
- ☐ Ropinirole (Requip) ☐ Current ☐ Previous
- ☐ Pramipexole (Mirapex and Sifrol) ☐ Current ☐ Previous
- ☐ Other: _____ ☐ Current ☐ Previous

☐ Levodopa:
- ☐ CD/LD IR (Sinemet) ☐ Current ☐ Previous
- ☐ CD/LD CR (Sinemet CR) ☐ Current ☐ Previous
- ☐ Orally disintegrating CD/LD (Parcopa) ☐ Current ☐ Previous

☐ COMT:
- ☐ Entacapone (Comtan) ☐ Current ☐ Previous
- ☐ CD/LD plus Entacapone (Stalevo) ☐ Current ☐ Previous

RYTARY PRESCRIPTION INFORMATION

RYTARY (Carbidopa and Levodopa) Extended-Release Capsules, available in: 23.75 mg/95 mg 36.25 mg/145 mg 48.75 mg/195 mg 61.25 mg/245 mg

Dosing Instructions: _____

_____

Start Date: _____ Refills: _____ Number of Tablets: _____

PRESCRIBER ATTESTATION

By signing below, I verify that the information provided in this MyRYTARY® Patient Enrollment Form is complete and accurate to the best of my knowledge. I understand that Impax Laboratories, Inc. reserves the right at any time and for any reason, without notice, to modify this MyRYTARY® Patient Enrollment Form or to modify or discontinue any services or assistance provided through MyRYTARY® Patient Support Program. Finally, I authorize Impax and TrialCard, Inc. as my designated agents to use and disclose health information as necessary to verify the accuracy of any information provided, to provide reimbursement services through MyRYTARY® Patient Support Program and (as applicable) to assess my patient's eligibility for copay assistance. My patient has provided a signed HIPAA Authorization that allows me to share protected health information with Impax and TrialCard, Inc. for purposes of the MyRYTARY® Patient Support Program.

Prescriber's Signature: _____ Date of Signature: _____

Please see Important Safety Information on the following page, and Full Prescribing Information at http://documents.impaxlabs.com/rytary/pi.pdf.

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.

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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.

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, and believed that they were alert immediately prior to the event. Some of these events have been reported more than 1 year after initiation of treatment. Before initiating treatment with RYTARY, 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. Prescribers should consider discontinuing RYTARY in patients who report significant daytime sleepiness or episodes of falling asleep during activities that require active participation (e.g., conversations, eating). 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.

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. If the decision is made to discontinue RYTARY, the dose should be tapered to reduce the risk of hyperpyrexia and confusion.

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.

Hallucinations/Psychosis: There is an increased risk for hallucinations and psychosis in patients taking RYTARY. Hallucinations present shortly after the initiation of therapy and may be responsive to dose reduction in levodopa. Hallucinations may be accompanied by confusion, insomnia, and excessive dreaming. Abnormal thinking and behavior may present with one or more symptoms, including paranoid ideation, delusions, hallucinations, confusion, psychotic behavior, disorientation, aggressive behavior, agitation, and delirium.

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.

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. In some cases, although not all, these urges were reported to have stopped when the dose was reduced or the medication was discontinued. Because patients may not recognize these behaviors as abnormal, it is important for prescribers to specifically ask patients or their caregivers about the development of new or increased gambling urges, sexual urges, uncontrolled spending, or other urges while being treated with RYTARY. Consider a dose reduction or stopping the medication if a patient develops such urges while taking RYTARY.

Dyskinesia: RYTARY can cause dyskinesias that may require a dosage reduction of RYTARY or other medications used for the treatment of Parkinson's disease.

Peptic Ulcer Disease: Treatment with RYTARY may increase the possibility of upper gastrointestinal hemorrhage in patients with a history of peptic ulcer.

Glaucoma: RYTARY may cause increased intraocular pressure in patients with glaucoma. Monitor intraocular pressure in patients with glaucoma after starting RYTARY.

Melanoma: Patients with Parkinson's disease have a higher risk of developing melanoma than the general population. Patients and providers are advised to monitor for melanoma frequently and on a regular basis when using RYTARY.

ADVERSE REACTIONS
Clinical Trials Experience:

Early Parkinson's Disease: Most common adverse reactions (incidence ≥ 5 % and greater than placebo) are nausea, dizziness, headache, insomnia, abnormal dreams, dry mouth, dyskinesia, anxiety, constipation, vomiting, and orthostatic hypotension.

Advanced Parkinson's Disease: Most common adverse reactions (incidence ≥ 5 % and greater than oral immediate-release carbidopa-levodopa) are nausea and headache.

Post-marketing Experience: Reported adverse reactions identified during post-approval use of RYTARY include suicide attempt and ideation. Because these reactions are reported voluntarily from a population of unknown size, it is not always possible to reliably estimate their frequency or establish a causal relationship to RYTARY exposure.

DRUG INTERACTION
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. Monitor patients for worsening Parkinson's symptoms.

USE IN SPECIFIC POPULATION
Pregnancy and nursing mothers: RYTARY should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Caution should be exercised when RYTARY is administered to a nursing woman.

Pediatrics: Safety and efficacy in pediatric populations have not been established.

OVERDOSAGE
The acute symptoms of levodopa/dopa decarboxylase inhibitor overdosage 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). 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. Swallow RYTARY whole with or without food. A high-fat, high-calorie meal may delay the absorption of levodopa by about 2 hours.

For patients who have difficulty swallowing capsules, administer RYTARY by carefully twisting apart both halves of the capsule. 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. Do not store the drug/food mixture for future use.

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.
To report SUSPECTED ADVERSE REACTIONS, contact Impax Laboratories, Inc. at 1-877-994-6729.

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