

## I brake for moments, not for Parkinson's.<sup>TM</sup>

Add NOURIANZ®, the only treatment for "off" episodes that lifts the brake of adenosine, to help you brake for what matters to you.

Ask your doctor if adding NOURIANZ is right for you.

Actor Portrayals.

#### What is NOURIANZ?

NOURIANZ is a prescription medicine used with levodopa and carbidopa to treat adults with Parkinson's disease (PD) who are having "off" episodes. It is not known if NOURIANZ is safe and effective in children.

#### **Important Safety Information**

**The most common side effects of NOURIANZ include** uncontrolled movements (dyskinesia), dizziness, constipation, nausea, hallucinations, and problems sleeping (insomnia).

These are not all the possible side effects of NOURIANZ.

Please see Important Safety Information throughout. <u>Click here for Patient Information</u>.

# Is "off" time keeping you from moments that matter to you?

NOURIANZ<sup>®</sup> is a prescription medicine used with levodopa and carbidopa to treat adults with Parkinson's disease (PD) who are having "off" episodes. It is not known if NOURIANZ is safe and effective in children.

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If you need help paying for NOURIANZ, you can learn more about our support programs at the end of this guide.

Actor Portrayals.

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Please see Important Safety Information throughout. <u>Click here for Patient Information</u>.

## Whether you are considering NOURIANZ, about to start treatment, or are already taking NOURIANZ, this guide is for you.

Inside you will find:

- **INFORMATION** about "off" time and what it may mean for you
- CLINICAL RESULTS of people taking NOURIANZ
- INSTRUCTIONS AND TIPS on how to take NOURIANZ

If you're a care partner to a loved one with PD, this guide is for you, too. You play an important role in supporting your loved one's care.



Talk to your doctor about how adding NOURIANZ can help reduce "off" time.

#### **Important Safety Information**

Before you take NOURIANZ, tell your healthcare provider about all your medical conditions, including if you:

- have a history of abnormal movement (dyskinesia)
- have reduced liver function
- smoke cigarettes
- are pregnant or plan to become pregnant. NOURIANZ may harm your unborn baby
- are breastfeeding or plan to breastfeed. It is not known if NOURIANZ passes into breast milk. You and your healthcare provider should decide if you will take NOURIANZ or breastfeed



# About PD

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### As Parkinson's disease (PD) progresses, you may have more "off" time.

There are many signs of "off" time, including:

TREMOR DIFFICULTY WALKING SLOWNESS STIFFNESS PARTIAL OR TOTAL INABILITY TO MOVE

# "Off" time in PD can keep you from moving the way you want to.

You can have "off" time when your PD medications start to wear off.

WITHIN 5 YEARS OF STARTING LEVODOPA/CARBIDOPA, HALF OF PEOPLE LIVING WITH PD BEGIN TO HAVE "OFF" TIME, INCLUDING PROBLEMS WITH MOVEMENT.

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Think you're having "off" time? Call your doctor right away to discuss your options.

**Important Safety Information** 

#### Tell your healthcare provider about all the medicines you take,

including prescription and over-the-counter medicines, vitamins, and herbal supplements.

NOURIANZ and other medicines may affect each other causing side effects. NOURIANZ may affect the way other medicines work, and other medicines may affect how NOURIANZ works.

Please see Important Safety Information throughout. <u>Click here for Patient Information</u>. What are the possible side effects of NOURIANZ? NOURIANZ may cause serious side effects, including:

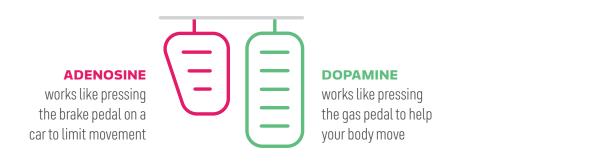
• **uncontrolled sudden movements (dyskinesia).** Uncontrolled sudden movements is one of the most common side effects.

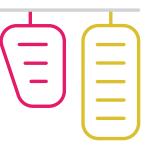


Dopamine and adenosine are naturally occurring chemicals in the brain that help control movement.

### In PD, there is too little dopamine activity and too much adenosine activity.

This imbalance causes symptoms such as difficulty in moving.





IN PARKINSON'S DISEASE It's like pressing on the brake pedal while letting off the gas

Typically, both adenosine and dopamine work together in balance to help you move the way you want to. But in Parkinson's disease (PD), that's not the case.

Please see Important Safety Information throughout.

Many treatments for PD such as levodopa/carbidopa focus on increasing dopamine. **But over time, PD symptoms can return, and people may experience "off" time.** 



There's more to think about than just dopamine.

Talk to your doctor if you're experiencing "off" time—it may be time to add on something different.



**Click here for Patient Information.** 

# NOURIANZ® is an add-on treatment for "off" time.

NOURIANZ works together with your current levodopa/carbidopa regimen to reduce "off" time in Parkinson's disease (PD).

Actor Portrayals.

Please see Important Safety Information throughout. <u>Click here for Patient Information</u>.

## NOURIANZ is the first and only treatment for "off" time in PD that lifts the brake of adenosine.

The exact way NOURIANZ works to treat "off" time in PD is unknown, but unlike any other medication for PD, NOURIANZ is believed to work by targeting adenosine A<sub>2A</sub> receptors. This is like lifting the brake in a car, helping to increase movement if you are experiencing "off" time.

To learn more about the NOURIANZ story, visit <u>www.NOURIANZ.com</u>.

#### **Important Safety Information**

What are the possible side effects of NOURIANZ? (continued) NOURIANZ may cause serious side effects, including:

- hallucinations and other symptoms of psychosis. NOURIANZ can cause abnormal thinking and behavior, including:
- being overly suspicious or feeling people want to harm you (paranoid ideation)
- believing things that are not real (delusions)
- seeing or hearing things that are not real (hallucinations)
- confusion
- increased activity or talking (mania)
- disorientation
- aggressive behavior
- agitation
- delirium (decreased awareness of things around you)



### If your levodopa/carbidopa treatment is no longer working as it should, adding NOURIANZ<sup>®</sup> may help.

#### **IN CLINICAL TRIALS:**

- All patients were on levodopa. Most were also taking other Parkinson's disease (PD) medications. All of them were still experiencing "off" time
- All patients in the trials were given NOURIANZ or placebo (sugar pill) in addition to their other PD medications

At 12 weeks, NOURIANZ reduced "off" time significantly more than placebo, based on diaries of people living with PD in clinical studies.\*\*

#### **NOURIANZ REDUCED "OFF" TIME BY ABOUT 1 HOUR PER DAY\***



- NOURIANZ 20 mg reduced "off" time by 0.99-1.31 hours per day
- NOURIANZ 40 mg reduced "off" time by 0.96-1.58 hours per day
- Placebo reduced "off" time by 0.23-0.66 hours per day

\*Average "off" time at the start of the study was about 6 hours per day. <sup>†</sup>In Studies 3 and 4.

#### **Important Safety Information**

#### What are the possible side effects of NOURIANZ? (continued)

• unusual urges (impulse control or compulsive behaviors). Some people taking NOURIANZ get urges to behave in a way unusual for them. Examples of this are unusual urges to gamble, increased sexual urges, strong urges to spend money, binge eating, and the inability to control these urges.

#### Please see Important Safety Information throughout. **Click here for Patient Information.**

#### Additional data suggests that NOURIANZ may increase good "on" time.\*

Input from the diaries of people in clinical studies living with Parkinson's disease suggests that NOURIANZ may increase good "on" time, which is "on" time without uncontrolled, sudden movements at 12 weeks.\* A change in good "on" time was a secondary efficacy endpoint.

"On" time is when medication is working to treat symptoms such as slowness, stiffness, or issues with mobility.

#### PEOPLE TAKING NOURIANZ EXPERIENCED AN INCREASE IN GOOD "ON" TIME<sup>‡</sup>



 NOURIANZ 20 mg increased "on" time by 1.09-1.35 hours per day

#### NOURIANZ 40 mg increased "on" time by 0.21-1.29 hours per day

- Placebo increased "on" time by 0.49-0.80 hours per day

<sup>‡</sup>In Studies 1-4.



Ask your doctor if adding NOURIANZ is right for you.

#### **Important Safety Information**

#### What are the possible side effects of NOURIANZ? (continued)

If you notice or your family notices that you are developing any new or unusual symptoms or behaviors, talk to your healthcare provider.



# Taking NOURIANZ

### The safety profile of NOURIANZ<sup>®</sup> has been demonstrated in multiple clinical studies.

#### PEOPLE TAKING NOURIANZ MAY EXPERIENCE:

- Uncontrolled movements (dyskinesia)
- Dizziness
- Constipation
- Nausea
- Hallucinations
- Problems sleeping (insomnia)

#### Talk to your doctor if you experience any of these side effects.

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NOURIANZ has been prescribed to more than 90,000 people living with Parkinson's in the US and Japan.

#### Please see Important Safety Information throughout. <u>Click here for Patient Information</u>.

# In NOURIANZ studies, the number of patients who stopped taking NOURIANZ due to side effects was similar to that of patients taking placebo (sugar pill)

- The incidence of patients discontinuing for any adverse reaction was 5% for NOURIANZ 20 mg, 6% for NOURIANZ 40 mg, and 5% for placebo
- 1% of patients discontinued NOURIANZ due to dyskinesia compared to 0% of patients on placebo
- In patients treated with NOURIANZ 40 mg, 1% discontinued because of hallucinations compared to 0% for placebo and 0% for patients treated with NOURIANZ 20 mg

NOURIANZ, in combination with levodopa, may cause dyskinesia or exacerbate pre-existing dyskinesia. The incidence of dyskinesia was 15% for NOURIANZ 20 mg, 17% for NOURIANZ 40 mg, and 8% for placebo, in combination with levodopa.

You may report side effects to the FDA at 1-800-FDA-1088 or to Kyowa Kirin, Inc., at 1-844-768-3544.

#### **Important Safety Information**

**The most common side effects of NOURIANZ include** uncontrolled movements (dyskinesia), dizziness, constipation, nausea, hallucinations, and problems sleeping (insomnia).

These are not all the possible side effects of NOURIANZ.



# About PD

# Taking NOURIANZ

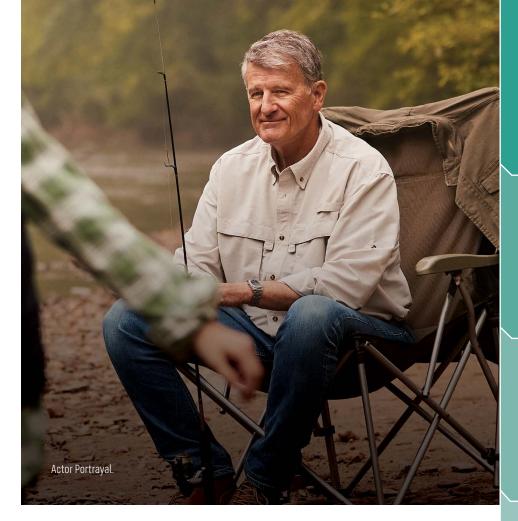
# NOURIANZ<sup>®</sup> can offer flexibility with a once-daily pill that can be taken any time of day, with or without food.



- NOURIANZ comes in 20 mg and 40 mg strengths—you and your doctor will work together to figure out which dosage works for you
- No dose adjustment of levodopa/carbidopa is required when taken with NOURIANZ
- Take NOURIANZ exactly as your doctor tells you to
- If you take too much NOURIANZ, call your doctor or go to the nearest hospital emergency room right away
- NOURIANZ should be stored at room temperature between 68°F to 77°F (20°C to 25°C)
- Keep NOURIANZ and all medicines out of the reach of children

#### BEFORE YOU TAKE NOURIANZ, TELL YOUR HEALTHCARE PROVIDER ABOUT ALL YOUR MEDICAL CONDITIONS, INCLUDING IF YOU:

- have a history of abnormal movement (dyskinesia)
- have reduced liver function
- smoke cigarettes
- are pregnant or plan to become pregnant. NOURIANZ may harm your unborn baby
- are breastfeeding or plan to breastfeed. It is not known if NOURIANZ passes into breast milk. You and your healthcare provider should decide if you will take NOURIANZ or breastfeed



Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or <u>www.fda.gov/medwatch</u>.

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If "off" time is keeping you from moments that matter to you, ask your doctor about adding once-daily NOURIANZ.



## We're here for you on your Parkinson's disease (PD) treatment journey with NOURIANZ<sup>®</sup>.

For eligible patients, the Kyowa Kirin Cares program can provide cost-saving options.

#### Actor Portrayal.

Please see Important Safety Information throughout. Click here for Patient Information.

#### **COST-SAVING OPTIONS ON NOURIANZ**

Eligible commercially insured patients may pay as little as \$20 per month for each prescription of NOURIANZ. See full eligibility requirements, terms, and conditions at www.KyowaKirinCares.com.

# IF YOUR DOCTOR HAS PRESCRIBED NOURIANZ, HERE'S HOW THE PRESCRIPTION CAN BE FILLED:



STEP 1 NOURIANZ is available at Accredo, CVS, and Walgreens specialty pharmacy.



**STEP 2** NOURIANZ can be picked up at the pharmacy, or the prescription can be shipped.



Get support for your PD treatment with NOURIANZ at KyowaKirinCares.com.

#### **Important Safety Information**

Before you take NOURIANZ, tell your healthcare provider about all your medical conditions, including if you:

- have a history of abnormal movement (dyskinesia)
- have reduced liver function
- smoke cigarettes
- are pregnant or plan to become pregnant. NOURIANZ may harm your unborn baby
- are breastfeeding or plan to breastfeed. It is not known if NOURIANZ passes into breast milk. You and your healthcare provider should decide if you will take NOURIANZ or breastfeed



## NOURIANZ<sup>®</sup> is not just another add-on treatment for "off" time in Parkinson's disease.

Talk to your doctor about adding NOURIANZ, the only treatment for "off" episodes that lifts the brake of adenosine, to help you brake for what matters to you.

Actor Portrayals.

#### What is NOURIANZ?

NOURIANZ is a prescription medicine used with levodopa and carbidopa to treat adults with Parkinson's disease (PD) who are having "off" episodes. It is not known if NOURIANZ is safe and effective in children.

#### **Important Safety Information**

**The most common side effects of NOURIANZ include** uncontrolled movements (dyskinesia), dizziness, constipation, nausea, hallucinations, and problems sleeping (insomnia).

These are not all the possible side effects of NOURIANZ.

Please see Important Safety Information throughout. <u>Click here for Patient Information</u>.

#### **Gyowa** kirin

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#### **Patient Information** NOURIANZ<sup>®</sup> (nue'-ree-anz) (istradefylline)

#### tablets. for oral use

#### What is NOURIANZ?

NOURIANZ is a prescription medicine used with levodopa and carbidopa to treat adults with Parkinson's disease (PD) who are having "off" episodes.

It is not known if NOURIANZ is safe and effective in children.

#### Before you take NOURIANZ, tell your healthcare provider about all your medical conditions, including if you:

- have a history of abnormal movement (dyskinesia).
- have reduced liver function.
- smoke cigarettes.
- are pregnant or plan to become pregnant. NOURIANZ may harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if NOURIANZ passes into breast milk. You and your healthcare . provider should decide if you will take NOURIANZ or breastfeed.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

NOURIANZ and other medicines may affect each other causing side effects. NOURIANZ may affect the way other medicines work, and other medicines may affect how NOURIANZ works.

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 take NOURIANZ?

- Take NOURIANZ exactly as your healthcare provider tells you to. .
- Take NOURIANZ one time each day. .
- You can take NOURIANZ with or without food.
- If you take too much NOURIANZ, call your health care provider or go to the nearest hospital emergency room right . away.

#### What are the possible side effects of NOURIANZ?

#### NOURIANZ may cause serious side effects, including:

- uncontrolled sudden movements (dyskinesia). Uncontrolled sudden movements is one of the most common side effects. NOURIANZ may cause uncontrolled sudden movements or make such movements you already have worse or more frequent. Tell your healthcare provider if this happens.
- hallucinations and other symptoms of psychosis. NOURIANZ can cause abnormal thinking and behavior • including:
  - being overly suspicious or feeling people want to harm 0 vou (paranoid ideation)
- disorientation 0
- believing things that are not real (delusions) 0
- seeing or hearing things that are not real (hallucinations) 0
- confusion 0

- aggressive behavior 0 0 agitation
- 0
- delirium (decreased awareness of things around you)

increase activity or talking (mania) 0

If you have hallucinations or any other abnormal thinking or behavior, talk with your healthcare provider.

unusual urges (impulse control or compulsive behaviors). Some people taking NOURIANZ get urges to behave • in a way unusual for them. Examples of this are unusual urges to gamble, increased sexual urges, strong urges to spend money, binge eating, and the inability to control these urges. If you notice or your family notices that you are developing any unusual behaviors, talk to your healthcare provider.

The most common side effects of NOURIANZ include uncontrolled movements (dyskinesia), dizziness, constipation, nausea, hallucinations, and problems sleeping (insomnia).

These are not all the possible side effects of NOURIANZ.

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 NOURIANZ?

- Store NOURIANZ at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep NOURIANZ and all medicines out of the reach of children.

#### General information about the safe and effective use of NOURIANZ.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use NOURIANZ for a condition for which it was not prescribed. Do not give NOURIANZ to other people, even if they have the same symptoms that you have. It may harm them. You can ask your healthcare provider or pharmacist for information about NOURIANZ that is written for health professionals.

#### What are the ingredients in NOURIANZ?

Active ingredient: istradefylline

Inactive ingredients: crospovidone, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyvinyl alcohol, hypromellose, polyethylene glycol 3350, titanium dioxide, triacetin, iron oxide red, iron oxide yellow, and carnauba wax.

Manufactured by: Kyowa Kirin Inc., Bedminster, NJ 07921 U.S. NOURIANZ is a registered trademark of Kyowa Kirin Inc.

For more information, call 1-844-768-3544 or go to www.NOURIANZ.com.

This Patient Information has been approved by the U.S. Food and Drug Administration

Issued: 5/2020