

### 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.

### 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.

## Taking the next step in your treatment for "off" time in PD



Whether you have already been prescribed NOURIANZ by your doctor, or are just considering NOURIANZ as a potential treatment option, this guide can help you understand "off" time, and how NOURIANZ may help to reduce it. You will also find information on NOURIANZ clinical study results and dosing. If you need help paying for NOURIANZ, you can find information on prescription support programs at the end of this guide.

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

- have a history of abnormal movement (dyskinesia)
- have a history of psychotic thinking or behavior
- have reduced liver function
- smoke cigarettes or use other tobacco products
- are pregnant or plan to become pregnant. NOURIANZ may harm your unborn baby
- are breastfeeding or plan to breastfeed

### Also for care partners

If you're a care partner to a loved one with PD, this guide is for you, too. The important role you play in helping your loved one requires understanding all their medications.

## A different approach to treating "off" time



As your PD progresses, you may experience "off" time. You might wonder what other options you may have for treating your PD. NOURIANZ is a different type of medicine that seems to work in a different way.

NOURIANZ is a prescription medicine used with carbidopa and levodopa to treat adults with PD who are having "off" episodes.

**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.

### 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.

An "off" episode is a time when a patient's medications are not working well, causing a return in PD symptoms, such as tremor and difficulty walking.

- In PD, dopamine levels are decreased
- Levodopa helps to replace dopamine in the brain, but, over time, many patients will experience "off" time

Talk to your doctor if you have any questions about your medications.



## There can be more to your "off" time than dopamine...



### Adenosine $A_{2A}$ receptors play an important role in PD.

 Dopamine signals the body to move and adenosine works to slow the body down

Dopamine works like pushing down on the gas pedal of a car, resulting in movement. Adenosine works like applying the brake, slowing movement.



 In PD, adenosine A<sub>2A</sub> receptors are increased, which can cause problems with movement

### 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)

NOURIANZ is the first and only medicine for PD that targets the adenosine  $A_{2A}$  receptor.

### The exact way that NOURIANZ works to treat PD is unknown

- Until now, there have been no medications for PD that target adenosine A<sub>2A</sub> receptors
- NOURIANZ is different, and specifically targets the adenosine  $A_{2\Delta}$  receptors, unlike other medications for PD
- NOURIANZ is nondopaminergic

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

- -confusion
- -increased activity or talking (mania)
- -disorientation
- aggressive behavior
- -agitation
- -delirium (decreased awareness of things around you)

## NOURIANZ can help reduce "off" time



### In clinical trials:

- All patients were on levodopa. Most were also taking other
   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
- Per participants' diaries, NOURIANZ reduced "off" time by 0.96-1.58 hours per day\*†
- Per participants' diaries, placebo reduced "off" time by 0.23-0.66 hours per day\*†
- At 12 weeks, NOURIANZ helped reduce "off" time significantly more than placebo

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

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

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 new or unusual symptoms or behaviors, talk to your healthcare provider.



NOURIANZ has been tested in more than 700 patients with PD across multiple clinical studies.

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



### Safety information

### Adverse reactions in multiple clinical studies.

Patients taking NOURIANZ may experience:

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

Since 2013, NOURIANZ has been prescribed to more than 60,000 people in Japan.



### 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, 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
- 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
- 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)

Talk to your doctor to find out if NOURIANZ is right for you. You may report side effects to the FDA at 1-800-FDA-1088 or to Kyowa Kirin, Inc., at 1-844-768-3544.

## Taking NOURIANZ with other medications



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

- Have a history of abnormal movement (dyskinesia)
- 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
- Have reduced liver function
- Smoke cigarettes

**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.

### **NOURIANZ** is a tablet taken once a day.



- NOURIANZ can be taken at any time of day or night, and with or without food
- Talk to your doctor to see if NOURIANZ is right for you

Talk to your doctor if you have any questions about your medications.



### 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, or at <a href="https://www.fda.gov/medwatch">www.fda.gov/medwatch</a>.





The Kyowa Kirin Cares program can help you get the information and resources you need to start and stay with NOURIAN7.



### **Cost savings on NOURIANZ**

Eligible patients may pay as little as \$20 for a 1-month supply of NOURIANZ.\*

\*See full eligibility requirements, terms, and conditions at <a href="https://www.KyowaKirinCares.com">www.KyowaKirinCares.com</a>.

### 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)

If your doctor has prescribed NOURIANZ, here's how the prescription can be filled:

 NOURIANZ is available at Accredo, CVS, and Walgreens specialty pharmacy





 NOURIANZ can be picked up at the pharmacy, or the prescription can be shipped

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

- -confusion
- -increased activity or talking (mania)
- -disorientation
- -aggressive behavior
- -agitation
- -delirium (decreased awareness of things around you)

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  - -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)
- 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 new or unusual symptoms or 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, or at <a href="https://www.fda.gov/medwatch">www.fda.gov/medwatch</a>.



# Talk to your doctor to find out if NOURIANZ is right for you.

Visit <a href="www.NOURIANZ.com">www.NOURIANZ.com</a> to learn more about managing "off" time with NOURIANZ.



### Patient Information NOURIANZ® (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.

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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 you (paranoid ideation)
  - believing things that are not real (delusions)
  - seeing or hearing things that are not real (hallucinations)
  - confusion

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

increase activity or talking (mania)

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.

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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

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