

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 Parkinson's disease

Your doctor has prescribed NOURIANZ for you to take with your carbidopa/levodopa for the "off" time you experience with Parkinson's disease (PD). 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, tolerability, and dosing. If you need help paying for NOURIANZ, you can find information on prescription support programs at the end of this guide.



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, including NOURIANZ.



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



A different approach to treating "off" time



As your Parkinson's disease (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 works in a different way.

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



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

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

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.

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



Adenosine A_{2A} receptors play an important role in Parkinson's disease (PD).

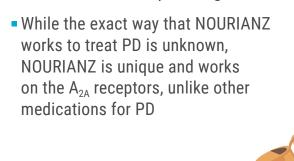
- Dopamine signals the body to move and adenosine works to slow the body down
- In PD, A_{2A} receptors are increased, which can cause problems with movement

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



NOURIANZ is the first and only medicine for Parkinson's disease that targets the adenosine A_{2A} receptor.

- Until now, there have been no medications for PD that target A_{2A} receptors
- NOURIANZ is nondopaminergic





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 also given NOURIANZ or placebo (sugar pill)
- NOURIANZ reduced "off" time by 0.96-1.58 hours per day*†
- Placebo reduced "off" time by 0.23-0.66 hours per day*†
- NOURIANZ reduced "off" time significantly more than placebo

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 has been tested in more than 700 patients with Parkinson's disease (PD) across multiple clinical studies.



^{*}Mean baseline "off" time was about 6 hours per day.
†In Study 3 and Study 4.

NOURIANZ: Safety profile



The safety profile of NOURIANZ has been demonstrated in multiple clinical studies.

Patients taking NOURIANZ may experience:

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

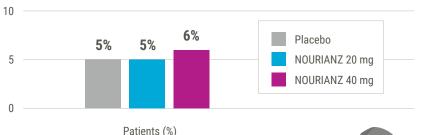
Since 2013, NOURIANZ has been prescribed to more than 50,000 people in Japan.



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

- 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)

The number of patients who stopped taking NOURIANZ because of side effects during clinical studies was similar to that of patients taking placebo (sugar pill).



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)



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.



- You can take NOURIANZ at a time that works best for you
- NOURIANZ can be taken at any time of day or night, and with or without food

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



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.

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

We're here to help



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



*See full eligibility requirements, terms, and conditions at www.KyowaKirinCares.com.

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.

Filling your prescriptions for NOURIANZ:

■ NOURIANZ is available at **CVS** and **Walgreens** pharmacies





 You can choose to pick it up at the pharmacy or have the prescription shipped to you

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- · 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
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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.



- 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)
- 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.



Visit <u>www.NOURIANZ.com</u> 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.

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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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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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