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.

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

- disorientation
- o 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.

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., Princeton, NJ 08540 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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