

PATIENT INFORMATION

XADAGO® (ZA-da-go)
(safinamide) Tablets

What is XADAGO?

XADAGO is a type of prescription medicine known as monoamine oxidase type B (MAO-B) inhibitor used with levodopa and carbidopa to treat adults with Parkinson's disease (PD) who are having "off" episodes.

It is not known if XADAGO is effective to treat PD when taken as a single medicine (monotherapy).

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

Do not take XADAGO if you:

- take another medicine called a Monoamine Oxidase Inhibitor (MAOI) because it may cause a sudden severe increase in your blood pressure (hypertensive crisis)
 - Do not take an MAOI within 14 days after you stop taking XADAGO.
 - Do not start XADAGO if you stopped taking an MAOI in the last 14 days.
- take an opioid drug, St. John's wort, serotonin-norepinephrine reuptake inhibitors (SNRIs), tricyclic antidepressants, tetracyclic antidepressants, triazolopyridine antidepressants, cyclobenzaprine, methylphenidate (or similar drugs), or amphetamine (or similar drugs) because it could be life-threatening. Ask your healthcare provider if you are not sure if you are taking any of these medicines.
 - Do not take XADAGO within 14 days after you stop taking any of these medicines.
 - Do not start taking XADAGO if you stopped taking any of these medicines in the last 14 days.
- take a medicine used to treat a cough or cold called dextromethorphan because it may cause psychosis or abnormal behavior
- have a history of an allergic reaction to safinamide. Signs of an allergic reaction to safinamide could include swelling of your tongue, mouth or trouble breathing. Ask your healthcare provider if you are not sure if you have had an allergic reaction to safinamide in the past.
- have severe liver problems

Before taking XADAGO, tell your healthcare provider about all of your medical conditions, including if you:

- have high or low blood pressure.
- have a sleep disorder, have unexpected or unpredictable daytime sleepiness or take a medicine to help you sleep .
- drink alcoholic beverages. This may increase your chances of becoming drowsy or sleepy while taking XADAGO.
- have a history of abnormal movement (dyskinesia).
- have or have had a mental health problem such as schizophrenia, bipolar disorder or psychosis.
- have or have had unusual urges.
- have or have had problems with the retina in your eye or have a family history of problems with the retina.
- are pregnant or plan to become pregnant. It is not known if XADAGO will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if XADAGO passes into breast milk. You and your healthcare provider should decide if you will take XADAGO or breastfeed. You should not do both.

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

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

Especially tell your healthcare provider if you take:

- selective serotonin reuptake inhibitors (SSRIs)
- meperidine, methadone, propoxyphene, tramadol
- methotrexate, mitoxantrone, imatinib, irinotecan, lapatinib, rosuvastatin, sulfasalazine, topotecan
- metoclopramide

Ask your healthcare provider if you are not sure if you are taking any of these medicines.

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 XADAGO?

- Take XADAGO exactly as your healthcare provider tells you to take it.
- Take XADAGO at the same time each day.
- Take XADAGO with or without food.
- If you miss a dose, take your next dose of XADAGO at the same time the next day.
- Your healthcare provider may need to change the dose of XADAGO until the dose is right for you.
- Do not start or stop taking XADAGO without talking to your healthcare provider first.
- If you take too much XADAGO, call the Poison Control Center at 1-800-222-1222 or go to the nearest hospital emergency room right away.

What should I avoid while taking XADAGO?

- Certain foods and beverages that are high in tyramine such as aged, fermented, cured, smoked and pickled foods.
- Do not drive, operate heavy machinery, work in high places or do other dangerous activities until you know how XADAGO affects you.

XADAGO® (safinamide) tablets

What are the possible side effects of XADAGO?

XADAGO may cause serious side effects, including:

- **high blood pressure (hypertension).** XADAGO may raise your blood pressure or make your high blood pressure worse. Your healthcare provider will check your blood pressure while you take XADAGO.
- **serotonin syndrome.** A potentially life-threatening problem called serotonin syndrome can happen when medicines such as XADAGO are taken with certain other medicines. Symptoms of serotonin syndrome may include:
 - o agitation, hallucinations, coma, or other changes in mental status
 - o problems controlling your movements or muscle twitching
 - o fast heartbeat
 - o high or low blood pressure
 - o sweating or fever
 - o muscle stiffness or tightness
 - o seizures
 - o nausea or vomiting
 - o diarrhea
- **falling asleep during normal activities.** You may fall asleep while doing normal activities such as driving a car, doing physical tasks, or using hazardous machinery while taking XADAGO. You may suddenly fall asleep without being drowsy or without warning. This may result in having accidents. Your chances of falling asleep while doing normal activities while taking XADAGO are greater if you take other medicines that cause drowsiness. Tell your healthcare provider right away if this happens. Before starting XADAGO, be sure to tell your healthcare provider if you take any medicines that make you drowsy.
 - o Do not drive or operate machinery until you know how XADAGO affects you.
- **uncontrolled, sudden movements (dyskinesia).** XADAGO may cause uncontrolled sudden movements or make such movements you already have worse or more frequent. Tell your healthcare provider if this happens. The doses of your anti-Parkinson's medicine may need to be changed
- **hallucinations and other psychosis.** XADAGO can cause or worsen psychotic symptoms including hallucinations (seeing or hearing things that are not real), confusion, agitation, delusional beliefs (believing things that are not real), and disorganized thinking. If you have hallucinations or any of these other psychotic-like changes, talk with your healthcare provider.
- **unusual urges.** Some patients taking XADAGO get urges to behave in a way unusual for them. Examples of this are unusual urge 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.
- **problems with the retina in your eye (retinal changes).** Tell your healthcare provider if your eye sight changes.

The most common side effects of XADAGO include uncontrolled, sudden movements (dyskinesia), falls, nausea, trouble sleeping or falling asleep (insomnia). These are not all the possible side effects of XADAGO.

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 XADAGO?

Store XADAGO at room temperature, about 68°F to 77°F (20°C to 25°C).

Keep XADAGO and all medicines out of the reach of children.

General information about the safe and effective use of XADAGO.

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

What are the ingredients in XADAGO?

Active ingredient: safinamide mesylate

Inactive ingredients: microcrystalline cellulose, crospovidone, colloidal silicon dioxide, magnesium stearate, hypromellose, polyethylene glycol 6000, iron oxide (red), potassium aluminum silicate, and titanium dioxide

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For more information, go to www.xadago.com or call 1-888-492-3246.

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

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