

# iMedix: Your Personal Health Advisor.

## Xadago

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## Description

Side Effects Dizziness or drowsiness may occur. If either of these effects lasts or gets worse, tell your doctor or pharmacist promptly. To reduce the risk of dizziness and lightheadedness, get up slowly when rising from a sitting or lying position, especially when you first start taking safinamide. Remember that this medication has been prescribed because your doctor has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects. Tell your doctor right away if you have any serious side effects, including: fainting, loss of balance, mental/mood changes (such as anxiety, agitation, hallucinations), worsening muscle stiffness/twitching/uncontrollable movements, unusual strong urges (such as increased gambling, increased sexual urges). Some people taking safinamide have fallen asleep suddenly during their usual daily activities (such as talking on the phone, driving). In some cases, sleep occurred without any feelings of drowsiness beforehand. This sleep effect may occur anytime during treatment with safinamide even if you have used this medication for a long time. If you experience increased sleepiness or fall asleep during the day, do not drive or take part in other possibly dangerous activities until you have discussed this effect with your doctor. Your risk of this sleep effect is increased by using alcohol or other medications that can make you drowsy. This medication may increase serotonin and rarely cause a very serious condition called serotonin syndrome/toxicity. The risk increases if you are also taking other drugs that increase serotonin, so tell your doctor or pharmacist of all the drugs you take. Get medical help right away if you develop some of the following symptoms: fast heartbeat, hallucinations, loss of coordination, severe dizziness, severe nausea/vomiting/diarrhea, twitching muscles, unexplained fever, unusual agitation/restlessness. This drug may rarely cause an attack of extremely high blood pressure (hypertensive crisis), which may be fatal. Many drug and food interactions can increase this risk. Get medical help right away if any of these serious side effects occur: severe headache, fast/slow/irregular/pounding heartbeat, chest pain, neck stiffness/soreness, severe nausea/vomiting, sweating/clammy skin (sometimes with fever), widened pupils, vision changes (such as double/blurred vision), sudden sensitivity to light (photophobia). A very serious allergic reaction to this drug is rare. However, get medical help right away if you notice any symptoms of a serious allergic reaction, including: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing. This is not a complete list of possible side effects. If you notice other effects not listed above, contact your doctor or pharmacist. In the US – Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or at [www.fda.gov/medwatch](http://www.fda.gov/medwatch). In Canada – Call your doctor for medical advice about side effects. You may report

side effects to Health Canada at 1-866-234-2345. How long does it take for this medicine to take effect? The onset of action for Xadago in improving Parkinson's disease symptoms can vary among individuals. Clinical improvement may be observed within the first week of treatment, but it could take longer for some patients to experience the full benefits. How long do the effects of this medicine last? Xadago is administered once daily, and its effects last throughout the day to help manage symptoms of PD. The half-life of safinamide is approximately 22 hours, contributing to its once-daily dosing regimen. Is it safe to consume alcohol while taking this medicine? While there is no specific contraindication against consuming alcohol while taking Xadago, it is generally advisable for patients with Parkinson's disease to limit or avoid alcohol. Alcohol can worsen the neurological symptoms of PD and may increase the risk of side effects from PD medications. Is this a habit forming medicine? Xadago is not considered habit-forming and has no known potential for abuse or dependence. It is used specifically for its pharmacological effects in managing symptoms of Parkinson's disease. Can this medicine be taken during pregnancy? Xadago is classified as FDA Pregnancy Category C. Animal studies have shown adverse effects on the fetus, but there are no adequate and well-controlled studies in pregnant women. Xadago should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Pregnant women or those planning to become pregnant should discuss the use of Xadago with their healthcare provider. Can this medicine be taken while breast-feeding? It is not known whether Xadago is excreted in human breast milk. Due to the potential for serious adverse reactions in nursing infants from Xadago, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother's health. Uses Safinamide is used with another medication (levodopa/carbidopa) to treat symptoms of Parkinson's disease. It can help improve symptoms such as shakiness, stiffness, and difficulty moving. It can also help reduce the amount of "off" time (periods of slow movement or stiffness). Safinamide belongs to a class of drugs known as MAO inhibitors. It works by increasing the levels of certain natural substances in the brain (such as dopamine). Parkinson's disease is thought to be caused by too little dopamine in the brain. How to use Xadago Read the Patient Information Leaflet if available from your pharmacist before you start taking safinamide and each time you get a refill. If you have any questions, ask your doctor or pharmacist. Take this medication by mouth with or without food as directed by your doctor, usually once daily. The dosage is based on your medical condition and response to treatment. Do not increase your dose or take it more often than prescribed. Your condition will not improve any faster, and your risk of side effects will increase. Use this medication regularly to get the most benefit from it. To help you remember, take it at the same time each day. Do not stop taking this medication without consulting your doctor. Some conditions may become worse when this drug is suddenly stopped. Your dose may need to be gradually decreased. A very serious high blood pressure reaction may rarely occur if you eat a large amount of tyramine while taking safinamide and for 2 weeks after you stop it. Avoid foods that are high in tyramine, like aged cheeses. Consult your doctor or dietician about which foods you should avoid and if you do not feel well after eating or drinking certain foods while taking this medication. Tell your doctor if this medication stops working well or if your condition gets worse. Precautions Before taking safinamide, tell your doctor or pharmacist if you are allergic to it; or if you have any other allergies. This product may contain inactive ingredients, which can cause allergic reactions or other problems. Talk to your pharmacist for more details. Before using this medication, tell your doctor or pharmacist your medical history, especially of: liver disease, high blood pressure, mental/mood disorders (such as schizophrenia, bipolar disorder, depression), eye problems (such as macular degeneration, uveitis), sleep disorders. This drug may make you drowsy or dizzy. Alcohol or marijuana (cannabis) can make you more drowsy or dizzy. Do not drive, use machinery, or do anything that needs alertness until you can do it safely. Limit alcoholic beverages. Talk to your doctor if you are using marijuana (cannabis). Before having surgery, tell your doctor or dentist about all the products you use (including prescription drugs, nonprescription drugs, and herbal products). During pregnancy, this medication should be used only when clearly needed. Discuss the risks and benefits with your doctor. It is unknown if this drug passes into breast milk. Consult your doctor before breast-feeding. Overdose If someone has overdosed and has serious symptoms such as passing out or trouble breathing, call 911. Otherwise, call a poison control center right away. US residents can call their local poison control center at 1-800-222-1222. Canada residents can call a provincial poison control center. Do not share this medication with others. Lab and/or medical tests (such as blood pressure, liver function) should be done while you are taking this medication. Keep all medical and lab appointments. If you miss a dose, skip the missed dose. Take your next dose at the regular time. Do not

double the dose to catch up. Store at room temperature away from light and moisture. Do not store in the bathroom. Keep all medications away from children and pets. Do not flush medications down the toilet or pour them into a drain unless instructed to do so. Properly discard this product when it is expired or no longer needed. Consult your pharmacist or local waste disposal company. Interactions Drug interactions may change how your medications work or increase your risk for serious side effects. This document does not contain all possible drug interactions. Keep a list of all the products you use (including prescription/nonprescription drugs and herbal products) and share it with your doctor and pharmacist. Do not start, stop, or change the dosage of any medicines without your doctor's approval. Some products that may interact with this drug are: apraclonidine, bupropion, buspirone, carbamazepine, diet pills/appetite suppressants (such as diethylpropion), deutetrabenazine, dextromethorphan, methyl dopa, metoclopramide, certain supplements (such as tryptophan, tyramine), tetra benazine, certain "triptans" used to treat migraine headaches (such as rizatriptan, sumatriptan, zolmitriptan), valbenazine. The risk of serotonin syndrome/toxicity increases if you are also taking other drugs that increase serotonin. Examples include street drugs such as MDMA/"ecstasy," St. John's wort, certain antidepressants (including trazodone, SSRIs such as fluoxetine/paroxetine, SNRIs such as duloxetine/venlafaxine, tricyclics such as amitriptyline/doxepin), drugs for attention deficit disorder (such as amphetamine, methylphenidate), cyclobenzaprine, certain opioid medications (such as meperidine, methadone, propoxyphene, tramadol), among others. The risk of serotonin syndrome/toxicity may be more likely when you start or increase the dose of these drugs. Some products can interact with safinamide if you take them together, or even if you take them weeks before or after taking safinamide. Tell your doctor or pharmacist if you take anything in the list of products that may interact with this drug, or any of the products that increase serotonin, within 2 weeks before or after taking safinamide. Also tell them if you have taken fluoxetine within 5 weeks before starting safinamide. Ask your doctor how much time to wait between starting or stopping any of these drugs and starting safinamide. Taking other MAO inhibitors with this medication may cause a serious (possibly fatal) drug interaction. Do not take any other MAO inhibitors (isocarboxazid, linezolid, metaxalone, methylene blue, moclobemide, phenelzine, procarbazine, rasagiline, selegiline, tranylcypromine) during treatment with this medication. Most MAO inhibitors should also not be taken for two weeks before and after treatment with this medication. Ask your doctor when to start or stop taking this medication. Before using safinamide, report the use of drugs that may increase the risk of extremely high blood pressure (hypertensive crisis) when combined with safinamide, including herbal products (such as ephedra/ma Huang), allergy and cough-and-cold products (including decongestants such as phenylephrine/pseudoephedrine), and stimulants (such as amphetamines, ephedrine, epinephrine, phenylalanine). Talk to your doctor or pharmacist for more details. Tell your doctor or pharmacist if you are taking other products that cause drowsiness such as opioid pain or cough relievers (such as codeine, hydrocodone), alcohol, marijuana (cannabis), drugs for sleep or anxiety (such as alprazolam, lorazepam, zolpidem), muscle relaxants (such as carisoprodol), or antihistamines (such as cetirizine, diphenhydramine).

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## Side Effects

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## Uses

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**Interactions**

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**Other Details**

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