

FOR PARKINSON'S DISEASE

# WHERE WILL YOU XADAGO NEXT?



XADAGO can **increase your daily on time**  
without troublesome dyskinesia<sup>1</sup>

**XADAGO**<sup>®</sup>  
(safinamide) tablets

Please see the complete Important Safety Information on pages 12-13 and  
the accompanying full Prescribing Information and Patient Information.

# What is XADAGO?

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

XADAGO has not been shown to be effective to treat PD when taken as a single medicine (monotherapy).



**XADAGO can help  
increase your *on time* and  
decrease your *off time*<sup>1</sup>**

## Important Safety Information

Tell your physician if you are taking, or planning to take, any prescription or over-the-counter drugs.

Do not take XADAGO if you are taking other monoamine oxidase inhibitors (MAOIs), as it could cause a sudden severe increase in your blood pressure.

The combination of MAO-B inhibitors such as XADAGO and antidepressants has resulted in a serious and sometimes fatal condition called serotonin syndrome.

## What is *ON* and *OFF* time?

During a typical day, you experience *on* and *off* time.<sup>2</sup>



- Your PD symptoms are at a minimum
- Your oral levodopa/carbidopa medication is working well
- You are moving and able to go about your day



- Your PD symptoms have re-emerged and are at or near their worst
- Your oral levodopa/carbidopa medication isn't working well
- Symptoms like stiffness (rigidity), freezing, shaking (tremor), slowness, cramping, difficulty moving, shuffling, low voice, and loss of facial expression re-emerge

## What is “good” *ON* time?

“Good” *on* time is when you don’t experience **troublesome dyskinesia**. As you experience diminishing benefits of levodopa/carbidopa over time, it’s important to have “good” *on* time each day.<sup>2-4</sup>

**Troublesome Dyskinesia** is when:

- Uncontrollable (involuntary), abnormal movements interfere with your daily activities —even during *on* time<sup>5</sup>
- These abnormal movements often occur as a side effect of long-term treatment with levodopa/carbidopa<sup>6</sup>
- Examples of dyskinesia include fidgeting, writhing or wriggling, head bobbing, and body swaying<sup>7</sup>

### Important Safety Information

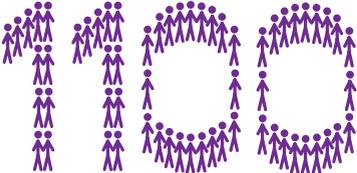
Do not take XADAGO with opioid medications including meperidine, tramadol, methadone, or propoxyphene, as this could result in serious, sometimes fatal, reactions.

Also, do not take XADAGO with amphetamine, cyclobenzaprine, methylphenidate, or St. John’s wort. Taking these drugs together can also result in serotonin syndrome, which could be fatal.

Do not use XADAGO with dextromethorphan, as this has been reported to cause episodes of psychosis or abnormal behavior.

# How can XADAGO help me?

XADAGO can increase your daily *on* time without troublesome dyskinesia and can help reduce your *off* time.<sup>3</sup>

Studied In Over  Patients

## Clinical trials showed that once-daily XADAGO can<sup>3</sup>:

- Increase daily *on* time—without troublesome dyskinesia
- Reduce *off* time and *off* time symptoms
- Help improve your ability to move and take on your day

Get more *on* time—up to 1 hour

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(safinamide) tablets

# What can I expect when taking XADAGO?

XADAGO can give you lasting *on* time without troublesome dyskinesia. Clinical trials showed that patients taking once-daily XADAGO<sup>1</sup>:

- Saw improvements in their ability to move and take on their day as early as 2 to 4 weeks
- Maintained those improvements over time without troublesome dyskinesia

**XADAGO patients reported significant improvements in their health status at 6 months<sup>2,3\*</sup>**



\*As assessed by the Parkinson's Disease Questionnaire (PDQ-39), a PD-specific health status questionnaire. Results are based on the 100 mg/day dose of XADAGO.<sup>8</sup>

## Important Safety Information

Do not use XADAGO if you have hypersensitivity to safinamide, as this can cause swelling of the tongue and mouth and trouble breathing.

The most common side effects seen with XADAGO are uncontrolled movements (dyskinesia), falls, nausea, and insomnia.

# What can I expect when taking XADAGO?\*

During clinical trials, physicians reported that XADAGO, when added to levodopa/carbidopa, helped control PD motor symptoms such as<sup>3,9</sup>:



More ability to speak



Less shaking (tremor)



More freedom of facial expression



Less stiffness (rigidity)



Improved balance



Less slowed movement (bradykinesia)

\*As assessed by the UPDRS III scale.

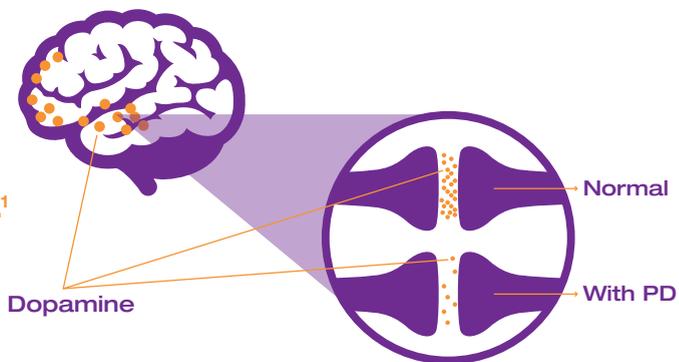
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## How does XADAGO Work?

MAO-B is a substance that naturally breaks down chemicals in your brain, like dopamine. Too little dopamine in your brain can cause impaired movement and PD motor symptoms like stiffness (rigidity), freezing, and shaking (tremor).<sup>1</sup>

**XADAGO helps block MAO-B from breaking down dopamine in your brain.<sup>1</sup>**



Adding XADAGO to levodopa/carbidopa increases dopamine levels by preserving your body's dopamine, as well as dopamine made from levodopa, at all stages of PD.

### Important Safety Information

During treatment with XADAGO you may experience increases in blood pressure. Inform your physician if you have a history of high blood pressure. Possible symptoms of an unsafe rise in blood pressure include severe headache, blurred vision, confusion, seizures, shortness of breath, severe anxiety, and nausea and vomiting. Contact your doctor or seek immediate medical attention if you experience any of these symptoms.

# How do I take XADAGO?

Take XADAGO once daily in addition to your levodopa/carbidopa.<sup>1</sup>

- XADAGO can be taken at any time of the day, with or without food<sup>1</sup>
- Over 87% of patients in clinical trials did not require a change in their levodopa dose<sup>2,3</sup>
  - XADAGO was simply added on!



**50 mg\***

The recommended starting dose of XADAGO is 50 mg once daily



**100 mg\***

After 2 weeks, your healthcare provider may decide to increase your daily dose to 100 mg once daily, if necessary

\*Images above are not actual size of XADAGO tablets

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# What are the possible side effects of XADAGO?

Before taking XADAGO, tell your healthcare provider about all the medications and supplements you are taking.<sup>1</sup>

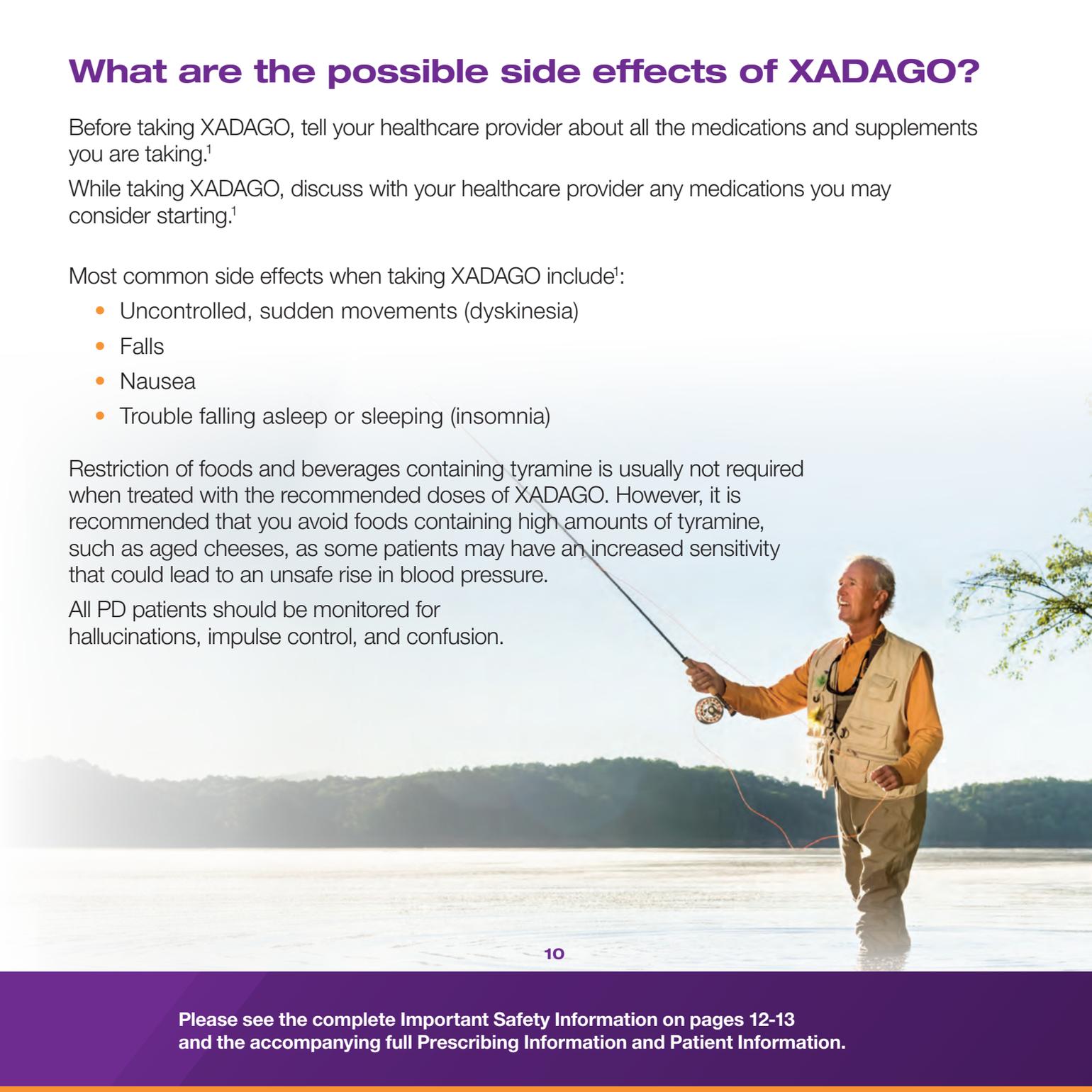
While taking XADAGO, discuss with your healthcare provider any medications you may consider starting.<sup>1</sup>

Most common side effects when taking XADAGO include<sup>1</sup>:

- Uncontrolled, sudden movements (dyskinesia)
- Falls
- Nausea
- Trouble falling asleep or sleeping (insomnia)

Restriction of foods and beverages containing tyramine is usually not required when treated with the recommended doses of XADAGO. However, it is recommended that you avoid foods containing high amounts of tyramine, such as aged cheeses, as some patients may have an increased sensitivity that could lead to an unsafe rise in blood pressure.

All PD patients should be monitored for hallucinations, impulse control, and confusion.



## Are there financial assistance programs available?

The XADAGO Prescription Savings Program helps eligible patients save on their XADAGO prescriptions. With the program you can receive automatic savings at over 67,000 pharmacies—**no card needed!**



Pay  
**as little as \$25\***  
(save up to \$125)  
on your XADAGO prescription each month

**XADAGO**  
Together™

If you cannot afford your medication there are programs that may be able to help.

**Call 1-888-4XADAGO, Option 3, to learn more.**

Visit **XADAGO.com** to learn more

\*Patients whose prescriptions will be paid for in part or in whole by Medicare, Medicaid, or any similar federal or state healthcare program, are not eligible for savings or rebates according to federal and state law. The actual savings on your out-of-pocket costs for XADAGO will vary according to refill quantity, personal healthcare insurance coverage, and adherence to FDA dosing guidelines.

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# Important Safety Information

## Indication

XADAGO is a prescription medicine known as a monoamine oxidase type B (MAO-B) inhibitor. XADAGO is used with levodopa/carbidopa to treat adults with PD who are having *off* episodes.

## Limitations of Use

XADAGO has not been shown to be effective to treat PD when taken as a single medicine (monotherapy).

## Important Safety Information for Patients

Tell your physician if you are taking, or planning to take, any prescription or over-the-counter drugs.

- Do not take XADAGO if you are taking other monoamine oxidase inhibitors (MAOIs), as it could cause a sudden severe increase in your blood pressure.
- The combination of MAO-B inhibitors such as XADAGO and antidepressants has resulted in a serious and sometimes fatal condition called serotonin syndrome.
- Do not take XADAGO with opioid medications including meperidine, tramadol, methadone, or propoxyphene, as this could result in serious, sometimes fatal, reactions.
- Also, do not take XADAGO with amphetamine, cyclobenzaprine, methylphenidate, or St. John's wort. Taking these drugs together can also result in serotonin syndrome, which could be fatal.
- Do not use XADAGO with dextromethorphan, as this has been reported to cause episodes of psychosis or abnormal behavior.

Do not use XADAGO if you have hypersensitivity to safinamide, as this can cause swelling of the tongue and mouth and trouble breathing.

You should not take XADAGO if you have severe liver disease. Do not exceed a dose of 50 mg per day of XADAGO if you have moderate liver disease.

During treatment with XADAGO you may experience increases in blood pressure. Inform your physician if you have a history of high blood pressure. Possible symptoms of an unsafe rise in blood pressure include severe headache, blurred vision, confusion, seizures, shortness of breath, severe anxiety, and nausea and vomiting. Contact your doctor or seek immediate medical attention if you experience any of these symptoms.

Some patients treated with XADAGO experienced drowsiness or sudden onset of sleep. Do not drive, operate heavy machinery, work in high places or do other dangerous activities until you know how XADAGO affects you.

Restriction of foods and beverages containing tyramine is usually not required when treated with the recommended doses of XADAGO. However, it is recommended that you avoid foods containing high amounts of tyramine, such as aged cheeses, as some patients may have an increased sensitivity that could lead to an unsafe rise in blood pressure.

All PD patients should be monitored for hallucinations, impulse control and confusion.

The most common side effects seen with XADAGO are uncontrolled movements (dyskinesia), falls, nausea, and insomnia.

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

**To report SUSPECTED ADVERSE REACTIONS or product complaints, contact US WorldMeds at 1-888-492-3246 (1-888-4XADAGO). You may also report SUSPECTED ADVERSE REACTIONS to the FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).**

**Please see the accompanying full Prescribing Information and Patient Information.**

#### References

**1.** XADAGO Full Prescribing Information. Louisville, KY: US WorldMeds; 2017. **2.** Schapira AHV, Fox SH, Hauser RA, et al. Assessment of safety and efficacy of safinamide as a levodopa adjunct in patients with Parkinson disease and motor fluctuations: a randomized clinical trial. *JAMA Neurol.* 2017;74(2):216-224. **3.** Borgohain R, Szasz J, Stanzione P, et al. Randomized trial of safinamide add-on to levodopa in Parkinson's disease with motor fluctuations. *Mov Disord.* 2014;29(2):229-237. **4.** Jankovic J. Motor fluctuations and dyskinesias in Parkinson's disease: clinical manifestations. *Mov Disord.* 2005;20(Suppl 11):S11-S16. **5.** U.S. Department of Health and Human Services, National Institutes of Health, National Institute of Neurological Disorders and Stroke. (2014). Parkinson's Disease: Hope Through Research (NIH Publication No. 15-139). Bethesda, MD: U.S. Government Printing Office. **6.** Olanow CW, Stern MB, Sethi K. The scientific and clinical basis for the treatment of Parkinson's disease. *Neurology.* 2009;72(Suppl 4):S1-S136. **7.** Dyskinesia. The Michael J. Fox Foundation for Parkinson's Research. <https://www.michaeljfox.org/understanding-parkinsons/living-with-pd/topic.php?dyskinesia>. Last accessed April 12, 2018. **8.** Jenkinson C, Fitzpatrick R, Peto V, et al. The Parkinson's Disease Questionnaire (PDQ-39): development and validation of a Parkinson's disease summary index score. *Age Ageing.* 1997;26(5):353-357. **9.** Data on file. Louisville, KY: US WorldMeds; 2017.





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# WHERE WILL YOU XADAGO NEXT?

## Once-daily XADAGO can<sup>3</sup>:

- Provide more daily *on* time—without troublesome dyskinesia
- Reduce the amount of *off* time that you experience during the day
- Improve your ability to move and take on your day

Visit [XADAGO.com](https://www.xadago.com) to learn more

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