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## Safinamide

pronounced as (sa fin' a mide)

### Why is this medication prescribed?

Safinamide is used along with the combination of levodopa and carbidopa (Duopa, Rytary, Sinemet, others) to treat "off" episodes (times of difficulty moving, walking, and speaking that may happen as medication wears off or at random) in people with Parkinson's disease (PD; a disorder of the nervous system that causes difficulties with movement, muscle control, and balance). Safinamide is in a group of medications called monoamine oxidase type B (MAO-B) inhibitors. It works by increasing the amount of dopamine (a natural substance that is needed to control movement) in the brain.

### How should this medicine be used?

Safinamide comes as a tablet to take by mouth. It is usually taken with or without food once daily. Take safinamide at around the same time every day. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take safinamide exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

Your doctor will probably start you on a low dose of safinamide and may increase your dose once after at least 2 weeks of treatment.

Do not stop taking safinamide without talking to your doctor. Your doctor will probably decrease your dose before stopping. If you suddenly stop taking safinamide, you may experience withdrawal symptoms such as a fever; muscle stiffness; confusion; or changes in consciousness. Tell your doctor if you experience any of these symptoms when your dose of safinamide is decreased.

Ask your pharmacist or doctor for a copy of the manufacturer's information for the patient.

### Other uses for this medicine

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

### What special precautions should I follow?

#### Before taking safinamide,

- tell your doctor and pharmacist if you are allergic to safinamide (mouth or tongue swelling, shortness of breath), any other medications, or any of the ingredients in safinamide tablets. Ask your pharmacist

for a list of the ingredients.

- tell your doctor if you are taking any of the following: amphetamines (stimulants, 'uppers') such as amphetamine (Adderall, Adzenys, Dyanavel XR, in Adderall), dextroamphetamine (Dexedrine, in Adderall), and methamphetamine (Desoxyn); certain antidepressants such as amitriptyline (Elavil), amoxapine, clomipramine (Anafranil), desipramine (Norpramin), doxepin (Sinequan), imipramine (Tofranil), mirtazapine (Remeron) and trazodone; buspirone; cyclobenzaprine (Amrix); methylphenidate (Aptensio, Metadate, Ritalin, others); opioids such as meperidine (Demerol), methadone (Dolophine, Methadose), propoxyphene (no longer available in U.S.; Darvon), or tramadol (Conzip, Ultram, in Ultracet); selective serotonin and norepinephrine reuptake inhibitors (SSNRIs) such as duloxetine (Cymbalta) and venlafaxine (Effexor); and St. John's wort; Also tell your doctor if you are taking an MAO inhibitor such as isocarboxazid (Marplan), linezolid (Zyvox), methylene blue, phenelzine (Nardil), selegiline (Eldepryl, Emsam, Zelapar), or tranylcypromine (Parnate). or have stopped taking them within the past two weeks. Your doctor will probably tell you that you should not take safinamide along with any of these medications. If you stop taking safinamide, you should wait at least 14 days before you start to take any of these medications. Also, do not take dextromethorphan (in Robitussin DM; found in many nonprescription cough and cold products) along with safinamide.
- tell your doctor and pharmacist what other prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking or plan to take. Be sure to mention any of the following: antipsychotics such as clozapine (Clozaril, Fazaclo, Versacloz) and olanzapine (Zyprexa); benzodiazepines such as alprazolam (Xanax), diazepam (Diastat, Valium), lorazepam (Ativan), temazepam (Restoril), and triazolam (Halcion); medications for colds and allergies (decongestants) including those placed in the eye or nose; imatinib (Gleevec); irinotecan (Camptosar, Onivyde); isoniazid (Laniazid, in Rifamate, in Rifater); lapatinib (Tykerb); methotrexate (Otrexup, Rasuvo); metoclopramide (Reglan); mitoxantrone; rosuvastatin (Crestor); selective serotonin reuptake inhibitors such as citalopram (Celexa), escitalopram (Lexapro), fluoxetine (Prozac, Sarafem, Symbyax, others), fluvoxamine (Luvox), paroxetine (Brisdelle, Paxil, Pexeva), and sertraline (Zoloft); sulfasalazine (Azulfidine); and topotecan (Hycamtin). Your doctor may need to change the doses of your medications or monitor you carefully for side effects.
- tell your doctor if you have liver disease. Your doctor will probably tell you not to take safinamide.
- tell your doctor if you have or have ever had a mental illness such as schizophrenia (a mental illness that causes disturbed thinking, loss of interest in life, and strong or unusual emotions), bipolar disorder (mood that changes from depressed to abnormally excited), or psychosis; or if you have high or low blood pressure; dyskinesia (abnormal movements); or sleep problems. Also tell your doctor if you or a family member have or have had problems with the retina of your eyes or albinism (inherited condition that causes a lack of color in the skin, hair and eyes).
- tell your doctor if you are pregnant or plan to become pregnant. If you become pregnant while taking safinamide, call your doctor.
- tell your doctor if you are breast-feeding or plan to breastfeed.
- you should know that safinamide may make you drowsy or may cause you to suddenly fall asleep during your regular daily activities. You might not feel drowsy or have any other warning signs before you suddenly fall asleep. Do not drive a car, operate machinery, work at heights, or participate in potentially dangerous activities at the beginning of your treatment until you know how the medication affects you. If you suddenly fall asleep while you are doing something such as watching television, talking, eating, or riding in a car, or if you become very drowsy, especially during the daytime, call your doctor. Do not drive, work in high places, or operate machinery until you talk to your doctor.
- remember that alcohol can add to the drowsiness caused by this medication. Do not drink alcohol while you are taking safinamide.

- you should know that some people who took medications such as safinamide developed gambling problems or other intense urges or behaviors that were compulsive or unusual for them, such as increased sexual urges or behaviors. Call your doctor if you have an urge to gamble that is difficult to control, you have intense urges, or you are unable to control your behavior. Tell your family members about this risk so that they can call the doctor even if you do not realize that your gambling or any other intense urges or unusual behaviors have become a problem.

## What special dietary instructions should I follow?

You may experience a serious reaction if you eat foods that are high in tyramine during your treatment with safinamide. Tyramine is found in many foods and beverages, including meat, poultry, fish, or cheese that has been smoked, aged, improperly stored, or spoiled; certain fruits, vegetables, and beans; alcoholic beverages; and yeast products that have fermented. Your doctor or dietitian will tell you which foods you must avoid completely, and which foods you may eat in small amounts. If you eat a food that is high in tyramine while taking safinamide, contact your doctor.

## What should I do if I forget a dose?

Skip the missed dose and take your next dose at the usual time the next day. Do not take a double dose to make up for a missed one.

## What side effects can this medication cause?

**Safinamide may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:**

- nausea
- difficulty falling asleep or staying asleep

**Some side effects can be serious. If you experience any of these symptoms, call your doctor immediately or get emergency medical treatment:**

- worsening or more frequent body movements that you can not control
- vision changes
- hallucinations (seeing things or hearing voices that do not exist)
- delusional beliefs (believing things that are not real)
- agitation, hallucinations, fever, sweating, confusion, fast heartbeat, shivering, severe muscle stiffness or twitching, loss of coordination, nausea, vomiting, or diarrhea

Safinamide may cause other side effects. Call your doctor if you have any unusual problems while taking this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (<http://www.fda.gov/Safety/MedWatch> [<http://www.fda.gov/Safety/MedWatch>] ) or by phone (1-800-332-1088).

## What should I know about storage and disposal of this medication?

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store it at room temperature and away from excess heat and moisture (not in the bathroom).

Unneeded medications should be disposed of in special ways to ensure that pets, children, and other people cannot consume them. However, you should not flush this medication down the toilet. Instead, the best way to dispose of your medication is through a medicine take-back program. Talk to your pharmacist or contact your local garbage/recycling department to learn about take-back programs in your community. See the FDA's Safe Disposal of Medicines website (<http://goo.gl/c4Rm4p> [<http://goo.gl/c4Rm4p>] ) for more information if you do not have access to a take-back program.

It is important to keep all medication out of sight and reach of children as many containers (such as weekly pill minders and those for eye drops, creams, patches, and inhalers) are not child-resistant and young children can open them easily. To protect young children from poisoning, always lock safety caps and immediately place the medication in a safe location – one that is up and away and out of their sight and reach. <http://www.upandaway.org> [<http://www.upandaway.org>]

## In case of emergency/overdose

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help> [<https://www.poisonhelp.org/help>]. If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

## What other information should I know?

Keep all appointments with your doctor.

Do not let anyone else take your medication. Ask your pharmacist any questions you have about refilling your prescription.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

## Brand names

- Xadago®

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