



This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

Xadago™

(Za-da-go)

safinamide

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Xadago™.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Xadago™ against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Read this leaflet carefully and keep it with the medicine.

You may need to read it again.

What Xadago™ is used for

Xadago™ is used to treat Parkinson's disease. It is taken when levodopa on its own (or with other medicines) does not control the symptoms of Parkinson's Disease.

Xadago™ belongs to a group of medicines called monoamine oxidase inhibitors (MAOIs). It contains an active ingredient called safinamide.

Parkinson's disease is a condition of the brain that mainly affects movement. The three main

symptoms of Parkinson's disease are:

- Shaking (tremor)
- Muscle stiffness
- Slow and unsteady movement.

The symptoms of Parkinson's disease are caused by a lack of dopamine. Dopamine is a natural substance that is made in the brain and helps with movement. Xadago™ works by increasing the level of dopamine in the brain. This decreases the symptoms of Parkinson's disease.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason. This medicine is only available with a doctor's prescription. Xadago™ is not addictive.

There is not enough information to recommend the use of this medicine for children under the age of 18 years.

Before you take Xadago™

When you must not take it

Do not take Xadago™ if you have an allergy, or have ever had an allergic reaction to safinamide or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include:

- asthma, wheezing or coughing, shortness of breath
- swelling of the face, lips, tongue which may cause difficulty in swallowing or breathing
- hives, itching or skin rash
- stomach ache, fever, chills, nausea and vomiting, fainting.

Do not take Xadago™ if you are taking, or have recently taken, any of the following:

- a monoamine oxidase inhibitor (MAOI), which are a group of medicines that can be used to treat Parkinson's Disease, depression and some other conditions.
- Pethidine, a strong pain killer.

If you are not sure, ask your doctor or pharmacist

Do not take Xadago™ if you have:

- a serious liver problem or disease
- a condition which may affect your eyes such as:
 - albinism: a lack of pigment in your skin and eyes
 - retinal degeneration: a loss of cells from the light sensitive layer at the back of the eye
 - uveitis: inflammation inside of the eye
 - an inherited vision disorder
 - severe, progressive vision loss due to diabetes

Do not take Xadago™ after the expiry date (EXP) printed on the carton and blister foil.

Do not take Xadago™ if the packaging is torn or shows signs of tampering or if the tablets do not look quite right.

If you notice any of these things return the tablets to your pharmacist.

If you are not sure whether you should take Xadago™, talk to your doctor.

Before you take it

Tell your doctor if you:

1. Have allergies to any medicines or other substances such as, foods, preservatives or dyes.

2. Are pregnant or intend to become pregnant.

Xadago™ should not be used if you are pregnant or planning to become pregnant.

3. Are breast-feeding or planning to breast-feed.

Xadago™ should not be used while breast-feeding.

4. Have a liver problem or disease

If you have not told your doctor about any of the above, tell him/her before you start taking Xadago™.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket, health food shop, naturopath or herbalist.

Some medicines and Xadago™ may interfere with each other. These include:

- a monoamine oxidase inhibitor (MAOI), which are a group of medicines that can be used to treat Parkinson's Disease, depression and some other conditions.
- pethidine, a strong pain killer

- medicines used to treat depression, anxiety, panic disorders, obsessive compulsive disorder or pre-menstrual dysphoric disorders such as selective serotonin reuptake inhibitors (SSRIs), selective-norepinephrine reuptake inhibitors (SNRIs) or tricyclic and tetracyclic antidepressants.
- nasal and oral decongestants or 'cold and flu' medicines that contain ephedrine or pseudoephedrine
- cough medicines that contain dextromethorphan
- medicines to lower blood cholesterol such as pitavastatin or pravastatin
- antibiotics such as ciprofloxacin
- some pain medications such as diclofenac
- medicines used to treat diabetes such as glyburide
- medicines used to treat cancer such as topotecan
- methotrexate a medicine used to treat cancer, arthritis and autoimmune diseases.

These medicines may be affected by Xadago™ or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor will advise you.

Your doctor has more information on medicines to be careful with or to avoid while you are taking Xadago™.

How to take Xadago™

Follow all directions given to you by your doctor and pharmacist carefully.

These directions may differ from the information contained in this leaflet.

If you do not understand the instructions, ask your doctor or pharmacist for help.

How much to take

Your doctor will tell you how much Xadago™ to take.

The usual starting dose is one 50 mg tablet each day. After two weeks, the dose may be increased to one 100 mg tablet each day.

Your doctor will tell you the dose that you should take.

Only take the amount that your doctor tells you to.

How to take it

Xadago™ tablets should be swallowed whole with a glass of water. Xadago™ may be taken before, after or with food.

When to take it

Take your Xadago™ tablet at about the same time every day.

Take it at the same time that you take your other Parkinson's medication.

If you are taking a medicine that is a breast cancer resistance protein (BCRP) substrate (such as pitavastatin, pravastatin, ciprofloxacin, methotrexate, topotecan, diclofenac or glyburide), take it at least 5 hours before or after you take Xadago™.

Ask your doctor or pharmacist if you are not sure.

How long to take it

Do not stop taking this medicine without first checking with your doctor.

Talk with your doctor about how long you should take Xadago™. You may need to take it for a long time.

If you forget to take it

Skip the dose that you missed. Take the next dose at the usual time the next day.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you take too much (overdose)

If you think that you or anyone else may have taken too much Xadago™, immediately:

- Telephone your doctor or the Poisons Information Centre on 13 11 26 or
- Go to accident and emergency at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning.

While you are taking Xadago™

Things you must do

Tell your doctor immediately if you become pregnant.

Tell any doctors, dentists and pharmacists who treat you that you are taking Xadago™.

Things you must not do

Do not start taking any other medicine including any that you can buy without a prescription from your pharmacy, supermarket, health food shop, naturopath or herbalist, without first talking to your doctor.

Do not stop taking this medicine without checking with your doctor.

Your doctor may want you to gradually reduce the amount you are taking before stopping completely.

Do not give Xadago™ to anyone else, even if they have the same condition as you.

Things to be careful of

Be careful driving or operating machinery until you know how Xadago™ affects you.

As with some other Parkinson's disease medications, Xadago™ may make you feel sleepy, dizzy or lightheaded.

If you have any of symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Side effects

All medicines can have side effects. Sometimes they are serious, but most of the time they are not. Your doctor has weighed the risks of using this medicine against the benefits they expect it will have for you.

Do not be alarmed by the following lists of side effects.

You may not experience any of them.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Xadago™.

This medicine helps most people with Parkinson's disease but it may have unwanted side effects in a few people.

Tell your doctor if you notice any of the following and they worry you:

- dizziness on standing up, especially when getting up from a sitting or lying position
- dizziness or light-headedness
- nausea (feeling sick)
- accidental injury (e.g. falls)
- sleepiness
- trouble sleeping (insomnia)
- headache
- uncontrolled, sudden movements (dyskinesia)
- cough

- an uncomfortable feeling in the stomach or belching after eating (indigestion)

- nervousness or feeling anxious.

These are mild side effects of Xadago™.

Tell your doctor as soon as possible if you notice any of the following:

- cloudiness in your eye or vision changes
- unusual urges or behaviours for example a strong urge to gamble, increased sexual drive, compulsive spending or buying, impulsive behaviour or binge eating
- obsessive thoughts

These may be serious side effects that may require medical attention. Serious side effects are uncommon.

Tell your doctor immediately, or go to Accident and Emergency at your nearest hospital, if you notice any of the following:

- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- asthma, wheezing, breathlessness, sudden or severe itching, skin rash, hives
- Serotonin syndrome – this can sometimes happen when medicines like Xadago™ are taken with other medicines that are used to treat depression, anxiety, panic disorders, obsessive compulsive disorder or pre-menstrual dysphoric disorders. Symptoms may include: agitation, hallucinations, severe confusion; rapid heart rate, dizziness, sweating, or flushing; high or low blood pressure and seizures and/or problems controlling your movements, muscle twitching, stiffness or tightness might get worse.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are rare.

Tell your doctor or nurse if you notice anything else that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After taking Xadago™

Storage

Keep Xadago™ tablets in the blister pack until it is time to take them.

Keep it in a cool dry place where the temperature stays below 30°C.

Do not store Xadago™ or any other medicine in the bathroom or near a sink or stove. Do not leave it in a car or on a window sill.

Heat and dampness can destroy some medicines.

Keep Xadago™ where children cannot reach it.

A locked cupboard at least one-and-a-half meters above ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking Xadago™ or the expiry date has passed, take the left over tablets to your pharmacist.

Product description

What it looks like

Xadago™ tablets are available in two (2) different strengths:

Xadago™ 50 mg Tablets

Orange to copper, round, biconcave, immediate release, film-coated tablets (7 mm diameter) with metallic gloss and “50” embossed on one side.

Xadago™ 100 mg Tablets

Orange to copper, round, biconcave, immediate release, film-coated tablets (9 mm diameter) with

metallic gloss and “100” embossed on one side.

Xadago™ tablets are supplied in a blister tray packaged in a cardboard box.

Xadago™ tablets are supplied in boxes of 10 and 30 tablets. Not all pack sizes may be available.

Ingredients

Active ingredients:

Xadago™ 50 mg Tablets

Each tablet contains 50 mg safinamide (as mesilate)

Xadago™ 100 mg Tablets

Each tablet contains 100 mg safinamide (as mesilate)

Inactive ingredients:

Xadago™ tablets also contain the following inactive ingredients:

- microcrystalline cellulose
- crospovidone
- magnesium stearate
- colloidal anhydrous silica
- Opadry complete film coating system 02F59058 Clear
- Candurin Orange amber
- Candurin Gold sheen

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Ask your doctor, nurse or pharmacist if you are unsure about anything or want more information about Xadago™.

Sponsor

Seqirus Pty Ltd
ABN 26 160 735 035
63 Poplar Road,
Parkville, VIC, 3052
Australia

This leaflet was prepared in November 2018.

Australian Registration Numbers:

Xadago™ 50 mg: AUST R 292145

Xadago™ 100 mg: AUST R 292144

Xadago is a trademark of Zambon S.p.A. Under Licence from Newron Pharmaceuticals S.p.A