

# Xadago®

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## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

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This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

### 1. Why am I using Xadago?

Xadago contains the active ingredient safinamide mesilate. Xadago is used to treat Parkinson's disease.

For more information, see Section [1. Why am I using Xadago?](#) in the full CMI.

### 2. What should I know before I use Xadago?

Do not use if you have ever had an allergic reaction to Xadago® or any of the ingredients listed at the end of the CMI, if you are taking, or have recently taken a monoamine oxidase inhibitor (MAOI) or Pethidine, or if you have a serious liver problem or disease or a condition which may affect your eyes.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use Xadago?](#) in the full CMI.

### **3. What if I am taking other medicines?**

Do not use Xadago if you are taking, or have recently taken a monoamine oxidase inhibitor (MAOI) or Pethidine.

Some medicines may interfere with Xadago and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### **4. How do I use Xadago?**

- Follow all directions given to you by your doctor or pharmacist carefully.
- Take one tablet each day, or as told by your doctor.

More instructions can be found in Section [4. How do I use Xadago?](#) in the full CMI.

## 5. What should I know while using Xadago?

|                                 |  |
|---------------------------------|--|
| <b>Things you should do</b>     | <ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using Xadago</li><li>• Tell your doctor immediately if you become pregnant</li></ul> |
| <b>Things you should not do</b> | <ul style="list-style-type: none"><li>• Do not stop using this medicine suddenly without checking with your doctor.</li><li>• Do not start taking any other medicine without first</li></ul> |

|                                    |  |
|------------------------------------|--|
|                                    | <p>talking to your doctor.</p> <ul style="list-style-type: none"> <li>• Do not give Xadago to anyone else, even if they have the same condition as you.</li> </ul>                       |
| <b>Driving or using machines</b>   | <ul style="list-style-type: none"> <li>• Be careful driving or operating machinery until you know how Xadago affects you.</li> </ul>   |
| <b>Looking after your medicine</b> | <ul style="list-style-type: none"> <li>• Store in a cool, dry place, below 30°C.</li> <li>• Keep Xadago tablets in the blister pack until it is time to take them, and out of</li> </ul> |

reach of  
children.

For more information, see Section [5. What should I know while using \[insert medicine\]?](#) in the full CMI.

## 6. Are there any side effects?

Common side effects include 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), and cloudiness in your eye or vision changes. Serious side effects include unusual urges or behaviours, obsessive thoughts, allergic reactions, serotonin syndrome. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.



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](http://www.tga.gov.au/reporting-problems).

## Xadago®

**Active ingredient: *safinamide mesilate***

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### **Consumer Medicine Information (CMI)**

This leaflet provides important information about using Xadago. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Xadago.**

#### **Where to find information in this leaflet:**

- [\*\*1. Why am I using Xadago?\*\*](#)
- [\*\*2. What should I know before I use Xadago?\*\*](#)
- [\*\*3. What if I am taking other medicines?\*\*](#)
- [\*\*4. How do I use Xadago?\*\*](#)
- [\*\*5. What should I know while using Xadago?\*\*](#)
- [\*\*6. Are there any side effects?\*\*](#)
- [\*\*7. Product details\*\*](#)

## 1. Why am I using Xadago?

**Xadago contains the active ingredient safinamide mesilate.** Xadago belongs to a group of medicines called monoamine oxidase inhibitors (MAOIs).

**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.

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.

## 2. What should I know before I use Xadago?

### Warnings

#### Do not use Xadago if:

- you are allergic to safinamide mesilate, or any of the ingredients listed at the end of this leaflet.  
Always check the ingredients to make sure you can use this medicine.  
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.
- 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.
- 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

## **Check with your doctor if you:**

- Have allergies to any medicines or other substances such as, foods, preservatives or dyes.
- Are pregnant or intend to become pregnant.
- Are breast-feeding or planning to breast-feed.
- Have any other medical conditions such as liver problems or disease.
- Have or have had problems with your eyes or have a family history of retinal disease.
- Take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

## **Pregnancy and breastfeeding**

### **Tell your doctor if you are pregnant or intend to become pregnant.**

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

### **Tell your doctor if you are breast-feeding or planning to breast-feed.**

Xadago should not be used while breast-feeding.

## Children

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

### **3. What if I am taking other medicines?**

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

**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.

**Some medicines may interfere with Xadago and affect how it works.**

- 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, pravastatin or rosuvastatin
- antibiotics such as ciprofloxacin
- some pain medications such as diclofenac
- medicines used to treat diabetes such as glyburide or metformin
- medicines used to treat cancer such as topotecan
- methotrexate a medicine used to treat cancer, arthritis and autoimmune diseases.
- medicines to treat virus infections such as aciclovir or ganciclovir
- medicines that are breast cancer resistance protein (BCRP) substrates such as pitavastatin, pravastatin, ciprofloxacin, methotrexate, topotecan, diclofenac, glyburide or rosuvastatin
- medicines that are substrates of the liver protein OCT1 such as metformin, aciclovir, ganciclovir

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Xadago.**

## 4. How do I use Xadago?

### How much to take

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

- The usual starting dose is one 50mg tablet each day. After two weeks, the dosage may be increased to one 100mg tablet each day.
- Only take the amount that your doctor tells you to.

## **When to take Xadago**

- 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.

## **How to take Xadago**

- Xadago tablets should be swallowed whole and washed down with a glass of water.
- Xadago can be taken before, with or after eating food.

## **How long to take Xadago**

- 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 Xadago**

**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 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 use too much Xadago**

If you think that you have used too much Xadago, you may need urgent medical attention.

**You should immediately:**

- phone the Poisons Information Centre **(by calling 13 11 26)**, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## **5. What should I know while using Xadago?**

### **Things you should do**

**Call your doctor straight away if you:**

- become pregnant.

Remind any doctor, dentist or pharmacist you visit that you are using Xadago.

## Things you should not do

- 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 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 give Xadago to anyone else, even if they have the same condition as you.

## Driving or using machines

**Be careful before you drive or use any machines or tools 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.

## Looking after your medicine

- Store in a cool, dry place, below 30°C.
- Keep Xadago tablets in the blister pack until it is time to take them.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

**Keep it where young children cannot reach it.**

## **Getting rid of any unwanted medicine**

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## **6. Are there any side effects?**

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### **Less serious side effects**

| <b>Less serious side effects</b>   | <b>What to do</b>  |
|--|--|
| <b>Nervous system related:</b> <ul style="list-style-type: none"><li>• Dizziness or light headedness</li><li>• Dizziness upon standing up, especially when</li></ul> | <b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b> |

| <b>Less serious side effects</b>  | <b>What to do</b> |
|---|-------------------|
| <p>getting up from a sitting or lying position</p> <ul style="list-style-type: none"> <li>● Headache</li> <li>● Trouble sleeping (insomnia)</li> <li>● Sleepiness</li> <li>● Uncontrolled, sudden movements (dyskinesia).</li> </ul> <p><b>Mental health related:</b></p> <ul style="list-style-type: none"> <li>● Nervousness or feeling anxious</li> </ul> <p><b>Respiratory related:</b></p> <ul style="list-style-type: none"> <li>● Cough</li> </ul> <p><b>Gastrointestinal related:</b></p> <ul style="list-style-type: none"> <li>● Nausea</li> <li>● An uncomfortable feeling in the stomach or belching after eating (indigestion)</li> </ul> <p><b>Injury related:</b></p> <ul style="list-style-type: none"> <li>● Accidental injury (e.g. falls)</li> </ul> |                   |

## Serious side effects

| Serious side effects   | What to do   |
|--|--|
| <p><b>Eye related:</b></p> <ul style="list-style-type: none"><li>• Cloudiness in your eye or vision changes</li></ul> <p><b>Mental health related:</b></p> <ul style="list-style-type: none"><li>• Unusual urges or behaviours for example a strong urge to gamble, increased sexual drive, compulsive spending or buying, impulsive behaviour or binge eating</li><li>• Obsessive thoughts</li></ul> <p><b>Allergy related:</b></p> <ul style="list-style-type: none"><li>• Swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing</li><li>• Asthma, wheezing, breathlessness, sudden or severe itching, skin rash, hives</li></ul> <p><b>Nervous system related:</b></p> <ul style="list-style-type: none"><li>• Serotonin syndrome – this can sometimes</li></ul> | <p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p> |

| <b>Serious side effects</b>  | <b>What to do</b> |
|--|-------------------|
| <p>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.</p> |                   |

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

## Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

### What Xadago contains

|   |  |
|---|--|
| <b>Active ingredient<br/>(main ingredient)</b>      | Safinamide mesilate  |
| <b>Other ingredients<br/>(inactive ingredients)</b> | Microcrystalline cellulose<br>Crospovidone<br>Magnesium stearate<br>Colloidal anhydrous silica |

|                            |   |
|----------------------------|---|
|                            | Opadry complete film coating system 02F59058<br>Clear<br>Candurin Orange amber<br>Candurin Gold sheen |
| <b>Potential allergens</b> | N/A   |

**Do not take this medicine if you are allergic to any of these ingredients.**

## **What Xadago looks like**

Xadago 50 mg tablets are orange to copper, round, biconcave, immediate release, film-coated tablets (7 mm diameter) with metallic gloss and “50” embossed on one side, supplied in boxes of 10 and 30 tablets (AUST R 292145).

Xadago 100 mg tablets are orange to copper, round, biconcave, immediate release, film-coated tablets (9 mm diameter) with metallic gloss and “100” embossed on one side, supplied in boxes of 10 and 30 tablets (AUST R 292144).

Not all pack sizes may be available.

## **Who distributes Xadago**

Xadago® is supplied in Australia by:

Clinect Pty Ltd

120 - 132 Atlantic Drive  
Keysborough VIC 3173  
Australia

Customer enquiries: 1800 899 005

Sponsor:  
Atnahs Pharma Australia Pty Ltd  
Level 10  
10 Shelley Street  
Sydney, NSW, 2000  
Australia

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