



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.

ARX-SAFINAMIDE

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.

1. Why am I using ARX-SAFINAMIDE?

ARX-SAFINAMIDE contains the active ingredient safinamide. ARX-SAFINAMIDE 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.

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

2. What should I know before I use ARX-SAFINAMIDE?

Do not use if you have ever had an allergic reaction to safinamide or any of the ingredients listed at the end of the CMI.

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 ARX-SAFINAMIDE?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ARX-SAFINAMIDE 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 ARX-SAFINAMIDE?

- The usual starting dose is one 50 mg tablet each day. After two weeks, the dose will usually be increased to one 100 mg tablet each day. Your doctor will tell you the dose that you should take.
- ARX-SAFINAMIDE tablets should be swallowed whole with a glass of water. ARX-SAFINAMIDE may be taken before, after or with food.

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

5. What should I know while using ARX-SAFINAMIDE?

| | |
|------------------------------------|--|
| Things you should do | <ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are taking ARX-SAFINAMIDE.• Tell your doctor immediately if you become pregnant. |
| Things you should not do | <ul style="list-style-type: none">• Do not stop taking this medicine without checking with your doctor.• Do not give ARX-SAFINAMIDE to anyone else, even if they have the same condition as you. |
| Driving or using machines | <ul style="list-style-type: none">• Be careful while driving or operating machinery until you know how ARX-SAFINAMIDE affects you.• ARX-SAFINAMIDE may make you feel sleepy, dizzy or lightheaded. |
| Looking after your medicine | <ul style="list-style-type: none">• Keep your tablets in the blister pack until it is time to take them.• Keep it in a cool, dry place where the temperature stays below 25° C.• Do not store it or any medicine in the bathroom or near a sink or stove. Do not leave it on a windowsill or in the car. |

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

6. Are there any side effects?

All medicines can have side effects. Sometimes they are serious, most of the time they are not. Some serious side effects like swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing, you may need urgent medical attention or hospitalization.

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.

ARX-SAFINAMIDE

Active ingredient(s): *Safinamide(as mesilate)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using ARX-SAFINAMIDE. **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 ARX-SAFINAMIDE.**

Where to find information in this leaflet:

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

1. Why am I using ARX-SAFINAMIDE?

ARX-SAFINAMIDE contains the active ingredient safinamide. This belongs to a group of medicines called monoamine oxidase inhibitors (MAOIs).

ARX-SAFINAMIDE 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. ARX-SAFINAMIDE works by increasing the level of dopamine in the brain. This decreases the symptoms of Parkinson's disease.

Your doctor may prescribe this medicine for another use. Ask your doctor if you want more information. ARX-SAFINAMIDE is only available on a doctor's prescription.

ARX-SAFINAMIDE is not addictive.

2. What should I know before I use ARX-SAFINAMIDE?

Warnings

Do not use ARX-SAFINAMIDE if:

- you are allergic to safinamide, or any of the ingredients listed at the end of this leaflet. Always

check the ingredients to make sure you can use this medicine.

Some of the 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 ARX-SAFINAMIDE 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 ARX-SAFINAMIDE 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

Check with your doctor if you:

- **have allergies to any other medicines, foods, preservatives or dyes.**
- **you are due to have surgery (including dental work) at any time while taking ARX-SAFINAMIDE.** This is because of the increased risk of bleeding. Your doctor may want you to stop taking ARX-SAFINAMIDE for a short time.
- **have a liver problem or disease**
- **have or have had problems with your eyes or have a family history of retinal disease.**

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

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

Check with your doctor if you are pregnant or intend to become pregnant.

ARX-SAFINAMIDE should not be used if you are pregnant or planning to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

ARX-SAFINAMIDE 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.

Tell your doctor or pharmacist if you are taking any of the following medicines:

- 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, 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

These medicines may be affected by ARX-SAFINAMIDE or may affect how well it

works. You may need different amounts of your medicines, or you may need to take different medicines.

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

They will have more information on medicines to be careful with or avoid while taking ARX-SAFINAMIDE.

4. How do I use ARX-SAFINAMIDE?

Follow all directions given to you by your doctor carefully. They may differ from the information contained in this leaflet.

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

How much to take

Your doctor will tell you how much ARX-SAFINAMIDE to take.

- The usual starting dose is one 50 mg tablet each day. After two weeks, the dose will usually 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.

When to take ARX-SAFINAMIDE

- **Take your doses at around the same time every day.** Take it at the same time that you take your other Parkinson's medication.

How to take ARX-SAFINAMIDE

ARX-SAFINAMIDE tablets should be swallowed whole with a glass of water. ARX-SAFINAMIDE may be taken before, after or with food.

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 ARX-SAFINAMIDE. You may need to take it for a long time.

If you forget to use ARX-SAFINAMIDE

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

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

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you use too much ARX-SAFINAMIDE

If you think that you have used too much ARX-SAFINAMIDE, 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 ARX-SAFINAMIDE?

Things you should do

- Remind any doctor, dentist or pharmacist you visit that you are using ARX-SAFINAMIDE.
- Tell your doctor immediately if you become pregnant.

Things you should not do

- **Do not stop taking ARX-SAFINAMIDE without talking to 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 this medicine to anyone else, even if they have condition as you.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how ARX-SAFINAMIDE affects you.

As with some other Parkinson's disease medications, ARX-SAFINAMIDE 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

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

Store it in a cool dry place away from moisture, heat or sunlight; where the temperature stays below 25°C; for example, do not store it:

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

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine, the packaging is torn or shows signs of tampering 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

| Less serious side effects | What to do |
|---|---|
| <ul style="list-style-type: none"> • 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. | <p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p> |

Serious side effects

| Serious side effects | What to do |
|---|--|
| <ul style="list-style-type: none"> • 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 • 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 ARX-SAFINAMIDE 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 | <p>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.</p> |

| | |
|--|--|
| 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. | |
|--|--|

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

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

You may not experience any of them.

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. 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 ARX-SAFINAMIDE contains

| | |
|---|--|
| Active ingredient (main ingredient) | Safinamide (as mesilate) |
| Other ingredients (inactive ingredients) | <ul style="list-style-type: none"> • Microcrystalline cellulose • Crospovidone • Magnesium stearate • Colloidal anhydrous silica • Opadry fx special effects film coating system 64F530000 Orange (ID 148004) |
| Potential allergens | N/A |

ARX-SAFINAMIDE does not contain gluten, lactose, sucrose, tartrazine or any other azo dyes.

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

What ARX-SAFINAMIDE looks like

ARX-SAFINAMIDE 50 mg tablets

Orange coloured, round shaped, biconcave, film-coated tablet (7 mm diameter) with metallic gloss, debossed with "MS" on one side and "18" on other side, free from physical defects.

ARX-SAFINAMIDE 100 mg Tablets: Orange coloured, round shaped, biconcave, film-coated tablet (9 mm diameter) with metallic gloss debossed with "MS" on one side and "19" on other side, free from physical defects.

ARX-SAFINAMIDE tablets are supplied in a blister packs packaged in a cardboard box.

ARX-SAFINAMIDE tablets are supplied in boxes of 10 and 30 tablets.

Who distributes ARX-SAFINAMIDE

Sponsor

Arrotex Pharmaceuticals Pty Ltd
 15-17 Chapel Street
 Cremorne VIC 3121
www.arrotex.com.au

This leaflet was prepared in November 2025.

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 ARX-SAFINAMIDE 50 mg: AUST R 449608
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