

Consumer Medicine Information (CMI) summary

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

1. Why am I taking EDRONAX?

EDRONAX contains the active ingredient reboxetine mesilate. EDRONAX is taken to treat depression and to prevent relapse of depression.

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

2. What should I know before I take EDRONAX?

Do not take if you have ever had an allergic reaction to reboxetine or any of the ingredients listed at the end of the CMI. Do not take EDRONAX if you are taking other medicines to treat depression such as monoamine oxidase inhibitors (MAOIs) or have glaucoma (high pressure in the eye).

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 take EDRONAX?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with EDRONAX 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 take EDRONAX?

The usual dose of EDRONAX in adults is 4 mg taken twice a day. Swallow the tablets with a glass of water.

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

5. What should I know while using EDRONAX?

Things you should do	- Remind any doctor, dentist or pharmacist you visit that you are taking EDRONAX. - Watch out for worsening of depressive symptoms, especially in the first one to two months of treatment or when your dose has changed.
Things you should not do	- Do not stop using this medicine or change the dose without the advice of your doctor. - Do not take any other medicines, whether they require a prescription or not, without first telling your doctor.
Driving or using machines	Be careful driving or operating dangerous machinery until you know how EDRONAX affects you.
Drinking alcohol	Tell your doctor if you drink alcohol.
Looking after your medicine	- Keep EDRONAX tablets in their blister pack or bottle until it is time to take them. - Keep the tablet blisters in the carton and the bottle container tightly closed. - Keep EDRONAX tablets in a cool dry place where the temperature stays below 25°C.

For more information, see Section [5. What should I know while taking EDRONAX?](#) in the full CMI.

6. Are there any side effects?

Side effects include dry mouth, headache, nausea, vomiting, constipation, diarrhoea, difficulty sleeping, increased sweating, fast heartbeat, dizziness, eye problems, difficulty passing urine/wee, sexual problems, stomach pain, unusual tiredness or weakness, tingling or numbness of the hands or feet, decreased appetite, altered taste, restless leg syndrome, hair and skin problems, flushing of the skin, irritability, testicle pain, fits or seizures, chest pain, thoughts of suicide or self-harm, aggressive behaviour, change in heartbeat sometimes with fainting/loss of consciousness, itching skin rash or hives, shortness of breath, wheezing or trouble breathing, swelling of the face, lips, tongue or other part of the body.

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.

EDRONAX

Active ingredient(s): *reboxetine mesilate*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I taking EDRONAX?

EDRONAX contains the active ingredient reboxetine mesilate. EDRONAX belongs to a class of medication called noradrenaline reuptake inhibitors.

Noradrenaline is a chemical that regulates mood. EDRONAX increases noradrenaline, correcting the chemical imbalance to help relieve symptoms of depression.

EDRONAX is taken to treat depression and to prevent relapse of depression.

Depression is longer lasting and/or more severe than the 'low moods' everyone has from time to time due to the stress of everyday life. It is thought to be caused by a chemical imbalance in parts of the brain.

2. What should I know before I take EDRONAX?

Warnings

Do not take EDRONAX if:

- you are allergic to reboxetine, or any of the ingredients listed at the end of this leaflet.
Always check the ingredients to make sure you can take this medicine.
- you are taking other medicines to treat depression such as monoamine oxidase inhibitors (MAOIs).
- you have glaucoma (high pressure in the eye).

Check with your doctor if you have:

- liver or kidney disease
- fits or seizures
- severe mood swings (bipolar disorder, suicidal thoughts/behaviour)

- difficulty in passing urine/wee
- prostate disease
- heart problems, including high blood pressure, particularly if you are over 65 years old, heart failure, recent heart attack
- overactive thyroid gland

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.

Your doctor can discuss with you the risks and benefits of taking EDRONAX.

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

It is not known if EDRONAX is passed into breast milk, therefore it is not recommended in women who are breast-feeding.

Children or adolescents under the age of 18 years

Do not give this medicine to children or adolescents under the age of 18 years.

Safety and effectiveness in children or adolescents younger than 18 years have not been established.

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.

Some medicines may interfere with EDRONAX and affect how it works including:

- medicines taken to lower blood pressure
- medicines taken to treat fungal or bacterial infections
- carbamazepine and phenobarbital, medicines taken to control fits or seizures
- potassium-depleting diuretics, medicines taken to remove fluid
- fluvoxamine, a medicine taken to treat depression
- ergot derivatives or triptans medicines taken to treat migraine
- other medicines taken to treat depression, or mental health conditions or pain conditions (e.g., selective serotonin reuptake inhibitors, other serotonin-norepinephrine reuptake inhibitors, tricyclic and tetracyclic antidepressants, lithium, opioids, tryptophan, buspirone, MAOIs or St. John's Wort).

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

4. How do I take EDRONAX?

How much to take

The usual dose of EDRONAX in adults is 4 mg taken twice a day. After 3 weeks your doctor may increase the dose up to 10 mg per day, if required.

If you are over 65 years, the usual starting dose is 2 mg taken twice a day. After 3 weeks your doctor may increase the dose up to 6 mg per day, if required.

If you have poor kidney or liver function, the usual starting dose is 2 mg taken twice a day and may be increased depending on how you tolerate the medicine.

How to take EDRONAX

Swallow the tablets whole with a glass of water.

EDRONAX tablets can be broken in half along the breakline if your doctor has prescribed a half tablet.

When to take EDRONAX

Take your medicine at about the same time each day, once in the morning and once at night.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

It does not matter if you take this medicine before or after food.

How long to take EDRONAX

Most antidepressants take some time to work, so do not be discouraged if you do not feel better straight away. Some of your symptoms may improve after two weeks but it may take four to six weeks for you to start to feel the full benefit of EDRONAX. You may need to take EDRONAX for several months or longer.

Continue taking your medicine for as long as your doctor tells you.

This medicine helps to control your condition but does not cure it. It is important to keep taking your medicine even if you feel well.

If you forget to take EDRONAX

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

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

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 EDRONAX

If you think that you have taken too much EDRONAX, you must seek 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 EDRONAX?

Things you should do

If you become pregnant while taking this medicine, tell your doctor or pharmacist immediately.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking EDRONAX.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines taken during surgery.

Tell your doctor if, for any reason, you have not taken your tablets exactly as prescribed. Otherwise, your doctor may think that it was not effective and may change your treatment unnecessarily.

Tell your doctor immediately or go to the Emergency Department at your nearest hospital if you:

- a. have involuntary and rhythmic contraction of your muscles; or
- b. have unusual reflexes and are experiencing agitation or sweating for no apparent reason; or
- c. have irregular eye movements and are experiencing agitation or sweating for no apparent reason; or
- d. are experiencing tremors and unusual bouncing or twitching sensation in your muscles.

These may be signs of a life-threatening syndrome.

Tell your doctor immediately if you have any suicidal thoughts or other mental/mood changes.

A worsening of depressive symptoms including thoughts of suicide or self-harm may occur in the first one to two months of taking EDRONAX or when the doctor changes your dose. These symptoms should be controlled when the full effect of EDRONAX takes place.

Young adults under 24 years of age are more likely to experience these effects during the first few months of treatment.

Patients and caregivers should be alert and monitor for these effects.

Signs and symptoms of suicide include:

- Thoughts or talk of death or suicide
- Thoughts or talk of self-harm or harm to others
- Any recent attempts of self-harm
- Increase in aggressive behaviour, irritability or agitation

Any mention of suicide or violence must be taken seriously.

If you or someone you know is demonstrating these warning signs of suicide while taking EDRONAX, contact your doctor or a mental health professional right away.

Discuss with your doctor any problems you may have and how you feel, especially any feelings of severe sadness or unusual bursts of energy or anger.

This will help the doctor determine the best treatment for you.

Keep all your doctor's appointments so that your progress can be checked.

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Things you should not do

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

Do not take EDRONAX to treat any other complaints unless your doctor or pharmacist tells you to.

Do not take any other medicines, whether they require a prescription or not, without first telling your doctor.

Do not stop taking your medicine, or change the dosage, without checking with your doctor or pharmacist.

Driving or using machines

Be careful before you drive or take any machines or tools until you know how EDRONAX affects you.

As with other medicines for depression, this medicine may cause dizziness or drowsiness in some people. Make sure you know how you react to EDRONAX before you drive a car, operate machinery, or do anything else that could be dangerous.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

Keep your EDRONAX tablets in their blister pack or bottle until it is time to take them.

Blister pack: Keep the tablet blisters in the carton to protect from light.

Bottle: Keep the bottle container tightly closed to protect from light and moisture.

Store it in a cool dry place where the temperature stays below 25°C.

Store it 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.

Heat and dampness can destroy some medicines.

Keep EDRONAX where young children cannot reach it.

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

Getting rid of any unwanted medicine

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

Do not take 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.

Side effects

Side effects	What to do
• dry mouth • headache • nausea, vomiting • constipation or diarrhoea • difficulty sleeping • increased sweating • dizziness • eye problems • difficulty passing urine/wee • sexual problems • stomach pain • unusual tiredness or weakness • tingling or numbness of the hands or feet • decreased appetite • altered taste • restless leg syndrome • hair and skin problems • flushing of the skin (sudden reddening of the face, neck, or upper chest) due to increased blood flow • irritability • testicle pain	Speak to your doctor if you have any of these side effects and they worry you.

Side effects

Side effects	What to do
• anxiety, agitation • confusion, hallucinations • bleeding or bruising more easily than normal • frequent signs of infection such as fever, sore throat, severe chills, mouth ulcers	Call your doctor as soon as possible.

Side effects	What to do
- coldness or loss of blood to your extremities - involuntary muscle movements such as tremor, muscle contractions or spasms (that can lead to muscle tightness and pain), overactive reflexes - tiredness, headache, shortness of breath when exercising, dizziness or pale skin.	
- fits or seizures - chest pain - thoughts of suicide, attempting suicide or self-harm - aggressive behavior - change in heartbeat (fast, slow, irregular), sometimes with fainting/loss of consciousness - itching skin rash or hives - shortness of breath, wheezing or trouble breathing - swelling of the face, lips, tongue or other part of the body.	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.

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.

Some of these side effects (for example, high cholesterol, abnormal liver function tests) can only be found when your doctor does tests from time to time to check your progress.

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/safety/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 EDRONAX contains

Active ingredient (main ingredient)	reboxetine mesilate
Other ingredients (inactive ingredients)	magnesium stearate microcrystalline cellulose silicon dioxide crospovidone

	calcium hydrogen phosphate dihydrate
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Do not take this medicine if you are allergic to any of these ingredients.

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

What EDRONAX looks like

EDRONAX are white, convex, round tablets with a breakline on one side and engraved 'P' on the left of the breakline and 'U' on the right side of the breakline, and '7671' on the opposite side.

EDRONAX 4 mg tablets

- blister pack - AUST R 79745
- bottle - AUST R 521130

Who distributes EDRONAX

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

www.pfizermedicalinformation.com.au

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