

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 PAXAM?

PAXAM contains the active ingredient clonazepam. PAXAM is used to treat epilepsy in adults and children aged 2 years and over. For more information, see Section [1. Why am I taking PAXAM?](#) in the full CMI.

2. What should I know before I take PAXAM?

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

Do not take if you have severe and chronic lung disease or severe liver disease.

Do not take if you have an addiction to drugs or alcohol. This medicine may be addictive.

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 PAXAM?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with PAXAM 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 PAXAM?

- Take PAXAM exactly as your doctor has prescribed.
- PAXAM tablets can be broken in half or quarters if your doctor has prescribed half or quarter of a tablet.

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

5. What should I know while taking PAXAM?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are taking PAXAM.• Do not take any other medicines, prescription or non-prescription without first telling your doctor.• Tell your doctor if you become pregnant while taking PAXAM.• Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed.
Things you should not do	<ul style="list-style-type: none">• Do not stop taking or lower the dose of this medicine suddenly.• Do not take PAXAM for a longer time than your doctor has prescribed.• Do not take PAXAM while taking sedatives, tranquillisers or hypnotics.
Driving or using machines	<ul style="list-style-type: none">• Do not drive or use any machines or tools until you know how PAXAM affects you.
Drinking alcohol	<ul style="list-style-type: none">• You should not drink alcohol while taking PAXAM. Alcohol may increase the effects of PAXAM and lead to serious side effects.
Looking after your medicine	<ul style="list-style-type: none">• Keep your tablets in the bottle until it is time to take them.• Keep your 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 PAXAM?](#) in the full CMI.

6. Are there any side effects?

Mild side effects: drowsiness, tiredness, dizziness, unsteadiness, muscle weakness, tremor, loss of memory, inattentiveness, confusion, lack of concentration, headache, hangover feeling in the morning, slurred speech, unpleasant dreams, palpitations, vomiting, increased saliva in infants and children, chest congestion, double vision. **Serious side effects:** aggression, agitation, depression, restlessness, nervousness, sudden anxiety or excitation, hallucinations or delusions, severe sleep disturbances, severe withdrawal symptoms following discontinuation of PAXAM.

Very serious side effects: difficulty breathing, thoughts of self-harm. **This is not a complete list of all possible side effects.**

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.

Consumer Medicine Information (CMI)

This leaflet provides important information about taking PAXAM. **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 PAXAM.**

Where to find information in this leaflet:

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

1. Why am I taking PAXAM?

PAXAM contains the active ingredient clonazepam. PAXAM belongs to a group of medicines called benzodiazepines. They are thought to work by their action on brain chemicals.

PAXAM is used for the treatment of epilepsy in adults and children aged 2 years and over.

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.

The use of benzodiazepines may lead to dependence on the medicine. If you have any concerns, you should discuss this with your doctor.

2. What should I know before I take PAXAM?

Warnings

Do not take PAXAM if:

- you are allergic to clonazepam or have had an allergic reaction to PAXAM, any other benzodiazepine medicine or any ingredients listed at the end of this leaflet.
Some symptoms of an allergic reaction may include:
 - o shortness of breath
 - o wheezing or difficulty in breathing
 - o swelling of the face, lips, tongue or other parts of the body
 - o rash, itching or hives on the skin.
- you have severe and chronic lung disease.
- you have severe liver disease.
- you have an addiction to drugs or alcohol.
- you have galactose intolerance, total lactase deficiency or glucose-galactose malabsorption.

People with these rare hereditary problems should not take this medicine as it contains lactose.

- the package is torn or shows signs of tampering.
- the expiry date (EXP) printed on the pack has passed. If you take this medicine after the expiry date has passed it may not work as well.
- Always check the ingredients to make sure you can take this medicine.
- If you are not sure whether you should start taking this medicine, talk to your doctor.

This medicine may be addictive. The risks are greater for patients on higher doses or on long term treatment, or patients who have a history of alcohol or drug abuse.

Check with your doctor if you:

- are pregnant or plan to become pregnant.
- are breastfeeding or plan to breastfeed.
- have any other medical conditions including:
 - o liver, kidney or lung disease
 - o high or low blood pressure
 - o myasthenia gravis (severe muscle weakness)
 - o sleep apnoea (a condition where you have temporary stops in breathing during sleep) PAXAM is not recommended for use in patients with sleep apnoea due to possible additive effects on respiratory depression.
 - o glaucoma (a condition where you have high pressure in the eye)
 - o depression, psychosis or schizophrenia and /or you have had depression or suicidal thoughts in the past
 - o spinal or cerebellar ataxia, condition of clumsiness or in coordination of the muscles
 - o porphyria (a rare blood pigment disorder)
 - o ataxia (a condition where you have problems coordinating how your muscle works)
 - o a history of addiction, alcohol or drug abuse/dependence.
- drink alcohol.
- are galactose or lactose intolerant.
- are allergic to any other medicines, foods, dyes or preservatives.
- 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

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

It is not known whether PAXAM is safe to use during pregnancy. There have been reports of unwanted effects

occurring in the newborn with the use of medicines of this class when used during pregnancy.

Mothers taking more than one medicine to treat their epilepsy may be at greater risk of having a baby with malformation than mothers taking only one medicine for epilepsy. Your baby may develop withdrawal symptoms such as a low body temperature, floppy limbs, feeding problems and breathing difficulties. If there is a need to take PAXAM when you are pregnant, your doctor will discuss the risks and benefits to you and the unborn baby.

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

PAXAM may pass into the breast milk and cause drowsiness and/or feeding difficulties in the baby. PAXAM is not recommended for use while breastfeeding.

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 PAXAM and affect how it works.

- sleeping tablets, sedatives or tranquillisers
- some medicines for depression such as tricyclic antidepressants, monoamine oxidase inhibitors
- other medicines to control epilepsy such as phenytoin, carbamazepine, sodium valproate
- medicines for mental illness
- medicines for allergies or colds such as antihistamines
- pain relievers
- muscle relaxants
- anaesthetics
- cimetidine - a medicine used to treat reflux and stomach ulcers
- disulfiram - a medicine used to deter alcohol consumption in alcohol abuse
- lithium - a medicine used to treat mood swings and some types of depression
- Fluconazole - an antifungal medication used for a number of fungal infections

These medicines may be affected by PAXAM or may affect how well PAXAM works. Your doctor or pharmacist can tell you what to do if you are taking any of these medicines. They also have a more complete list of medicines to be careful with or avoid while taking PAXAM.

Taking central nervous system depressants/ sedatives

You should not take central nervous system depressants, such as sedatives, tranquillisers, and hypnotics, while taking PAXAM. These medicines have the potential to increase the effects of PAXAM resulting in severe effects including coma and death.

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

4. How do I take PAXAM?

How much to take

- Take PAXAM exactly as your doctor has prescribed.
- Your doctor will tell you how much PAXAM to take each day and when to take them.
- The dose varies from person to person depending on age, the condition being treated and whether or not you are taking any other medicines.
- PAXAM is usually started using a low dose. Your doctor may gradually increase this dose to the lowest amount needed to control your condition depending on how well you respond to and tolerate the medicine.
- The usual adult maintenance dose is between 4 mg and 8 mg a day.
- Children, the elderly and people with liver or kidney problems may need smaller doses.
- Follow the instructions provided and continue taking PAXAM until your doctor tells you to stop.

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.

When to take PAXAM

- PAXAM is usually taken twice a day (in the morning and evening). However, depending on your dose, your doctor may recommend you take it three or four times a day.
- PAXAM may be taken with or without food.
- Take your medicine at about the same time each day. Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

How to take PAXAM

- Swallow the PAXAM tablets with a glass of water.
- PAXAM tablets can be broken in half or quarters if your doctor has prescribed half or quarter of a tablet.

If you forget to take PAXAM

PAXAM should be taken regularly at the same time each day. If you miss your dose at the usual time, take it as soon as you remember and then go back to taking it as you would normally.

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 are not sure whether to skip the dose, talk to your doctor or pharmacist.

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

If you take too much PAXAM

If you think that you or anyone else have taken too much PAXAM, urgent medical attention may be needed.

You should immediately:

- phone the Poisons Information Centre (telephone 13 11 26) for advice, 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.

If you have taken too much PAXAM, you may feel drowsy, tired, confused, dizzy, have difficulty breathing, feel weak or become unconscious.

Keep telephone numbers for these places handy.

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

5. What should I know while taking PAXAM?

Things you should do

- **Tell all doctors, dentists and pharmacists who are treating you that you are taking PAXAM.**
- **Do not take any other medicines whether they require a prescription or not without first telling your doctor.**
- **If you are going to have surgery, including dental surgery, tell the surgeon, anaesthetist or dentist that you are taking this medicine.**

It may affect other medicines used during surgery.

- **Tell your doctor if you become pregnant while taking PAXAM.**
- **If you continue to have seizures (fits) your doctor may need to adjust or review your treatment.**
- **Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed.**

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

- **Tell your doctor if you feel PAXAM is not helping your condition.**
- **Be sure to keep all of your appointments with your doctor so that your progress can be checked.**

Your doctor may want to do some blood and other tests from time to time to check on your progress and detect any unwanted side effects.

All mentions of suicide or violence must be taken seriously. Tell your doctor or a mental health professional immediately if you have any suicidal thoughts or other mental/mood changes such as restlessness, aggression, rage, hallucinations or any adverse behavioural effects or unusual behaviour.

Things you should not do

- Do not stop taking PAXAM or lower the dose without first checking with your doctor.

Stopping this medicine suddenly may cause some unwanted effects. Your doctor will explain how you should slowly reduce your dose of PAXAM before you can stop taking it completely.

- Do not take PAXAM for a longer time than your doctor has prescribed.
- Do not let yourself run out of medicine over the weekend or on holidays.
- Do not give PAXAM to anyone else even if they have the same condition as you.
- Do not take PAXAM to treat other complaints unless your doctor says to.

Things to be careful of

- **Be careful if you are elderly, unwell, or taking other medicines.**

Some people may experience side effects such as drowsiness, confusion, dizziness and unsteadiness which may increase the risk of a fall.

- **If PAXAM is being given to a young child, you should be especially careful that they are breathing freely.**

PAXAM may increase the amount of saliva and fluid in the airways of infants and children.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how PAXAM affects you.

PAXAM may cause drowsiness or dizziness in some people and therefore may affect alertness.

Make sure you know how you react to PAXAM before you drive a car or operate machinery or do anything else that could be dangerous if you are drowsy, dizzy or not alert.

Children should not ride a bike, climb trees or do anything else that could be dangerous if they are feeling drowsy or sleepy.

Drinking alcohol

Tell your doctor if you drink alcohol.

Do not drink alcohol while taking PAXAM.

Combining PAXAM and alcohol can make you more sleepy or dizzy. Alcohol can also affect how well PAXAM works and may even cause more seizures (fits).

Alcohol may increase the effects of PAXAM and lead to serious side effects, resulting in coma or death.

Looking after your medicine

- Keep your tablets in the bottle until it is time to take them.

If you take the tablets out of the bottle they will not keep well.

- Keep your tablets in a cool dry place where the temperature stays below 25°C.

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.

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

When to discard your medicine

If your doctor tells you to stop taking PAXAM, or the medicine has passed its expiry date, ask your pharmacist what to do with any tablets that are left over.

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.

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

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

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> drowsiness, tiredness dizziness, light-headedness, unsteadiness muscle weakness tremor loss of memory, inattentiveness, confusion, lack of concentration, slowed reactions headache, hangover feeling in the morning slurred speech unpleasant dreams palpitations vomiting increased saliva in infants and children chest congestion double vision 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p> <p>This list includes the more common side effects of your medicine. Some side effects may disappear with continued treatment.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> hallucinations or delusions severe sleep disturbances, nightmares, vivid dreams behaviour changes such as aggression, agitation, irritability, depression, restlessness, nervousness, hostility, sudden 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you</p>

Serious side effects	What to do
<p>anxiety or excitation, sudden feelings of rage</p> <ul style="list-style-type: none"> bleeding or bruising more easily than normal signs of frequent infections such as fever, severe chills, sore throat, mouth ulcers severe withdrawal symptoms following discontinuation of PAXAM (including psychological disturbances such as delusional beliefs, feeling outside oneself, confusion, delirium, psychosis) 	<p>notice any of these serious side effects.</p> <p>This list includes serious side effects which may require medical attention.</p> <p>Some of these side effects are rare.</p>

Very serious side effects

Very serious side effects	What to do
<ul style="list-style-type: none"> swelling of the face, lips, mouth, throat or neck, which may cause difficulty swallowing or breathing fainting more fits than usual difficulty breathing, shortness of breath chest pain which may spread to your neck and shoulders and down your left arm. thoughts of self-harm 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these very serious side effects.</p> <p>You may need urgent medical attention or hospitalisation.</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. 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 PAXAM contains

Active ingredient (main ingredient)	Clonazepam
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Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> • lactose monohydrate • maize starch • microcrystalline cellulose • magnesium stearate • sunset yellow FCF aluminium lake [PAXAM 0.5 tablet only]
Potential allergens	Sugars as lactose and sulfites

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

What PAXAM looks like

PAXAM 0.5 mg: 8 mm, flat bevel edged, peach tablet, debossed "CN" over "0.5" on one side, and cross scored on the other (AUST R 54846).

PAXAM 2 mg: 8 mm, flat bevel edged, white tablet, debossed marked "CN" over "2" on one side, and cross scored on the other (AUST R 54847).

Each bottle contains 100 tablets.

Who distributes PAXAM

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

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