Paxam

clonazepam

Consumer Medicine Information

What is in this leaflet?

This leaflet answers some common questions about Paxam.

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 benefits and risks. Your doctor has weighed the risks of you taking Paxam against the benefits expected for you.

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

Keep this leaflet with your medicine.
You may need to read it again.

What Paxam is used for

Paxam is used to treat epilepsy in adults and in children aged 2 years and over.

Paxam contains the active ingredient clonazepam, which belongs to a group of medicines called benzodiazepines. These medicines are thought to work by their action on brain chemicals.

Ask your doctor if you have any questions about why Paxam has been prescribed for you.
Your doctor may have prescribed Paxam 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.

Paxam is available only with a doctor's prescription.

Before you take Paxam

When you must not take it

Do not take Paxam if you are allergic to:

- medicines containing clonazepam or other benzodiazepines
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include skin rash, itching or hives; swelling of the face, lips or tongue, which may cause difficulty in swallowing or breathing; wheezing or shortness of breath.

Do not take Paxam if you have:

- severe and chronic lung disease
- severe liver disease
- an addiction to drugs or alcohol.

Do not take this medicine if you have galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption.
People with these rare hereditary problems should not take Paxam as it contains lactose.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.
If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

Tell your doctor if you are pregnant or plan to become pregnant.

It is not known whether Paxam is safe to use during pregnancy. However, there have been reports of unwanted effects occurring in the newborn with the use of medicines of this class when used during pregnancy. Therefore, if there is a need to take Paxam during pregnancy, your doctor will discuss the risks and benefits with you.

Tell your doctor if you are breastfeeding or plan to breastfeed.
Paxam is not recommended for use during breastfeeding as it passes into the breast milk, and may cause drowsiness and feeding difficulties in the infant.

Tell your doctor if you have or have had any of the following medical conditions:

- liver problems
- kidney problems
- lung problems
- high or low blood pressure
- glaucoma, a condition characterised by an increased pressure in the eye
- myasthenia gravis, a condition characterised by severe muscle weakness
- depression, psychosis, schizophrenia
- spinal or cerebellar ataxia, condition of clumsiness or in co-ordination of the muscles
- history of addiction or drug dependence
- porphyria, a rare hereditary disorder which affects blood pigment
- sleep apnoea, a condition where you stop breathing during sleep; Paxam is not recommended for use in patients with sleep apnoea due to possible additive effects on respiratory depression.

Your doctor may want to take special care if you have any of these conditions.

Tell your doctor if you drink alcohol.
Alcohol may change the effects of Paxam and may even cause you to have epileptic fits.

Tell your doctor if you plan to have surgery, including dental surgery.

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking Paxam.

Taking other medicines

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

Some medicines may be affected by Paxam or may affect how well Paxam works. These include:

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

Your doctor can tell you what to do if you are taking any of these medicines.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.
Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking Paxam.

How to take Paxam

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

If you do not understand the instructions on the bottle, ask your doctor or pharmacist.

How much to take

The dose varies from person to person.

Take Paxam exactly as directed by your doctor.
Your doctor will tell you how many tablets you need to take each day and when to take them. The dose may depend on your age, your condition and whether or not you are taking any other medicines.

Paxam is usually started using low doses. Your doctor may then gradually increase this dose to the lowest amount needed to control your condition depending on how well you respond 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.

How to take it

Swallow the 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.

When to take it

Paxam is usually taken twice a day (morning and evening). However, depending on your dose, your doctor may recommend you take it three or four times a day.

Paxam can be taken with or without food.

Take Paxam at about the same time each day.
This will have the best effect and also help you remember when to take it.

How long to take it

Keep taking Paxam for as long as your doctor recommends.
Paxam helps to control your condition but does not cure it, so it is important to take it every day.

If you forget to take it

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 tablets as you would normally.

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

If you miss more than one dose, or are not sure what to do, check with your doctor or pharmacist.

If you take too much (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Paxam. Do this even if there are no signs of discomfort or poisoning.
You may need urgent medical attention.

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

While you are taking Paxam

Things you must do

Before starting any new medicine, tell your doctor or pharmacist that you are taking Paxam.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Paxam.

If you become pregnant while taking Paxam, tell your doctor immediately.

If you plan to have surgery (that requires an anaesthetic), including dental surgery, tell your doctor or dentist that you are taking Paxam.

Tell your doctor if you feel that Paxam is not helping your condition.
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 Paxam exactly as prescribed.
Otherwise, your doctor may adjust your treatment unnecessarily.

Visit your doctor regularly so that they can check your progress.
Your doctor may ask you to have regular blood tests to check your blood count, kidney and liver function.

Things you must not do

Do not drink alcohol while you are 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).

Do not drive or operate machinery until you know how Paxam affects you.
Paxam may cause drowsiness, dizziness or affect alertness in some people. These effects may continue the following day.

Therefore, make sure you know how Paxam affects you before you drive a car, operate machinery or do anything else that could be dangerous.

Children should not ride a bike, climb trees or do anything else that could be dangerous if they are feeling drowsy or sleepy.
Paxam may cause drowsiness or dizziness in some people and affect alertness.

Do not take Paxam for a longer time than your doctor has prescribed.

Do not stop taking Paxam or change the dose without first checking with your doctor.
Stopping this medicine suddenly may make your epilepsy worse and cause some unwanted effects. Your doctor will tell you how to gradually reduce the amount of Paxam you are taking before stopping completely.

Do not let yourself run out of Paxam over the weekend or on holidays.

Do not use Paxam to treat any other conditions unless your doctor tells you to.

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

Things to be careful of

If Paxam is being given to a small child, you should be especially careful that they are breathing freely.
Paxam may increase the amount of saliva and fluid in the airways.

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.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Paxam.
Paxam helps most people with their epilepsy, but it may have unwanted side effects in some people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

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

Ask your doctor or pharmacist to answer any questions you may have.

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

- drowsiness, tiredness
- dizziness, lightheadedness
- unsteadiness when walking
- muscle weakness
- slurred speech
- loss of memory, inattentiveness, confusion, lack of concentration, slowed reactions
- increased saliva
- chest congestion
- headaches, hangover feeling in the morning
- unpleasant dreams

The above list includes the milder side effects of Paxam, some of which may disappear with continued treatment.

Tell your doctor immediately if you notice any of the following:

- behaviour changes such as aggression, agitation, irritability, depression, restlessness, nervousness, hostility, anxiety, sudden feelings of rage
- severe sleep disturbances, nightmares, vivid dreams
- hallucinations or delusions
- bleeding or bruising more easily than normal
- signs of frequent infections such as fever, severe chills, sore throat, mouth ulcers.

The above list includes serious side effects which may require medical attention. Some of these side effects are rare.

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

- 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
- thoughts of self-harm.

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

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

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

After taking Paxam

Storage

Keep Paxam where children cannot reach it.
A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

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.

Do not store Paxam or any other medicine in the bathroom or near a sink.

Do not leave Paxam in the car or on window sills.
Heat and dampness can destroy some medicines.

Disposal

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

Product description

What it looks like

Paxam is available in 2 tablet strengths:

- Paxam 0.5 - round, peach coloured tablet marked "CN" over "0.5" on one side and cross scored on the other.

- Paxam 2 - round, white tablet marked "CN" over "2" on one side and cross scored on the other.

Each bottle contains 100 tablets.

Ingredients

The active ingredient in Paxam is clonazepam.

- Each Paxam 0.5 tablet contains 0.5 mg of clonazepam.
- Each Paxam 2 tablet contains 2 mg of clonazepam.

The tablets also contain the following inactive ingredients:

- Lactose monohydrate
- maize starch
- microcrystalline cellulose
- magnesium stearate
- sunset yellow FCF CI15985 (E110) [Paxam 0.5 tablet only].

Paxam tablets do not contain gluten.

Manufacturer

Alphapharm Pty Limited
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Australian registration numbers:

Paxam 0.5 - AUST R 54846

Paxam 2 - AUST R 54847

This leaflet was prepared on 22 September 2017.

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