

NEW ZEALAND CONSUMER MEDICINE INFORMATION

PAXAM

Clonazepam tablets, 0.5 mg and 2 mg



What is in this leaflet

Please read this leaflet carefully before you start taking Paxam.

This leaflet answers some common questions about Paxam.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Paxam against the benefits they expect it will have for you.

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

Keep this leaflet with the 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 5 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 these 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 after the expiry date printed on the bottle 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 Paxam this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

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

- liver problems
- lung problems
- kidney problems
- high or low blood pressure
- myasthenia gravis (severe muscle weakness)
- sleep apnoea (a condition where you have temporary stops in breathing during sleep)
- glaucoma (a condition where you have high pressure in the eye)
- depression, psychosis, schizophrenia
- epilepsy
- spinal or cerebellar ataxia, conditions of clumsiness or inco-ordination of the muscles
- history of addiction or drug dependence
- porphyria (a rare blood pigment disorder).

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

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 drink alcohol.

You should not drink alcohol whilst taking Paxam. Alcohol may increase the effects of Paxam.

Tell your doctor if you are lactose intolerant.

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

You should also tell any health professional who is prescribing a new medication for you that you are taking Paxam.

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

- other medicines for epilepsy, such as phenytoin, carbamazepine, lamotrigine, sodium valproate
- sleeping tablets, sedatives, tranquillisers or muscle relaxants
- some medicines for depression, anxiety, schizophrenia or other mental illnesses
- some antihistamines, used to treat allergies or colds
- pain relievers or opioids
- anaesthetics
- flumazenil
- cimetidine (a medicine used to treat ulcers)

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 for help.

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 per 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 quartered 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.

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

Take Paxam at about the same time each day.

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

How long to take it

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

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

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

While you are taking Paxam

Things you must do

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

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

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

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

Tell your doctor if you feel that Paxam is not helping your condition.

Tell your doctor if, for any reason, you have not taken Paxam exactly as prescribed.

Otherwise, your doctor may change your treatment unnecessarily.

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

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 take 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.

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 drink alcohol while you are taking Paxam.

Alcohol can change the way Paxam works. You should not drink alcohol while taking Paxam.

Things to be careful of

Be careful driving or operating machinery until you know how Paxam affects you.

This medicine may cause drowsiness, dizziness or affect alertness in some people. These effects may continue the following day. If you have any of these symptoms, do not drive, 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.

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.

In case of overdose

If you take too much (overdose)

Immediately contact your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) or go to the Accident and Emergency department at your 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.

Take the pack of Paxam with you if you can.

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

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.

If you are over 65 years of age you may have an increased chance of getting side effects.

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.

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, unsteadiness
- loss of memory, inattentiveness, confusion, lack of concentration
- slurred speech
- unpleasant dreams
- muscle weakness
- changes in mood, such as depression, anxiety, irritation, nervousness, hostility, aggression or agitation
- hyper activity
- inappropriate behaviour.

These are the more common side effects of Paxam. Your doctor will tell you more about them. Your doctor may also recommend that you change the dose of Paxam if you experience any of the above side effects.

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

- severe anxiety, aggression or agitation
- hallucinations or delusions (seeing, hearing or feeling things that other people cannot)
- suicidal thoughts
- severe sleep disturbances
- difficulty breathing
- severe rash, itching or hives
- swelling of the feet or ankles

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

If you suddenly stop taking Paxam, or take a lower dose without checking with your doctor, you may experience withdrawal symptoms. Symptoms of withdrawal include shaking, sweating, agitation, trouble sleeping, anxiety, headaches, muscle pain, tension, restlessness, confusion, irritability or fits.

Ask your doctor or pharmacist if you do not understand anything in this list.

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

Other side effects not listed above may also occur in some people. Tell your doctor if you notice any other effects

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

After taking Paxam

Storage

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

If you take the tablets out of the bottle they may 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 it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it 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.

Disposal

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

Product description

What it looks like

Paxam is available in 2 strengths:

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

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

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
- maize starch
- microcrystalline cellulose
- magnesium stearate
- sunset yellow [Paxam 0.5 tablet only].

Paxam tablets are gluten free.

If you want to know more

Should you have any questions regarding this product, please contact your doctor or pharmacist.

Who supplies this medicine

Paxam is supplied in New Zealand by:

Mylan New Zealand Ltd,
P O Box 11183,
Eilerslie,
Auckland.

Telephone: (09) 579 2792

Date of Preparation

2 May 2019 (based on data sheet dated 2 May 2019).