

Package Leaflet: Information for the user

Clonazepam Thame 0.5mg/5ml Oral Solution

Clonazepam Thame 2mg/5ml Oral Solution

clonazepam



Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- ▶ Keep this leaflet. You may need to read it again.
- ▶ If you have any further questions, ask your doctor or pharmacist.
- ▶ This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- ▶ If you get any of the side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

The name of your medicine is Clonazepam Thame 0.5mg/5ml or 2mg/5ml Oral Solution but will be referred to as Clonazepam throughout this leaflet.

What is in this leaflet:

1. What Clonazepam is and what it is used for
2. What you need to know before you take Clonazepam
3. How to take Clonazepam
4. Possible side effects
5. How to store Clonazepam
6. Contents of the pack and other information

1. What Clonazepam is and what it is used for

Clonazepam belongs to a group of medicines called benzodiazepines.

It is used to treat epilepsy in adults and elderly.

- ▶ It lowers the number of fits (seizures) that you have.
- ▶ Any fits that you do have will be less serious.

2. What you need to know before you take Clonazepam



Do not take Clonazepam if you are allergic (hypersensitive) to:

- ▶ Clonazepam or any of the other ingredients of this medicine (listed in Section 6).
- ▶ Other benzodiazepine medicines, such as diazepam, flurazepam and temazepam.

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Clonazepam.

Do not take Clonazepam if you have:

- ▶ Breathing problems or lung disease.
- ▶ Severe liver problems.
- ▶ A condition called 'myasthenia gravis' (where your muscles become weak and get tired easily).
- ▶ A condition called 'sleep apnoea syndrome' (where your breathing stops when you are asleep).
- ▶ Problems with alcohol or drug (prescription or recreational) use.

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Clonazepam.

Warnings and precautions

Talk to your doctor or pharmacist before taking Clonazepam.

A small number of people being treated with anti-epileptics such as clonazepam have had thoughts of harming or killing themselves. If at any time you have these thoughts, contact your doctor immediately.

Check with your doctor or pharmacist before taking Clonazepam if:

- ▶ You have liver, kidney or lung problems.
- ▶ You have ever had depression.
- ▶ You have ever tried to kill yourself.
- ▶ A close friend or relative has recently died.
- ▶ You regularly drink alcohol or take recreational drugs or you have had problems with alcohol or drug use in the past.
- ▶ You have ataxia (where you may become shaky and unsteady, have slurred speech or rapid eye movements).
- ▶ You have a rare, inherited blood condition called 'porphyria'.
- ▶ You are elderly or debilitated (weak); your doctor may adjust your dose.

If any of the above apply to you, or if you are not sure, talk to your doctor or pharmacist before you take Clonazepam.



Other medicines and Clonazepam

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription and herbal medicines. This is because clonazepam can affect the way some other medicines work. Also some other medicines can affect the way clonazepam works.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- ▶ Other medicines to treat epilepsy, such as carbamazepine, lamotrigine, hydantoin, phenobarbital, phenytoin, primidone or sodium valproate.
- ▶ Cimetidine (used to treat stomach problems and heartburn).
- ▶ Rifampicin (an antibiotic used to treat infections).
- ▶ Medicines used to make you sleep (hypnotics).
- ▶ Medicines that help with anxiety (tranquillisers).
- ▶ Pain-killers (analgesics) and medicines to relax your muscles (muscle relaxants).

Concomitant use of Clonazepam and opioids (strong pain killers, medicines for substitution therapy and some cough medicines) increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible.

However if your doctor does prescribe Clonazepam together with opioids the dose and duration of concomitant treatment should be limited by your doctor.

Please tell your doctor about all opioid medicines you are taking, and follow your doctor's dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

Operations

If you are going to have an anaesthetic for an operation or for dental treatment, it is important to tell your doctor or dentist that you are taking Clonazepam.

Clonazepam and alcohol

Do not drink alcohol while you are taking Clonazepam. This is because it may cause side effects or cause your fits to return. Alcohol can also increase the effects of Clonazepam, possibly leading to severe sedation that could result in coma or death.



Pregnancy and breast-feeding

You must not take Clonazepam if you are pregnant, might become pregnant or are breast-feeding, unless your doctor tells you to. Clonazepam is known to have harmful effects on the unborn child.

Driving and using machines

Talk to your doctor about driving and using machines or tools, whilst you are taking Clonazepam. This is because it can slow down your reactions, particularly when you start taking it. If you are in any doubt about whether you can do a particular activity, talk to your doctor.

The medicine can affect your ability to drive as it may make you sleepy or dizzy.

- ▶ Do not drive while taking this medicine until you know how it affects you.
- ▶ It is an offence to drive if this medicine affects your ability to drive.
- ▶ However, you would not be committing an offence if:
 - The medicine has been prescribed to treat a medical or dental problem and
 - You have taken it according to the instructions given by the prescriber or in the information provided with the medicine and
 - It was not affecting your ability to drive safely.

Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.

Dependence

When taking this medicine there is a risk of dependence which increases with the dose and duration of treatment and also in patients with a history of alcohol and/or drug abuse.

Clonazepam contains:

This medicine contains 64.68mg of alcohol (ethanol) in each 5 ml which is equivalent to 64.68mg of ethanol (96%) per 5ml dose. The amount in 5ml of this medicine is equivalent to less than 2 ml beer or 1 ml wine.

The small amount of alcohol in this medicine will not have any noticeable effects.

3. How to take Clonazepam

Always take Clonazepam exactly as your doctor has told you. Check with your doctor if you are not sure.

- ▶ Your doctor will start you on a low dose of Clonazepam and gradually increase it over 2 to 4 weeks until the right dose has been found for you.
- ▶ Your doctor will usually tell you to split your daily dose into three equal amounts which you will take at evenly spaced times throughout the day.
- ▶ If the daily dose cannot be split equally, take the largest dose at bedtime.
- ▶ Once your doctor has found the right dose for you, they may tell you to take Clonazepam as a single dose in the evening.

Starting dose:

Clonazepam Thame 0.5mg/5ml Oral Solution is recommended for starting dose.

Adults: The usual starting dose is 10ml (1mg) a day, or less.

Elderly: The usual starting dose is 5ml (0.5mg) a day, or less.

Maintenance dose:

Clonazepam Thame 2mg/5ml Oral Solution is recommended for maintenance dose.

Adults and elderly: The starting dose will be increased gradually as maintenance dose (usually to between 10ml (4mg) and 20ml (8mg) a day). The maximum dose is 50ml (20mg) a day.

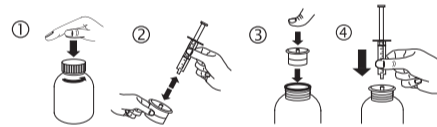
Route and method of administration

This medicine must be taken orally.

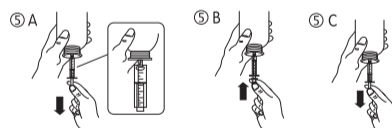
Use the 10ml oral syringe with 1ml measurement markings (0.25ml intermediate graduation) provided in the pack.

Instructions for the use of syringe:

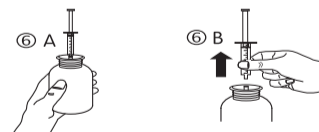
- a) Open the bottle: press the cap and turn it anticlockwise (figure 1).
- b) Separate the adaptor from the syringe (figure 2). Insert the adaptor into the bottle neck (figure 3). Ensure it is properly fixed. Take the syringe and put it in the adaptor opening (figure 4).



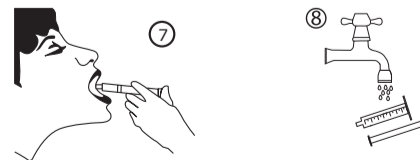
- c) Turn the bottle upside down. Fill the syringe with a small amount of solution by pulling the piston down (figure 5A), then push the piston upwards in order to remove any possible bubble (figure 5B). Pull the piston down to the graduation mark corresponding to the quantity in milliliters (ml) prescribed by your doctor (figure 5C).



- d) Turn the bottle the right way up (figure 6A). Remove the syringe from the adaptor (figure 6B).



- e) Empty the contents of the syringe into the patient's mouth by pushing the piston to the bottom of the syringe (figure 7). The contents of the syringe should be emptied into the side cheek of the patient's mouth to avoid a choking hazard. Close the bottle with the plastic screw cap. Wash the syringe with water (figure 8).



If you take more Clonazepam than you should

- ▶ If you take more Clonazepam than you should, talk to a doctor or go to a hospital straight away. Take the medicine pack with you.
- ▶ If you take more Clonazepam, you may feel drowsy, sleepy, light-headed, have a lack of co-ordination or be less responsive than normal.

If you forget to take Clonazepam

- ▶ If you forget to take a dose, skip the missed dose. Then take the next dose when it is due.
- ▶ Do not take a double dose (two doses at the same time) to make up for a forgotten dose.

If you stop taking Clonazepam

If you receive long term treatment with Clonazepam (are given the medicine for a long time) you may become dependent upon this medicine and get withdrawal symptoms (see Section 4).

- ▶ Do not stop taking your medicine without talking to your doctor. If you do, your fits may return and you may get withdrawal symptoms (see Section 4).
- ▶ If the dose of Clonazepam you take has to be reduced, or stopped, this must be done gradually. Your doctor will let you know how to do this.

If someone else takes your Clonazepam by mistake, they should talk to a doctor or go to a hospital straight away.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Clonazepam can cause side effects, although not everybody gets them.

Important side effects to look out for:

Allergic reactions

If you get an allergic reaction, **see a doctor straight away**.

The signs may include:

- ▶ Sudden swelling of the throat, face, lips and mouth. This may make it difficult to breathe or swallow.
- ▶ Sudden swelling of the hands, feet and ankles.
- ▶ Skin rash or itching.

Effects on the heart

If you notice any of the following effects, **see a doctor straight away**.

The signs may include:

- ▶ Breathlessness, swelling of the ankles, cough, tiredness and a racing heart.
- ▶ Chest pain which may spread to your neck and shoulders and down your left arm.

Effects on behaviour

If you notice any of the following effects, **talk to your doctor** as they may want you to stop taking Clonazepam. The signs may include:

- ▶ Being aggressive, hyperactive, irritable, nervous, agitated, hostile or anxious.
- ▶ Problems sleeping, nightmares and abnormal dreams.
- ▶ Mental problems such as seeing or hearing things that are not really there (hallucinations), delusions (believing in things that are not real) and problems with your speech.
- ▶ Inappropriate behaviour, emotional and mood changes.
- ▶ Types of fits (seizures) that you have not had before.

Infants and children

- ▶ If an infant or small child is taking Clonazepam, watch them carefully. This is because they could develop breathing problems, coughing or choking. This can be caused by too much saliva being made.
- ▶ Early puberty in children. This is reversible after stopping treatment with Clonazepam.

Other possible side effects

When you start taking Clonazepam you may notice the following effects:

- ▶ Feeling drowsy and tired.
- ▶ Feeling dizzy and light-headed.
- ▶ Weak or floppy muscles or jerky movements (poor co-ordination).
- ▶ Feeling unsteady when walking.

If you notice any of these effects, talk to your doctor. Your doctor may be able to help you by giving you a lower dose of Clonazepam and then increasing it slowly.

The following may occur at any time during your treatment

Mind and nervous system

- ▶ Poor concentration, confusion and a feeling of being lost (disorientation).
- ▶ Feeling restless.
- ▶ Difficulty remembering new things.
- ▶ Headache.
- ▶ Depression.
- ▶ Slowing or slurring of speech.
- ▶ Poor co-ordination, including feeling unsteady when walking.
- ▶ An increase in how often you have fits.

Liver, kidney and blood

- ▶ Changes in how well your liver is working (shown by blood tests).
- ▶ Loss of bladder control.
- ▶ Blood problems. The signs include feeling tired, bruising easily, being short of breath and nose bleeds. Your doctor may want you to have blood tests from time to time.

Stomach and gut

- ▶ Feeling sick (nausea).
- ▶ Stomach upset.

Eyes

- ▶ Double vision.
- ▶ Jerky movements of the eyes (nystagmus).

Breathing

- ▶ Breathing problems (respiratory depression). Early signs include suddenly noisy, difficult and uneven breathing. Your skin may become blue.

Skin and hair

- ▶ Skin rashes, hives (lumpy rash) and itchy skin.
- ▶ Changes to the colour of your skin.
- ▶ Hair loss (the hair usually grows back).

Sexual

- ▶ Changes in sex drive.
- ▶ Difficulty getting or keeping an erection (erectile dysfunction).

Withdrawal symptoms

Using benzodiazepines like Clonazepam may make you dependent on the medicine. This means that if you stop treatment quickly, or reduce the dose too quickly, you may get withdrawal symptoms. The symptoms can include:

- ▶ Problems sleeping.
- ▶ Muscle pain, shaking (tremor) and feeling restless.
- ▶ Feeling very anxious, tense, confused, irritable or agitated, or changes in your mood.
- ▶ Increased sweating.
- ▶ Headache.
- ▶ Diarrhoea.

Less common withdrawal symptoms include:

- ▶ Feeling sensitive to light, noise and physical contact.
- ▶ Seeing or hearing things that are not really there (hallucinations).
- ▶ Tingling and feeling numb in your arms and legs.
- ▶ A feeling of losing contact with reality.

Injury

- ▶ Patients taking benzodiazepine medicines are at risk of falling and breaking bones. This risk is increased in the elderly and those taking other sedative (including alcohol).

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Clonazepam

- ▶ Keep this medicine out of the sight and reach of children.
- ▶ Do not use this medicine after the expiry date which is stated on the carton or bottle label after Exp. The expiry date refers to the last day of that month.
- ▶ This medicinal product does not require any special temperature storage conditions.
- ▶ Keep the bottle tightly closed.
- ▶ Keep the bottle in the outer carton in order to protect from light.
- ▶ Discard 30 days after first opening.
- ▶ Do not use this medicine if you notice that the solution becomes discoloured or shows any signs of deterioration. Seek the advice of your pharmacist.
- ▶ Do not throw away any medicine via waste water or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Clonazepam contains

The active substance is Clonazepam.

For 0.5mg/5ml: Each 5ml Solution contains 0.5mg Clonazepam.

For 2mg/5ml: Each 5ml Solution contains 2mg Clonazepam.

The other ingredients are ethanol(96%) and medium chain triglycerides.

What Clonazepam looks like and contents of the pack

Clonazepam is clear, colourless to pale yellow colour oral solution supplied in an amber glass bottle with tamper-evident, child resistant plastic screw cap and a 10ml oral syringe with 0.25ml graduation for measuring the required dose and a syringe adaptor.

Clonazepam oral solution is supplied in bottles containing 150ml solution.

Marketing Authorisation Holder:

Thame Laboratories,
Unit 4, Bradfield Road,
Ruislip, Middlesex,
HA4 0NU, UK

Manufacturer:

Galenica Pharmaceutical Industry S.A.,
Asklipiou 4-6, Kryoneri, Attiki,
14568, Greece

If this leaflet is hard to see or read, please call +44 (0) 208 515 3700 for help.

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

UK (NI) and MT: Clonazepam Thame 0.5mg/5ml Oral Solution and Clonazepam Thame 2mg/5ml Oral Solution.

This leaflet was last revised in 06/2023.