

Package leaflet: Information for the user

Clonazepam Roma 0.5 mg Tablets

Clonazepam Roma 2 mg Tablets

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 symptoms are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Clonazepam Tablets are and what they are used for

The name of your medicine is Clonazepam Roma 0.5 mg or 2 mg Tablets (called Clonazepam Tablets throughout this leaflet).

The tablets contain a medicine called clonazepam. This belongs to a group of medicines called ‘benzodiazepines’.

It is used to treat epilepsy in infants, children and adults.

- 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 Tablets

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

- clonazepam or any of the other ingredients of this medicine (listed in section 6)
- other benzodiazepine medicines. These include diazepam, flurazepam and temazepam.

Do not take Clonazepam Tablets if you have:

- breathing problems or lung disease
- severe liver problems
- a condition called ‘sleep apnoea syndrome’ (where your breathing stops when you are asleep)
- a condition called myasthenia gravis (where your muscles become weak and get tired easily)
- problems with alcohol or drug (prescription or recreational) use

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

Warnings and precautions

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

Check with your doctor or pharmacist before taking Clonazepam Tablets if:

- you have a lung, liver or kidney problem
- you have ever had depression
- you have ever tried to harm or kill yourself
- a close friend or relative has recently died
- you regularly drink alcohol or use recreational drugs, or you have had problems with alcohol or drug use in the past. This is because you should not drink alcohol or take recreational drugs while you are taking clonazepam
- you have spinal or cerebellar 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

Other medicines and Clonazepam Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription, including 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, hydantoins, phenobarbital, phenytoin, primidone or sodium valproate
- cimetidine (used to treat stomach problems and heartburn)
- rifampicin (an antibiotic used to treat infections)
- medicines to make you sleep (hypnotics), or that make you feel sleepy as a side-effect
- medicines that help with anxiety (tranquillisers)
- pain-killers (analgesics) or medicines to relax your muscles (muscle relaxants)
- medicines that reduce your blood pressure, such as ramipril, candesartan, amlodipine, doxazosin

If any of the above applies to you (or you are not sure), talk to your doctor or pharmacist before taking Clonazepam Tablets.

Concomitant use of clonazepam and opioids (strong pain killers, medicines used 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 Tablets and alcohol

Do not drink alcohol whilst taking Clonazepam Tablets. 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

Do not take Clonazepam Tablets 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 machinery

Talk to your doctor about driving or using machines or tools while you are taking Clonazepam Tablets. 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. The risk increases with the dose and length of treatment period. The risk is greater if you have ever had a history of alcohol or drug abuse.

Clonazepam Tablets contain lactose.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Clonazepam Tablets

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

- Swallow the tablets with water. The tablets can be broken into equal halves to give a smaller dose.
- Your doctor will start you on a low dose and may increase it gradually 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 or four 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 your medicine as a single dose in the evening.

Adults and children over 12 years

The usual starting dose is 1 mg a day, or less. This will be increased gradually, usually to between 4 mg and 8 mg a day, although your doctor may tell you to take more. The maximum dose is 20 mg a day.

Elderly

The usual starting dose is 0.5 mg a day, or less. This will be increased gradually, usually to between 4 mg and 8 mg a day, although your doctor may tell you to take more. The maximum dose is 20 mg a day.

Infants (aged 0 to 1 year)

The usual starting dose is 0.25 mg a day, or less. This will be increased gradually, usually to between 0.5 mg and 1 mg a day.

Small children (aged 1 to 5 years)

The usual starting dose is 0.25 mg a day, or less. This will be increased gradually, usually to between 1 mg and 3 mg a day.

Older children (aged 5 to 12 years)

The usual starting dose is 0.5 mg a day, or less. This will be increased gradually, usually to between 3 mg and 6 mg a day.

If you take more Clonazepam Tablets than you should

If you take too many Clonazepam Tablets talk to a doctor or go to your nearest hospital straight away. Take the medicine pack with you.

If you take too much clonazepam you may feel drowsy, sleepy, light-headed, have a lack of coordination or be less responsive than normal. If someone else takes your Clonazepam Tablets by mistake, they should talk to a doctor or go to a hospital straight away.

If you forget to take Clonazepam Tablets

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.

Stopping Clonazepam Tablets and Withdrawal Effects

This medicine should not be stopped suddenly; keep taking it until your doctor tells you how to reduce the dose slowly.

If you stop taking the tablets suddenly your fits may return and you may experience withdrawal symptoms (see section 4), including the following effects:

- depression
- nervousness
- difficulty in sleeping
- irritability
- sweating
- upset stomach/diarrhoea
- or the symptoms you are being treated for can come back worse than before.

You may also experience mood changes, anxiety, restlessness and changes in sleep patterns. These effects may occur even after taking low doses for a short period of time.

If you stop taking these tablets suddenly after being treated with high doses of Clonazepam Tablets, you may experience confusion, hallucinations, shaking, faster heartbeat or fits.

Withdrawal may also cause unusual behaviour including aggressive outbursts, excitement or depression with suicidal thoughts or actions.

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

4. Possible side effects

Like all medicines, this medicine 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 Tablets. 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 Tablets, 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 Tablets 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

- loss of sex drive
- difficulty getting or keeping an erection (erectile dysfunction)

Withdrawal symptoms

Using benzodiazepines like Clonazepam Tablets 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. The risk is increased in the elderly and those taking other sedatives (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 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 Tablets

This medicine does not require any special temperature storage conditions.

Store in the original package in order to protect from light.

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 and on the blister after “EXP”. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Clonazepam Tablets contain

- The active substance is clonazepam. Each tablet contains either 0.5 mg or 2 mg of clonazepam.
- The other ingredients are: microcrystalline cellulose (E460), lactose and magnesium stearate (E572).

What Clonazepam Tablets look like and contents of the pack

Clonazepam Roma 0.5 mg Tablets are white to off white round, flat tablets, scored on one side and marked with “C5” on the other side.

Clonazepam Roma 2 mg Tablets are white to off white round, flat tablets, cross-scored on one side and marked with “C2” on the other side.

Clonazepam Tablets are packed in PVC/PVDC/aluminium blisters. Each blister contains 10 tablets.

Pack size: 100 tablets.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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