

Clonazepam Auden 500 microgram and 2 mg Tablets

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 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 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
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1. What Clonazepam is and what it is used for

The name of your medicine is Clonazepam Auden 500 microgram and 2 mg Tablets (called Clonazepam in this leaflet). Clonazepam belongs to a group of medicines called 'benzodiazepines'. It is used to treat epilepsy. Clonazepam works by preventing seizures or fits.

2. What you need to know before you take Clonazepam

Do not take Clonazepam:

- if you are allergic to clonazepam or any of the other ingredients of this medicine (listed in section 6).
- if you are allergic to other benzodiazepine medicines. These include diazepam, chlordiazepoxide, bromazepam and flurazepam.
- if you have lung disease.
- if you have myasthenia gravis (severe muscle weakness)
- if you suffer from sleeping disorders, such as difficulty breathing while asleep (sleep apnoea)
- if you have a severe liver condition
- if you have problems with alcohol or drug (prescription or recreational) use

Warnings and precautions

Talk to your doctor or pharmacist before taking Clonazepam if:

- you have a lung, liver or kidney condition
- you have a history of depression or have attempted suicide
- you have recently suffered a death of a close friend or relative
- you regularly drink alcohol or use recreational drugs
- you have porphyria (a disease that affects the skin and/or nervous system)
- you suffer from cerebellar ataxia (you have a problem co-ordinating movement)

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.

Other medicines and Clonazepam

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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 (medicine used to treat stomach problems)
- rifampicin (an antibiotic)
- anaesthetics
- medicines to make you sleep (hypnotics)
- medicines that help with anxiety (tranquillisers)
- pain killers (analgesics) or medicines to relax your muscles (muscle relaxants)

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

Concomitant use of Clonazepam and sedative medicines such as benzodiazepines or related drugs 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 sedative medicines the dose and duration of concomitant treatment should be limited by your doctor.

Please tell your doctor about all sedative 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.

Clonazepam with alcohol

Do not drink alcohol whilst taking Clonazepam as it may cause fits (epileptic seizures) and increase the risk of having side effects.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Clonazepam may affect your ability to drive, operate machinery and other hazardous activities, particularly in the first few days of treatment. This may be made worse if you drink alcohol. Increasing the dose of clonazepam or changing the time that you take it may also slow your reactions. You should not drive unless your doctor says you can.

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:
 - o The medicine has been prescribed to treat a medical or dental problem and
 - o You have taken it according to the instructions given by the prescriber or in the information provided with the medicine and
 - o 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 lactose

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

3. How to take Clonazepam

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

The recommended dose is:

Clonazepam is taken 3-4 times a day. It is started at a low dose and increased over 2-4 weeks until the right dose for you is reached (the maintenance dose). The maximum dose is 20 mg in a 24 hour period. Swallow the tablets with water. The tablets can be broken in half to give a smaller dose.

Adults

The starting dose should be no more than 1.0 mg in a 24 hour period. The maintenance dose is usually a total of 4 to 8 mg in a 24 hour period, but your doctor may tell you to take more.

Elderly

The starting dose should be no more than 0.5 mg in a 24 hour period, as elderly people are sensitive to the effects of clonazepam and may become confused to begin with. The maintenance dose is usually a total of 4 to 8 mg in a 24 hour period, but your doctor may tell you to take more.

Use in children and adolescents

Infants: The starting dose should be no more than 0.25 mg in a 24 hour period (half a 0.5 mg tablet) and the maintenance dose is usually a total of 0.5 - 1 mg in a 24 hour period.

Children 1-5 years: The starting dose should be no more than 0.25 mg in a 24 hour period (half a 0.5 mg tablet) and the maintenance dose is usually a total of 1 – 3 mg in a 24 hour period.

Children 5-12 years: The starting dose should be no more than 0.5 mg in a 24 hour period (one tablet) and the maintenance dose is usually a total of 3 – 6 mg in a 24 hour period.

If you take more Clonazepam than you should

If you take too many tablets or someone else accidentally takes your medicine, contact your doctor, pharmacist or nearest hospital immediately.

If you forget to take Clonazepam

If you forget to take a dose, simply take the next dose when it is due. Do not take a double dose to make up for a forgotten dose.

If you stop taking Clonazepam

Do not suddenly stop taking Clonazepam. If you need to stop taking Clonazepam, your doctor will tell you how to stop slowly to reduce any side effects as you can get withdrawal symptoms if you stop suddenly. These symptoms may include problems with sleeping, muscle pain, anxiety (sometimes severe), tension, restlessness, confusion, severe mood changes, irritability, sweating, shakes (tremor), headaches and agitation. In serious cases, withdrawal effects can also include being oversensitive to light, noise and touch, hallucinations, tingling, numbness and a feeling of being unreal.

If you think the effect of Clonazepam is too strong or too weak, talk to your doctor. Do NOT change the dose yourself.

4. Possible side effects

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

Tell your doctor immediately if you experience any of the following serious side effects – you may need urgent medical treatment:

- Changes in behaviour: aggressiveness, excitability, nervousness, hostility, anxiety, problems sleeping, nightmares, vivid dreams, irritability, agitation, extreme mood changes and new types of seizures may occur.
- Allergic reactions can occur (such as itching, swelling of the tongue, eyes, lips and hands).

The following side effects have been reported:

- Memory loss (amnesia) after a traumatic event which may be linked with some strange behaviour (more likely with higher doses).
- Depression.
- Loss of sex drive, impotence.
- Dependence on clonazepam – this is more of a risk when the dose is high or the treatment is for a long time, and is especially likely to occur in patients with a history of alcoholism or drug abuse.
- Dizziness, light-headedness, sleepiness, tiredness, lack of co-ordination, poor concentration, restlessness, confusion, disorientation, floppiness and weakness of the muscles, headache. Particularly at the start of treatment. The side effects are usually short-lived and may disappear by adjusting the dose.
- 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.
- Feeling unsteady when walking.
- Platelet count bruising easily, being short of breath and nose bleeds.
- Slurring of speech, lack of co-ordination of movement, double vision, rapid eye movements are all reversible effects that may occur particularly if on long-term or high-dose treatment.
- Increase in number of fits (epileptic seizures) may occur during long-term treatment or in patients with a rare condition called porphyria.
- Infants and small children may start to dribble or drool because of increased production of saliva and secretions from the airways. Children should therefore be watched carefully as this might cause problems in breathing and/or severe choking and coughing.
- Rarely, nausea and stomach problems can occur.
- Rarely there may be hives, rashes, short-term hair loss or change in skin colouring.
- Rarely, urinary incontinence (not being able to control when to pass water) may occur.

There have been some isolated reports of:

- changes to your blood or liver function (seen in test results).
- early development of puberty in children. This effect is reversible.

Withdrawal symptoms

Stopping Clonazepam suddenly may cause withdrawal symptoms. These include, shakes (tremors), sweating, agitation, problems sleeping, anxiety (sometimes severe), headaches, muscle pain, tension, restlessness, confusion, irritability and fits (epileptic seizures). In severe cases the following effects may happen: a feeling of being unreal, oversensitivity to noise, light and touch, numbness and tingling of the hands and feet or hallucinations.

Gradual withdrawal of Clonazepam will help to reduce these effects.

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

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 after EXP. The expiry date refers to the last day of that month.

Keep the blister in the outer carton in order to protect from light. 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 contains

- The active substance is clonazepam.
- The other ingredients are lactose monohydrate, magnesium stearate, microcrystalline cellulose and sodium starch glycolate.

What Clonazepam looks like and contents of the pack

Clonazepam Auden 500 micrograms Tablets are white round tablets cross-scored and marked 'CLN 0.5'.

Clonazepam Auden 2 mg Tablets are white round tablets cross-scored and marked 'CLN 2'.

Clonazepam Tables are available in pack sizes of 100.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation holder

TEVA UK Limited,
Eastbourne,
BN22 9AG,
UK

Manufacturer

Actavis Group PTC ehf
Reykjavikurvegur 76-78,
Hafnarfjorour, IS-220,
Iceland

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