



Clonazepam Celix 0.5 mg Tablets Clonazepam Celix 2 mg Tablets (clonazepam)

Your medicine is available using the above name, but will be referred to as Clonazepam Celix Tablets throughout this leaflet.

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

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

The name of your medicine is clonazepam (called Clonazepam Celix Tablets in this leaflet). Clonazepam belongs to a group of medicines called 'benzodiazepines'. It is used to treat epilepsy. Clonazepam Celix Tablets work by preventing seizures or fits. Any fits that you do have will be less serious.

2. What you need to know before you take Clonazepam Celix Tablets

Do not take Clonazepam Celix Tablets:

- 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, temazepam and flurazepam
- if you have lung disease or breathing problems
- 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

If you are not sure, talk to your doctor or pharmacist before taking this medicine.

Warnings and precautions

Talk to your doctor or pharmacist before taking Clonazepam Celix Tablets if: -

- you have a lung, liver or kidney condition
- you have a history of depression or have attempted suicide or tried to harm yourself
- 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)
- you are elderly or debilitated (weak); your doctor may adjust your dose

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 Celix 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, hydantoin, phenobarbital, phenytoin, primidone or sodium valproate
- cimetidine (medicine used to treat stomach problems)
- rifampicin (an antibiotic)
- anaesthetics
- 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 Celix Tablets.

Using Clonazepam Celix Tablets and opioids (strong painkillers, medicines used for substitution therapy and some cough medicines) or together with 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, using these medicines together should only be considered when other treatment options are not possible.

However if your doctor does prescribe Clonazepam Celix Tablets together with opioid or sedative medicines, the dose and duration of this treatment should be limited by your doctor.

Please tell your doctor about all opioid or 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.

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 Celix Tablets with alcohol

Do not drink alcohol whilst taking Clonazepam Celix Tablets as it may cause fits (epileptic seizures) and increase the risk of having side effects. Alcohol can also increase the effects of clonazepam, possibly leading to severe sedation that could result in coma or death.

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. Clonazepam is known to have harmful effects on the unborn child.

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:
 - 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 accordance with 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 Celix Tablets contain lactose

This medicine 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 Celix 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.

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 of 0.5 mg) and the maintenance dose is usually a total of 3 – 6 mg in a 24 hour period.

If you take more Clonazepam Celix Tablets than you should

If you take too many tablets or someone else accidentally takes your medicine, contact your doctor, pharmacist or go to your nearest hospital immediately. 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 you forget to take Clonazepam Celix Tablets

If you forget to take a dose, skip the missed dose and simply 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 Celix Tablets

Do not suddenly stop taking Clonazepam Celix Tablets. If you need to stop taking Clonazepam Celix Tablets, 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, upset stomach/diarrhoea, muscle pain, anxiety (sometimes severe), tension, restlessness, confusion, severe mood changes, irritability, sweating, shakes (tremor), headaches, hallucination, faster heart beat 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 Celix Tablets 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. You may also experience mental health 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.
- allergic reactions can occur (such as itching, skin rash, swelling of the throat, tongue, face, lips, mouth (which can make it difficult to breathe or swallow), eyes, and hands).
- effects on the heart: 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.

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 Celix 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 Celix Tablets 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

Stopping Clonazepam Celix Tablets suddenly may cause withdrawal symptoms. These include, shakes (tremors), sweating, agitation, problems sleeping, anxiety (sometimes severe), headaches, muscle pain, tension, restlessness, confusion, irritability, diarrhoea and fits (epileptic seizures). In severe cases the following effects may happen: a feeling of being unreal (losing contact with reality), oversensitivity to noise, light and touch, numbness and tingling of the hands and feet or hallucinations (seeing or hearing things that are not really there).

Gradual withdrawal of Clonazepam Celix Tablets 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 Celix Tablets

Keep Clonazepam Celix Tablets in their original blister packaging to protect from light and moisture. Keep the blister strips in the outer carton 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 the blister after EXP. The expiry date refers to the last day of that month.

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

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 Celix Tablets contains

- The active substance is clonazepam.
- Each tablet contains 0.5 mg or 2mg of clonazepam.
- The other ingredients are lactose monohydrate, microcrystalline cellulose, starch pregelatinized and magnesium stearate.

What Clonazepam Celix Tablets look like and contents of the pack

Clonazepam Celix 0.5 mg Tablets are white to off white circular tablets, debossed with 'CL0.5' on one side and breakline on other side.

Clonazepam Celix 2 mg Tablets are white to off white circular tablets, debossed with 'CL2' on one side and cross breakline on other side.

Clonazepam Celix Tablets are available in blister pack (aluminium-PVC) of 100 tablets.

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If you are blind or partially sighted and require this leaflet in a different format, call 0800 669 6825 or contact medinfo@celixpharma.com

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