

Package leaflet: Information for the user**Clonazepam Rosemont 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 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 Rosemont Oral Solution is and what it is used for
2. What you need to know before you take Clonazepam Rosemont Oral Solution
3. How to take Clonazepam Rosemont Oral Solution
4. Possible side effects
5. How to store Clonazepam Rosemont Oral Solution
6. Contents of the pack and other information

1. What Clonazepam Rosemont Oral Solution is and what it is used for

The name of your medicine is Clonazepam Rosemont 2mg/5ml Oral Solution (called Clonazepam in this leaflet). Clonazepam belongs to a group of medicines called benzodiazepines.

It is used to treat epilepsy in 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 Rosemont Oral Solution**Do not take Clonazepam Rosemont Oral Solution if you are allergic to:**

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

An allergic reaction can include a rash, itching or shortness of breath.

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 this medicine if:

- you have breathing problems or lung disease
- your breathing stops when you are asleep (sleep apnoea)
- you have severe liver problems
- your muscles become weak and get tired easily (myasthenia gravis)

- you have 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 Rosemont Oral Solution. A small number of people being treated with epilepsy medicines 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 this medicine if:

- you have any liver, kidney or lung problems
- 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 take 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 are shaky and unsteady, have slurred speech or have rapid eye movements (spinal or cerebellar ataxia)
- you have a rare, inherited blood problem called porphyria
- you are elderly or debilitated (weak); your doctor may adjust your dose.

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

Other medicines and Clonazepam Rosemont Oral Solution

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
- medicines used to make you sleep (hypnotics)
- medicines that help with anxiety (tranquillisers)
- pain killers (analgesics) or medicines to relax your muscles (muscle relaxants)
- cimetidine – for stomach problems and heartburn
- rifampicin – an antibiotic used to treat infections.

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

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 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 Rosemont Oral Solution with alcohol

Do not drink alcohol while you are taking Clonazepam. This is because it may cause side effects or cause your fits to return.

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. This is because Clonazepam may affect your baby.

Driving and using machines

Talk to your doctor about driving or using machines or tools while you are taking Clonazepam. This is because the medicine 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.

This medicine can affect your ability to drive.

Do not drive whilst taking this medicine until you know how this medicine affects you.

It may be an offence to drive if your ability to drive safely is affected.

There is further information for patients who are intending to drive in Great Britain - go to <https://www.gov.uk/drug-driving-law>

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 Rosemont Oral Solution contains ethanol (2.6% v/v alcohol).

This means that each 5ml contains 0.1g of alcohol. This is the same as 2.6ml of beer or 1.1ml of wine per 5ml dose. It is harmful if you have a drinking problem (alcoholism). You should be aware the medicine has alcohol in it if:

- you are pregnant or breast-feeding
- you have liver problems.

3. How to take Clonazepam Rosemont Oral Solution

Always take this medicine exactly as your doctor or pharmacist has told you. Look on the label and check with your doctor or pharmacist if you are not sure.

- Clonazepam Rosemont 2mg/5ml Oral Solution contains 2mg of clonazepam in one 5ml spoonful.
- Always use the 2.5ml/ 5ml double ended spoon with a 1.25ml dosing line within the 2.5ml end that is provided with the pack.
- Do not use a different spoon as it may be made of polystyrene or PVC and may react with the medicine.
- If a pharmacist gives you a different device such as an oral syringe or pipette, you may find that the plunger of the syringe may stop moving smoothly or the markings may fade over time. If this happens, take it back to your pharmacy and swap for a new one.

How to take

- Take this medicine by mouth.
- Make sure that everything you are using is dry. This is because the medicine should not be mixed with water before you take it. You can drink water after taking the medicine if you want, this will not affect the medicine
- This medicine can also be administered via specific nasogastric (NG) or percutaneous endoscopic gastrostomy (PEG) tubes. There is further information in the SmPC, ask your doctor, pharmacist or nurse for this information.
- Do not use with a tube which is made of PVC or polystyrene.
- It is recommended to administer the dose before feed is given via the tube, as the medicine is oily.
- Instructions for use via NG or PEG tube:
 1. Ensure the tube is clear before taking the medicine
 2. Flush the tube with a minimum of 10mL of water
 3. Administer the medicine with a suitable measuring device
 4. Flush the tube again by either:
 - i) Flushing the tube 3 times, using a minimum of 5mL of water each time, or
 - ii) Flushing the tube using a minimum of 5mL of water and then immediately delivering a minimum of 10ml of feed.
- Please consult your doctor if these instructions cannot be followed as the oily medicine may stick to the wall of the tube and therefore the dose you get may be less than required.

How much to take

- 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 four equal amounts which you will take at evenly spaced times throughout the day.
- If your 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.

Adults

- The usual starting dose is 1mg a day (2.5ml) or less.
- This will be increased gradually, usually to between 4mg and 8mg a day (10 to 20ml).
- The maximum dose is 20mg a day (50ml).

The elderly

- The usual starting dose is 0.5mg a day (1.25ml) or less.
- This will be increased gradually, usually to between 4mg and 8mg a day (10 to 20ml).
- The maximum dose is 20mg a day (50ml).

If you take more Clonazepam Rosemont Oral Solution than you should

- 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 you forget to take Clonazepam Rosemont Oral Solution

- If you forget a dose, take it as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose.
- Do not take a double dose (two doses at the same time) to make up for a forgotten dose.

If you stop taking Clonazepam Rosemont Oral Solution

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 Clonazepam without talking to your doctor. If you do your fits may return and you may get withdrawal symptoms (listed in Section 4: Possible side effects).
- If the dose of Clonazepam you take has to be lowered, 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. The side effects below may sometimes happen.

Important side effects to look out for

See a doctor straight away if you notice any of the following serious side effects – you may need urgent medical treatment:

- thoughts of harming or killing yourself
- allergic reactions – the signs may include skin rash, flaking skin, boils, sore lips and mouth, swelling of the face, fever, sudden wheezing, fluttering or tightness of the chest or collapse.

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, excited, irritable, nervous, agitated, hostile or anxious
- problems sleeping, nightmares or vivid dreams
- mental problems such as seeing or hearing things that are not really there (hallucinations), believing in things that are not real (delusions) or problems with your speech
- types of fits (seizures) that you have not had before.

Elderly patients

Older patients taking benzodiazepine medicines have a higher risk of falling and breaking bones.

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 coordination)
- 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 or a feeling of being lost (disorientation)
- feeling restless
- difficulty remembering new things
- headache
- depression
- slowing or slurring of speech
- poor coordination, 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 may include feeling tired, bruising easily, being short of breath and nose bleeds. Your doctor may want to give you 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 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 most common symptoms can include:

- problems sleeping
- muscle pain, shaking (tremor) or feeling restless
- feeling very anxious, tense, confused, irritable or agitated, or changes in your mood
- increased sweating
- headache.

Less common withdrawal symptoms can include:

- feeling sensitive to light, noise or 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 sedatives (including alcohol).

If any of the side effects gets serious, or if you notice any side effects not mentioned in this leaflet, please tell your doctor or pharmacist.

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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Ireland

HPRA Pharmacovigilance
Earlsfort Terrace, IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie

e-mail: medsafety@hpra.ie

5. How to store Clonazepam Rosemont Oral Solution

- Keep this medicine out of the sight and reach of children.
- Do not store above 25°C. Store in the original package in order to protect from light.
- Do not use 1 month after you first open it. Take it back to the pharmacy.
- Do not use this medicine after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.
- If it is out of date or you no longer want it, take it back to the pharmacy.
- Do not use this medicine if you notice anything wrong with the medicine. Talk to your pharmacist.
- 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 Rosemont Oral Solution contains

The active substance is clonazepam. Each 5ml contains 2mg clonazepam. The other ingredients are ethanol, saccharin, levomenthol and medium chain triglycerides.

What Clonazepam Rosemont Oral Solution looks like and contents of the pack

Clonazepam Rosemont Oral Solution is a clear, pale straw coloured liquid which smells of menthol. It comes in a brown glass bottle holding 150ml of solution and with a 2.5ml/5ml double ended spoon with 1.25ml measuring line.

Marketing Authorisation Holder

Perrigo Pharma International DAC,
The Sharp Building,
Hogan Place,
Dublin 2,
Ireland

Manufacturer

Omega Pharma International NV, Venecoweg 26, 9810 Nazareth, Belgium.
Rosemont Pharmaceuticals Ltd, Yorkdale Industrial Park, Braithwaite Street, Leeds,
LS11 9XE, UK.

This medicinal product is authorised in the member states of the EEA under the following names:

UK, Ireland – Clonazepam Rosemont 2mg/5ml Oral Solution

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