

Ireland

Package leaflet: Information for the patient

Rivotril® 0.5 mg and 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 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 Rivotril is and what it is used for
2. What you need to know before you take Rivotril
3. How to take Rivotril
4. Possible side effects
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1. What Rivotril is and what it is used for

Rivotril contains the active substance clonazepam, which belongs to a group of medicines called benzodiazepines.

Rivotril 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 Rivotril

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

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

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

Do not take Rivotril 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).
- problems with alcohol or drug (prescription or recreational) use.

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Rivotril.

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 Rivotril if:

- You have liver, kidney or lung problems.
- You have a condition called ‘myasthenia gravis’ (where your muscles become weak and get tired easily).
- 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 Rivotril.

Other medicines and Rivotril

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 Rivotril can affect the way some other medicines work. Also some other medicines can affect the way Rivotril 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, hydantoins, 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).

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 Rivotril.

Rivotril and Alcohol

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

Pregnancy and breast-feeding

You must not take Rivotril if you are pregnant, might become pregnant or are breast-feeding, unless your doctor tells you to. Rivotril 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 Rivotril. 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.

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.

Rivotril contains lactose

This medicine contains lactose, which is a type of sugar. If you have been told by your doctor that you cannot tolerate or digest some sugars (have an intolerance to some sugars), talk to your doctor before taking this medicine.

3. How to take Rivotril

Always take Rivotril 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 Rivotril 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 Rivotril 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). 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). 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 Rivotril than you should

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

If you forget to take Rivotril

- 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 Rivotril

If you receive long term treatment with Rivotril (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 tablets 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 Rivotril 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 Rivotril tablets 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, Rivotril 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 Rivotril.

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 Rivotril, 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 Rivotril.

Other possible side effects

When you start taking Rivotril 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 Rivotril 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 Rivotril 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 sedatives (including alcohol).

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL-Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Rivotril

Keep Rivotril tablets in their original bottle and in the outer carton to protect from light.

Rivotril tablets do not need special storage conditions.

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 bottle label.

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. Only keep the tablets if your doctor tells you to.

6. Contents of the pack and other information

What Rivotril contains

The active substance in Rivotril is clonazepam. There are two different sizes of tablets:

- Rivotril 0.5 mg Tablets. Each tablet contains 0.5 mg (half a milligram) clonazepam.
- Rivotril 2 mg Tablets. Each tablet contains 2 mg clonazepam.

The other ingredients in Rivotril 0.5 mg Tablets are lactose monohydrate, maize starch, pregelatinised potato starch, talc, magnesium stearate, yellow iron oxide (E172) and red iron oxide (E172).

The other ingredients in Rivotril 2 mg Tablets are lactose anhydrous, pregelatinised maize starch, microcrystalline cellulose and magnesium stearate.

What Rivotril looks like and contents of the pack

- Rivotril 0.5 mg Tablets are round, pinkish-buff in colour, marked 'ROCHE 0,5' on one side and a single break mark on the other.
- Rivotril 2 mg Tablets are round, white in colour, marked 'ROCHE ·2·' on one side and cross break marks on the other.
- Rivotril 0.5 mg Tablets are scored so that they can easily be broken into halves. This can allow you to take lower doses at the start of your treatment.
- Rivotril 2 mg Tablets are cross scored so that they can easily be broken into halves or quarters. This can allow you to take lower doses at the start of your treatment.
- Rivotril 0.5 mg Tablets are supplied in glass bottles which contain 50, 100 or 150 tablets. Not all packs may be marketed.

- Rivotril 2 mg Tablets are supplied in glass bottles which contain 30 or 100 tablets. Not all packs may be marketed.

Marketing Authorisation Holder and Manufacturer

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