

PROPOSED CLEAN PATIENT LEAFLET INFORMATION

SCHEDULING STATUS

S5

Rivotril® 1 mg/1 mL Injection

Clonazepam

Read all of this leaflet carefully before you start taking Rivotril

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your pharmacist.

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
5. How to store Rivotril
6. Contents of the pack and other information

1. What Rivotril is and what it is used for

Rivotril contains clonazepam as the active substance, which belongs to a group of medicines known as benzodiazepines. Clonazepam has anticonvulsant properties, that is, it prevents seizures (fits).

Rivotril is used for the treatment of epilepsy [in infants, children and adults].

Rivotril is used for the treatment of panic disorder, with or without fear of closed spaces.

2. What you need to know before you receive Rivotril

Do not take Rivotril:

- If you are allergic to the group of medicines known as benzodiazepines, such as diazepam, chlordiazepoxide, bromazepam, or flurazepam for example.
- If you are allergic to any of the ingredients it contains.
- If you suffer from lung disease.

- If you suffer from myasthenia gravis (severe muscle tiredness).
- If you suffer from sleeping disorders, such as difficulty breathing while asleep.
- If you have a liver condition.
- If you are at risk of having an attack of acute narrow angle glaucoma.

Rivotril ampoules should not be used to treat new born babies, especially those born prematurely

Warnings and precautions

Make sure your doctor knows if you:

- have a lung, liver or kidney condition.
- have a condition called 'myasthenia gravis' (where your muscles become weak and get tired easily).
- regularly drink alcohol or use recreational drugs or you have had problems with alcohol or drug use in the past.
- suffer from a form of inco-ordination of the muscles called cerebellar ataxia (where you may become shaky and unsteady, have slurred speech or rapid eye movements).
- have a history of depression and/or suicide attempts.
- have a rare, inherited blood condition called 'porphyria'.
- are elderly or debilitated (weak); your doctor may adjust your dose
- are prone to an eye condition called 'acute narrow angle glaucoma'

Important

You must not drink alcohol whilst taking Rivotril as this may provoke epileptic seizures.

Other medicines and Rivotril

Take special care if you are taking any other medicines, including those not prescribed by your doctor. This is extremely important, as using more than one medicine at the same time can strengthen or weaken the effect of the medicines involved, as for example, when Rivotril is used in combination with other anti-epileptic medicines e.g. hydantoins, phenobarbitone, sodium valproate and

lamotrigine. Rivotril may also be affected by other medicines, e.g. those used to treat stomach problems (cimetidine) and certain antibiotics (rifampicin). The effects of Rivotril may be increased by other anticonvulsant (antiepileptic) medicines, anaesthetics, hypnotics (sleep inducing medicines), tranquillisers, analgesics (medicines that relieve pain) as well as muscle relaxants. Taking phenytoin or primidone with Rivotril may affect the amount of medicine in your blood.

If you are taking medicines on a regular basis, including complementary or traditional medicines, the use of Rivotril with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other health care professional for advice.

Important information about an ingredient in Rivotril

Rivotril injection contains benzyl alcohol and must not be administered to new born babies or infants as it can cause serious side effects, see “Do not take Rivotril” above.

Pregnancy and breastfeeding

Do not take this medicine if you are pregnant, or might become pregnant, unless advised by your doctor. Contact your doctor if you think you may be pregnant, or are intending to become pregnant.

Clonazepam passes into breast milk therefore, if you are breastfeeding, this medicine should be avoided. Your doctor will be able to discuss this with you. Mothers who are not breastfeeding may use Rivotril.

If you are pregnant or breastfeeding your baby whilst taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

Driving and using machines

Rivotril may affect your ability to operate machinery. Driving, operating machinery and other hazardous activities should therefore be avoided altogether or at least during the first few days of treatment. This may be made worse if you take alcoholic drinks. If you increase your dose or change the timings of when you take your medication this may also modify your reactions

3. How to Rivotril will be given to you

Rivotril will be administered to you by a doctor or nurse into a vein. It should always be used as directed by your doctor.

- The normal adult dose is 1 mg (2 mL) by slow intravenous injection. The normal dose in children is 0,5 mg (1 mL) by slow intravenous injection. The dose given to the elderly will differ from the normal adult dose.
- Alternatively, up to 3 mg may be given by intravenous infusion.

If you take more Rivotril than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take Rivotril

If you forget to receive a Rivotril injection, go to your doctor as soon as you remember. If you don't get your regular dose of Rivotril it can cause you to have fits or panic attacks.

Effects when treatment with Rivotril is stopped

Your doctor will advise you when to stop taking Rivotril. As treatment with Rivotril may last all your life, you must always tell your doctor if you want to stop taking Rivotril or other medicines you are taking, as because sudden discontinuation of treatment can cause the reappearance of seizures as well as withdrawal symptoms.

After a period of usage it is advisable to reduce dosage gradually. Sometimes withdrawal effects occur if the medicine is stopped suddenly and these may include sleep disturbances, muscle pain, extreme anxiety, tension, restlessness, confusion, mood changes, irritability, sweating, tremor, headaches and agitation. In serious cases, withdrawal effects can also include being oversensitive to light, noise and physical contact, hallucinations, tingling and numbness and a feeling of being unreal.

4. Possible side effects

Not all side effects reported for Rivotril are included in this leaflet. Should your general health worsen while taking Rivotril, consult your doctor, pharmacist or other health care professional for advice.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Important side effects to look out for:

Allergic reactions

If you get an allergic reaction, contact a doctor straight immediately.

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 contact a doctor straight ~~away~~ immediately.

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, contact your doctor immediately.

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. Contact your doctor immediately if you observe these effects.

Other possible side effects

When you take 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
- Difficulty breathing
- Poor concentration
- Restlessness and confusion
- Disorientation
- Memory loss

Other unwanted effects which can also occur less frequently include:

- hives or itching,
- swelling of the soft tissue, especially around the eyes, lips and hands,
- hair loss,
- changes in your skin colouring,
- nausea,
- headache,
- change in your sexual desire,
- impotence,
- urinary incontinence,
- early sexual development in children,
- nausea,
- stomach upsets,
- allergic reactions including severe hypersensitivity and shock, • depression,
- changes in your blood and liver function,
- development of physical and psychological dependence may make it difficult to come off or stop treatment.

With long-term Rivotril treatment, the following may occur:

- increase in seizures (only with certain forms of epilepsy),
- slowing or slurring of speech,

- reduced co-ordination of movements or changes in vision (e.g. double vision, involuntary jerky movements of the eye).

If you are concerned about these or any other unwanted side effects, talk to your doctor.

Reporting of side effects

If you get side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications:

<https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of Rivotril.

5. How to store Rivotril

Rivotril injection: store below 30 °C.

Rivotril ampoules must be stored in the original package and in the outer carton, protected from light.

Rivotril should not be used after the expiry date shown on the container.

Store out of reach of children

6. Contents of the pack and other information

What Rivotril contains:

Rivotril 1 mg/1 mL Injection: Each ampoule contains 1 mg clonazepam per mL, and 3 % benzyl alcohol as a preservative.

Contains 15 % m/v ethyl alcohol (undiluted ampoule). Other ingredient: propylene glycol.

1 mL water for Injection is used as a diluent. After adding the diluent, the solution for injection contains 1 mg clonazepam per 2 mL.

What Rivotril looks like and contents of the pack

Rivotril ampoules: 1 mL clonazepam in 1 mL solvent, each accompanied by an ampoule containing 1 mL water as a diluent.

Rivotril ampoule pack: packs of 5 ampoules active substance and 5 ampoules Water for Injections.

Not all packs may be marketed



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Roche Ethical Assistance Line (REAL) toll-free: 0800 21 21 25

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