

Rivotril® Tablets
0.5mg and 2mg

Roche

Clonazepam

Please read this leaflet carefully before you start to take your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

What is Rivotril?

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

The round pinkish-buff tablets contain 0.5mg (500 micrograms) clonazepam and are marked ROCHE 0.5.

The round white tablets contain 2mg clonazepam and are marked ROCHE 2.

The 0.5mg tablets also contain the inactive ingredients lactose monohydrate, maize starch, pregelatinised starch, talc, magnesium stearate, the colours yellow iron oxide (E172) and red iron oxide (172).

The 2mg tablets also contain the inactive ingredients lactose anhydrous, pregelatinised maize starch, microcrystalline cellulose, magnesium stearate.

All tablets are cross scored so that they can easily be broken into halves or quarters.

The tablets are supplied in packs of 100.

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What is Rivotril taken for?

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

When must Rivotril not be taken?

- 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.

When should you be extra careful while taking Rivotril?

Make sure your doctor knows if you:

- have a lung, liver or kidney condition.
- 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 drugs e.g. hydantoins, phenobarbital, sodium valproate. 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) drugs, anaesthetics, hypnotics (sleep inducing drugs), tranquillisers, analgesics (drugs that relieve pain) as well as muscle relaxants. Taking phenytoin or primidone with Rivotril may affect the amount of drug in your blood.
- regularly drink alcohol or use recreational drugs.
- suffer from a form of inco-ordination of the muscles called cerebellar ataxia.
- have a history of depression and/or suicide attempts.
- suffer from the disease which affects the skin and/or nervous system called porphyria.
- have recently suffered a death of a near friend or relative.

Important

As a general rule, epileptics are not allowed to drive. 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.

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

May Rivotril be used during pregnancy or while breast feeding?

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. If advised to take this medicine during late pregnancy or during labour, your baby might have a low body temperature, floppiness, breathing and feeding difficulties, an irregular heart beat and may have developed physical dependence and suffer withdrawal symptoms.

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

How should Rivotril be taken?

- Always take the tablets exactly as your doctor tells you to. He/she will prescribe a suitable dose for you. The dose your doctor prescribes will depend on the nature of your illness, your reaction to the medicine, your age and body weight. The table below shows the different doses that your doctor may prescribe according to your age. Your doctor will start you on an initial low dose and gradually increase it until the desired effect is achieved. The elderly are particularly sensitive to the effects of Rivotril and may experience some confusion.

	Initial Dose	Maintenance Dose
Adults	1mg/day	4 → 8mg/day
Elderly	0.5mg/day	4 → 8mg/day
Small children (5 → 12 years)	0.5mg/day	3 → 6mg/day
Small children (1 → 5 years)	0.25mg/day	1 → 3mg/day
Infants (0 → 1 year)	0.25mg/day	0.5 → 1mg/day

- The total daily dose should be taken as advised by your doctor in three or four divided doses at intervals throughout the day up to a maximum of 20mg per day. Swallow the tablets with water.
- If you forget to take one dose, you should never make up for it by doubling the dose next time. Instead, you should simply continue with the next dose when it is due.
- Do not change the prescribed dose yourself. If you think the effect of your medicine is too weak or too strong, talk to your doctor.
- If you take too many tablets or someone else accidentally takes your medicine, contact your doctor, pharmacist or nearest hospital straight away.

When and how does treatment with Rivotril end?

Your doctor will advise you when to stop taking the medicine. Treatment with Rivotril may last all your life, therefore you must always tell your doctor if you want to stop taking Rivotril or other drugs you are taking, as 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.

What are the possible unwanted effects of Rivotril?

Some patients will feel drowsy or tired, especially at the start of treatment and may experience some muscle weakness, dizziness, light-headedness, floppiness of the muscles or bad co-ordination and unsteadiness when walking. In rare cases breathing difficulties may occur. Your doctor can help to avoid most of these effects by adjusting the dose. The effects are temporary and disappear over the course of treatment. Poor concentration, restlessness, confusion, disorientation and memory loss may also occur when taking Rivotril.

In infants and small children increased salivation and secretion from the lungs may occur. Children should therefore be watched carefully as this might cause difficulties in breathing and/or severe choking and coughing.

Other unwanted effects which can also occur more rarely include: hives or itching, swelling of the soft tissue, especially around the eyes, lips and hands, hairloss, changes in your colouring (i.e. skin), nausea, headache, loss of sexual desire, impotence, urinary incontinence, early sexual development in children (this is reversible), abdominal problems or allergic reactions including severe hypersensitivity and shock.

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).

Depression may occur in patients treated with Rivotril, but it may also be associated with the underlying disease.

In rare cases changes in your blood and liver may occur and your doctor will monitor for these.

Rivotril may cause convulsions in patients with a metabolic disorder called porphyria.

Development of physical and psychological dependence may make it difficult to come off or stop treatment if taken for too long.

Rarely, changes in behaviour may occur including aggression, excitement, irritability, nervousness, hostility, agitation, anxiety, sleep disturbances, nightmares, vivid dreams, psychotic disorders, severe behavioural disturbances, and new types of seizure may arise. If these symptoms occur, you must inform your doctor immediately. He/ she may want you to stop taking this medicine.

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

How should Rivotril be stored?

- The tablets should be stored in the original package and in the outer carton, protected from light.
- Keep this medicine out of the reach and sight of children.
- This medicine must not be used after the date (EXP) printed on the pack. Return any left over medicine to your pharmacist. Only keep it if your doctor tells you to.
- REMEMBER this medicine is for you. Only a doctor can prescribe it for you. Never give it to others. It may harm them even if their symptoms are the same as yours.

Further information:

You can get more information from your doctor or pharmacist.

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