

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed with a doctor's prescription only

Rivotril®

2.5 mg/ml

Drops



Composition:

1 ml of **Rivotril** contains:
Clonazepam 2.5 mg

* For information regarding inactive ingredients, see section 6 - "Further Information".

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist. This medicine has been prescribed for the treatment of your ailment. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

Important information for your review

- Following the doctor's instructions (dosage, instructions for use and duration of treatment) increases the chance of treatment success. In any case, do not discontinue treatment without consulting with the attending doctor. Please read sections 2 and 4 for detailed safety information.
- Do not breastfeed when using the medicine. Consult the doctor before using the medicine if you are pregnant. For information regarding pregnancy and breastfeeding, read section 2, subsection "Pregnancy and breastfeeding".

1) WHAT IS THE MEDICINE INTENDED FOR?

The medicine is intended for treatment of epilepsy or anxiety.

Therapeutic group:

Rivotril belongs to a group of medicines called benzodiazepines.

2) BEFORE USING THE MEDICINE

- Do not use the medicine if:**
- you are breastfeeding.
 - you are sensitive (allergic) to the active ingredient or to any of the other ingredients contained in the medicine (see section 6 - "Further Information").
 - you are suffering from severe respiratory failure or from severe liver failure.
 - you are suffering from a narrow-angle glaucoma attack.

Special warnings regarding use of the medicine

Do not use the medicine without consulting the doctor before commencing treatment:

- if you are suffering from ataxia (a disease of the central nervous system characterised by tremor, unsteady gait, slurred speech or rapid eye movements).
- in patients suffering from acute intoxication by alcohol or drugs.
- if you regularly drink alcohol or if you take drugs or if you have a history of alcohol or drug addiction.
- if you have severe liver damage (e.g., cirrhosis of the liver) or impaired kidney function.
- if you are suffering, or have suffered in the past, from impaired function of the eyes (e.g., glaucoma).
- if you are suffering from a lung disease (e.g., chronic obstructive pulmonary disease [COPD]) or from a liver disease or if you are being treated, in addition to **Rivotril**, with additional medicines affecting the central nervous system or with medicines for treatment of epilepsy - the doctor may need to adjust the dose of **Rivotril** for you individually.
- if you have ever attempted suicide or if you are suffering, or have suffered in the past, from depression.
- if you suffer from a blood disease called porphyria.
- prolonged use of **Rivotril** may cause dependence! This risk increases with higher dosages and longer durations of treatment, and in patients with a history of addictions. If dependence develops, discontinuation of treatment must be done gradually to avoid withdrawal symptoms (see section 4 - "Side Effects").
- during the course of treatment with **Rivotril**, abstain from drinking alcohol or from concomitant treatment with medicines that depress the nervous system. This combination may increase the side effects of **Rivotril** (e.g., severe hypnotic effect, cardiac or respiratory depression).
- discontinue **Rivotril** treatment gradually. Abrupt discontinuation of **Rivotril** treatment, as with all medicines to treat epilepsy, may cause the occurrence of severe epileptic attacks.
- it is very important to be under medical surveillance during the course of treatment with the medicine, especially patients with a history of suicide attempts or depression.
- if you are taking the medicine and feel depressed, have suicidal thoughts or want to hurt yourself - refer to the doctor immediately!
- if you are sensitive to any food or medicine, inform the doctor before taking the medicine.
- Elderly:** In elderly patients, the dosage should be increased under strict medical supervision. In addition, since the medicine impairs alertness, these patients should be careful when walking, due to the higher risk of falls and fractures.
- Children:** **Rivotril** may increase the production of saliva and phlegm in children. Pay attention that there is no airway obstruction.

Rivotril and other medicines

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. It is especially important to inform the doctor or the pharmacist if you are taking:

- medicines for treatment of epilepsy, such as phenytoin, phenobarbital, valproate and carbamazepine. These medicines may increase the rate of breakdown of the medicine, thereby shortening its duration of activity.
- a combination of valproate with **Rivotril** may cause an epileptic attack.
- medicines and substances that depress the central nervous system (alcohol, sedatives, hypnotics, etc.).
- medicines that affect liver enzyme activity, such as cimetidine, which may slow the rate of breakdown of the medicine, thereby extending the duration of its activity, or rifampicin, which may increase the rate of breakdown of the medicine, thereby shortening its duration of activity.

Rivotril can be combined with other antiepileptics and medicines affecting the central nervous system; however, the dosage of each medicine must be adjusted to prevent accumulation of side effects of multiple drugs.

Use of the medicine and alcohol consumption

Abstain from drinking alcohol during the course of treatment with **Rivotril**, since alcohol may increase the side effects of **Rivotril**.

Pregnancy and breastfeeding

Do not use this medicine if you are pregnant or think you may be pregnant, unless the doctor has instructed otherwise. Do not use this medicine when breastfeeding. If there is an indication requiring use of **Rivotril**, stop breastfeeding before commencing treatment with the medicine.

Driving and use of machines

Do not drive or operate dangerous machines when using the medicine, since use of this medicine may impair alertness, especially during the first few days of treatment. Children should be cautioned about riding bicycles or playing near the street and the like.

3) HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain.

The dosage and treatment regimen will be determined by the doctor only.

Special populations

Elderly patients: Increasing the dosage should be performed under strict medical supervision.

Patients with impaired kidney and liver function: There is no information regarding the safety and efficacy of clonazepam.

Do not exceed the recommended dose.

Directions for use:

Do not drip directly from the bottle into the mouth. The drops should be given in a spoon. The drops can be diluted in water, tea or juice.

If you took an overdose or if a child accidentally swallowed the medicine, immediately refer to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you. **Do not induce vomiting** unless explicitly instructed to do so by the doctor!

Symptoms of overdose include drowsiness, impaired coordination, lack of muscle control (tremor and unsteady gait), impaired ability to speak, rapid eye movements.

If you forget to take this medicine at the required time, take a dose as soon as you remember; but never take two doses together!

Adhere to the treatment regimen recommended by the doctor. Even if there is an improvement in your health, do not discontinue treatment with the medicine without consulting the doctor or pharmacist.

Lowering the dosage or discontinuing treatment must be done in accordance with the doctor's instructions and gradually. Abrupt discontinuation of **Rivotril** treatment, as with all antiepileptics, may cause the occurrence of severe epileptic attacks and withdrawal symptoms (see section 4 - "Side Effects").

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.

If you have any further questions regarding use of the medicine, consult the doctor or pharmacist.

4) SIDE EFFECTS

As with any medicine, use of **Rivotril** may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Refer to the doctor immediately in the following cases:

- If you suffer from allergic reactions (uncommon): a sudden and severe allergic reaction to the active ingredient clonazepam (anaphylactic shock); rash or itching, sudden swelling of the throat, face, lips and mouth, which may cause swallowing and breathing difficulties; sudden swelling of the hands, legs or ankles.
- Cardiac failure (including cardiac arrest).
- If you experienced types of convulsions with which you are unfamiliar.
- If you experienced a tendency for outbursts, irritability, aggressiveness, flared temper, nervousness, hostility, anxiety, sleep disturbances, nightmares and vivid dreams.

During prolonged use of **Rivotril**, withdrawal symptoms may occur, especially when using a high dosage or when the dosage is reduced quickly or treatment is stopped abruptly. Withdrawal symptoms include tremor, sweating, nervousness, restlessness, tension, confusion, sleep disturbances, anxiety, headache, muscle pain and epileptic attacks.

Additional side effects

Difficulty concentrating, restlessness, confusion, disorientation, depression, upper respiratory tract infection, sinusitis, involuntary movements, loss of consciousness, difficulty performing rapid movements and impaired coordination, glazed eyes, weakness on one side of the body, hallucinations, hysteria, increased or decreased libido, partial or full loss of touch with reality, chest congestion, increased secretion in the upper respiratory tract, hirsutism, loss of or increased appetite, furred (white) tongue, constipation, diarrhoea, dry mouth, gum pain, pain when urinating, need to urinate at night, urinary retention, muscle pain, dehydration, deterioration of general state, fever, enlarged lymph nodes, changes in body weight, anaemia, leukopenia (decreased number of white blood cells [leukocytes] in the blood), eosinophilia (increased number of eosinophils [cells which participate in the immune response] in the blood), enlarged liver, temporary increase in liver enzymes. Sleepiness, slowed reactions, floppy muscles, muscle weakness, lack of muscle control (tremor and unsteady gait), dizziness, tiredness - these side effects are relatively common and usually disappear during the course of treatment or on the reduction of the dosage. These side effects can be partially avoided by gradually increasing the dosage.

During long-term or high-dosage treatment reversible side effects, such as impaired ability to speak, impaired coordination, lack of muscle control (tremor and unsteady gait), jerky eye movements, amnesia, which may be associated with inappropriate behaviour, double vision may occur.

During prolonged treatment, an increase in the frequency of attacks may occur for certain types of epilepsy.

Respiratory depression may occur. This can be avoided by careful adjustment of the dosage.

Falls and fractures. The risk rises in patients concomitantly taking sedatives (including alcoholic beverages) and in elderly patients. Since the medicine impairs alertness, it is recommended to be careful when walking.

Side effects which have been rarely reported: headache, nausea, problems with the esophagus and stomach, hives (urticaria), itching, rash, temporary hair loss, pigmentation changes, loss of libido, erectile dysfunction, early puberty, difficulty retaining urine, decreased platelet (involved in the blood coagulation process) count.

If one of these side effects worsens, or if you suffer from a side effect not listed in the leaflet, consult with the doctor.

Side effects and drug interactions in children and infants:

Parents must inform the attending doctor about any side effect, as well as any additional medicines being taken by the child!

In children, the preparation may cause increased production of saliva or phlegm in the airways. Therefore, airway patency should be assured in the child.

Cases of earlier puberty have been reported. This effect disappears when treatment is stopped.

5) HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine must be kept in a safe place out of the reach of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package and bottle. The expiry date refers to the last day of that month.
- Do not store at a temperature that exceeds 25°C. Store the bottle in an upright position.
- After first opening, the medicine can be used for up to 120 days.
- In any case of doubt, consult the pharmacist who dispensed the medicine to you.
- Do not store different medications in the same package.

6) FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains: Peach flavour, Saccharin sodium, Brilliant Blue FCF (E133), Acetic acid glacial, Propylene glycol.

What does the medicine look like and what are the contents of the package: **Rivotril** is sold as clear, blue drops meant for swallowing. Each package contains a bottle with 10 ml of **Rivotril** drops.

Manufacturer: Roche S.p.A., Italy.

License holder: Roche Pharmaceuticals (Israel) Ltd., P.O.B. 6391, Hod Hasharon 4524079.

This leaflet was checked and approved by the Ministry of Health in August 2013.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 061.31.21476.00

