

**Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) – 1986**

This medicine is dispensed with a doctor's prescription only

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**Rivotril®**

**2.5 mg/ml**

Drops

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**Composition:**

1 ml **Rivotril** contains:

clonazepam 2.5 mg

\* For information on inactive ingredients, see section 6 - 'Additional information'.

**Read the entire leaflet carefully before you start using this medicine.** This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

**Introduction to patient leaflet for benzodiazepines**

This medicine belongs to a group of medicines called benzodiazepines, which have special properties, and require extreme caution when used. Close medical follow-up is very important when taking this medicine.

The following section relates only to short-term treatment with the medicine:

When you take this medicine, be sure to contact your doctor after 2 to 4 weeks, as the treatment is only intended for short periods of time.

Prolonged use of the medicine may cause it to become less effective.

Prolonged use may cause a serious side effect of dependence, where it will be difficult for the patient to stop taking the medicine.

Uncontrolled discontinuation of treatment may be accompanied by withdrawal symptoms such as tension, nervousness, confusion, tremor, insomnia, abdominal pain, vomiting, nausea, sweating, spasms, cramps and muscle pain.

At times, prolonged use of medicine may cause changes in behavioral patterns and intrusive thoughts.

Particularly in the elderly, it is recommended to use caution when walking, as the medicine inhibits alertness and at times coordination of body movements, and therefore there is a concern of slips or falls.

Taking this medicine along with opioids, other central nervous system depressants (including drugs) or alcohol may cause a sense of deep drowsiness, difficulty breathing (respiratory depression), coma and death.
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**1. What is this medicine intended for?**

The medicine is intended for treatment of epilepsy or panic disorder.

**Therapeutic group:**

**Rivotril** belongs to a group of medicines called benzodiazepines.

## 2. Before using this medicine

### Do not use this medicine if:

- you are sensitive (allergic) to the active ingredient, clonazepam, or to any other benzodiazepines or to any of the other ingredients in this medicine (see section 6 - 'Additional information').
- you have chronic obstructive airways disease with incipient respiratory failure.
- you have severe liver failure, as benzodiazepines may accelerate hepatic encephalopathy.
- you are dependent on addictive medicines and central nervous system depressants, including alcohol.

This medicine may be addictive. The risks are greater for patients with higher dosages or long-term treatment, or patients with a history of alcohol or drug abuse.

### Special warnings about using this medicine

**Rivotril should be taken as drops only. See section 3 - 'How to use this medicine?' for more information. If you are unsure about whether you need to use Rivotril, contact your doctor.**

### Before treatment with Rivotril, tell your doctor if:

- **you are pregnant, became pregnant during treatment with Rivotril or are planning to become pregnant:** It is unknown whether **Rivotril** harms an unborn baby when taken by a pregnant woman. If you need to take **Rivotril** when you are pregnant, your doctor will discuss with you the risks and benefit for you and your unborn baby.
- **you have health problems, including:**
  - liver, kidney or lung disease
  - high or low blood pressure
  - myasthenia gravis (severe muscle weakness)
  - sleep apnea (a condition in which you have temporary pauses in breathing during sleep)
  - glaucoma (a condition in which there is high pressure in the eye)
  - depression, psychosis or schizophrenia and/or if you have had depression or suicidal thoughts in the past
  - porphyria (a rare disorder in blood pigment)
  - history of alcohol or drug abuse

### Additional warnings:

- **Tell the doctor, dentist and pharmacist treating you that you are taking Rivotril.**
- **Tell your doctor if, for any reason, you did not take the medicine according to their instructions.** This is because the doctor may think that the medicine is ineffective and change your treatment unnecessarily.
- **Tell your doctor if you feel that Rivotril is not helping your medical condition.**
- **Make sure you are under continuous medical follow-up.**
- **Make sure that you have a sufficient amount of the medicine over the weekend or on holidays.**
- **Do not use Rivotril to treat other medical conditions without being instructed to do so by your doctor.**
- **Caution is required with the elderly, patients who do not feel well, after drinking alcohol or after taking other medicines** - some of the users may feel side effects such as drowsiness, confusion, dizziness or instability, which may increase the risk of falls. The treating doctor will instruct abstaining from alcohol during treatment with Rivotril.

### Children and adolescents

The safety and efficacy of the **Rivotril** in treatment of panic disorder in children under the age of 18 is unknown.

### Tests and follow-up

While being treated with **Rivotril**, your doctor may refer you for blood tests and other tests for time to time to check your progress and identify side effects.

### Drug interactions

**If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist.** Particularly if you are taking:

- sleeping pills, sleep-inducing or relaxing substances
- medicines for depression
- medicines for epilepsy
- medicines for allergies or colds such as antihistamines
- pain relievers
- muscle relaxants
- anesthetics
- cimetidine - a medicine used to treat ulcers
- disulfiram - a medicine used to treat alcohol abuse

These medicines may affect **Rivotril** or may affect the manner in which **Rivotril** works. Your doctor or pharmacist can tell you what to do if you take any of these medicines. They also have a more complete list of medicines you should be cautious with or refrain from using when taking **Rivotril**.

If you have not informed your doctor about any medicine mentioned above, tell them before you start using **Rivotril**.

### Using this medicine and alcohol consumption

Do not drink alcohol when taking **Rivotril**. Alcohol may increase the effects of **Rivotril** and lead to severe side effects.

### Pregnancy and breastfeeding

If you need to take **Rivotril** when you are pregnant, your doctor will discuss the risks and benefit for you and your unborn baby.

**you are breastfeeding or plan to breastfeed:** **Rivotril** is excreted into breast milk and may cause drowsiness and/or feeding difficulties in the baby. **Rivotril** is not recommended for use when breastfeeding.

### Driving and using machines

Do not drive or operate machines until you know how the medicine affects you.

**Rivotril** may cause drowsiness or dizziness in some patients and therefore could affect alertness.

Make sure that you know how the medicine affects you before you drive a car or operate machines or perform any other action that could be dangerous if you are drowsy, dizzy or unfocused.

Children should be cautioned against riding a bicycle, playing near a road, and the like.

### **3. How to use this medicine?**

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine. Only your doctor will determine your dose and how you should take this medicine.

**Rivotril** can be taken with or without food.

#### **Standard dosage in epilepsy**

The dosage of **Rivotril** must be individually adjusted for each patient according to the patient's clinical response, tolerance of the drug and the patient's age.

A single oral dose of **Rivotril** begins to take effect within 30-60 minutes and remains effective for 6-8 hours in children and 8-12 hours in adults.

To avoid side effects at the beginning of treatment, it is essential to start treatment with **Rivotril** at a low dose and increase the daily dose progressively until the maintenance dose suited to the individual patient has been reached.

The initial dose for infants and children up to the age of 10 years (or up to 30 kg of body weight):

The initial dose is 0.01-0.03 mg/kg of bodyweight daily, given in 2-3 divided doses. The daily maximum dose in children is 0.2 mg/kg of bodyweight and should not be exceeded.

Children aged 10 to 16: The initial dose is 1-1.5 mg/day, given in 2-3 divided doses. The dose may be increased gradually until the individual maintenance dose (usually 3-6 mg/day) is reached.

Adults: The initial dose for adults should not exceed 1.5 mg/day divided into 3 doses. Usually a maintenance dose of 3-6 mg per day is sufficient. The maximum therapeutic dose for adults is 20 mg daily and should not be exceeded.

The daily dose should be divided into 3 equal doses. If doses are not equally divided, the largest dose should be taken before retiring. The maintenance dose level is best attained after 1-3 weeks of treatment. Once the maintenance dose level has been reached, the daily amount may be given in a single dose in the evening.

#### **Standard dosage in panic disorder**

The initial dose for adults with panic disorder is 0.25 mg twice daily (0.5 mg/day).

The usual maintenance dose is 1 mg twice daily (2 mg/day). A maximum dose of 2 mg twice daily (4 mg/day) may be prescribed by the doctor in exceptional cases.

Once a stable dose is achieved, patients may switch to a once daily dose, usually taken at bedtime.

Treatment should be discontinued gradually.

**Do not exceed the recommended dose.**

#### **Directions for use:**

**Measure the prescribed dose of Rivotril as drops only.**

Do not administer drops directly into the mouth from the bottle.

After each administration, ensure that the dropper is secure in the neck of the bottle. Drops should be given with a spoon.

After each opening of the bottle, make sure the dropper is secured within the neck of the bottle.

**Rivotril** may be diluted in water, tea or fruit juice.

Continue taking **Rivotril** until your doctor tells you to stop. Do not take the medicine for a longer period of time than prescribed by the doctor.

If you are not sure what to do, ask your doctor or pharmacist.

**If you have accidentally taken a higher dose**

If you think that you or any other person has used a higher dose of **Rivotril** or if a child has accidentally swallowed some medicine, tell the doctor immediately or go to a hospital emergency room and bring the medicine package with you.

Do this even if there are no signs of discomfort or poisoning. You may require urgent medical care.

If you have taken too much **Rivotril**, you may feel drowsiness, tired, confused, dizzy, you have difficulty breathing, you feel weak or are unconscious.

**If you forget to take the medicine**

If it is almost time for your next dose, skip the forgotten dose and take the next dose at your regular time. If not, take the dose you missed immediately after remembering and then continue as usual.

Do not take a double dose to make up for a forgotten dose.

Adhere to the treatment as recommended by your doctor. Even if your health improves, do not stop taking this medicine without consulting your doctor.

Reducing the dosage or discontinuing treatment must be done gradually according to the doctor's instruction. Sudden termination of treatment with **Rivotril** may cause the appearance of undesirable effects. Your doctor will explain to you how you should gradually lower the dose of **Rivotril** until you can completely discontinue use.

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

**If you have any further questions about using this medicine, consult your doctor or pharmacist.**

#### **4. Side effects**

Like with all medicines, using **Rivotril** may cause side effects in some users. Do not be alarmed by this list of side effects. You may not experience any of them. You may require medical care if you experience some of the side effects.

Tell your treating doctor or pharmacist as soon as possible if you do not feel well during treatment with **Rivotril**.

**Contact your doctor immediately or go to the hospital emergency room closest to your home if you feel one of the following:**

- difficulty breathing
- sudden anxiety or excitement
- delusions or hallucinations
- severe sleep disorders

These are severe side effects that may require urgent medical care. These side effects are rare.

**Tell your doctor if you one of the following side effects:**

- drowsiness, tiredness
- dizziness, instability
- muscular weakness
- tremor

- memory loss, inattention, confusion, lack of focus
- headache, feeling hungover in the morning
- slurred speech (swallowing words)
- unpleasant dreams
- palpitations
- vomiting

Additional side effects:

- drowsiness
- depression
- dizziness
- nervousness
- ataxia
- reduced intellectual ability
- abnormal coordination
- problem speaking
- memory impairment
- emotional instability
- decreased sex drive (libido)
- confusion
- upper respiratory infection
- sinusitis
- rhinitis
- cough
- pharyngitis
- bronchitis
- constipation
- decreased appetite
- abdominal pain
- tiredness
- allergic reaction
- muscle pain
- flu
- frequent urination
- urinary tract infection
- blurry vision
- Women: menstrual pain, vaginitis
- Men: delayed ejaculation, impotence
- Body as a whole: weight increase, accident, weight decrease, wound, edema, fever, shivering, abrasions, ankle edema, foot edema, swelling around the eyes (periorbital edema), malaise, pain, inflammation of tissue beneath the skin (cellulitis), localized inflammation.
- Heart disorders: chest pain, postural hypotension
- Central and peripheral nervous system disorders: migraine, prickling sensation (paresthesia), drunkenness, feeling unable to control urination (enuresis), partial paralysis (paresis), tremor, burning skin, falling, head fullness, hoarseness, hyperactivity, loss of sensation (hypoesthesia), thick tongue, twitching.
- Gastrointestinal system disorders: abdominal discomfort, gastrointestinal inflammation, upset stomach, toothache, flatulence, heartburn (pyrosis), increased saliva, tooth disorders, frequent bowel movements, pelvic pain, indigestion (dyspepsia), hemorrhoids
- Hearing and vestibular disorders: vertigo, ear infection (otitis), earache, motion sickness
- Heart rhythm disorders: palpitations
- Metabolic and nutritional disorders: thirst, gout
- Musculoskeletal system disorders: back pain, traumatic fracture, sprains, leg pain, nape pain, muscle cramps, leg cramps, ankle pain, shoulder pain, tendinitis, joint pain (arthralgia), hypertonia, lower back pain (lumbago), pain in feet, jaw pain, knee pain, swollen knee
- Blood system disorders: dermal bleeding

- Psychiatric disorders: insomnia, organic disinhibition, anxiety, depersonalization, excessive dreaming, loss of sex drive (libido), increased appetite, increased sex drive (libido), decreased reactions, aggression, apathy, disturbance in attention, excitement, anger, abnormal hunger, illusions, nightmares, sleep disorder, suicidal thoughts, yawning
- Female reproductive system disorders: breast pain, menstrual irregularity
- Male reproductive system disorders: decreased ejaculation
- Resistance mechanism disorders: fungal infection, viral infection, streptococcal infection, herpes simplex infection, mononucleosis, candidiasis
- Respiratory system disorders: Excessive sneezing, asthmatic attack, shortness of breath (dyspnea), nosebleed, pneumonia, pleurisy
- Skin and appendages disorders: acne flare, balding (alopecia), xeroderma, contact dermatitis, flushing, itching (pruritus), pustular reaction, skin burns, skin disorders
- Disorders of the senses: taste loss
- Urinary system disorders: painful urination (dysuria), inflammation of the bladder (cystitis), excessive urination (polyuria), urinary incontinence, bladder dysfunction, urinary retention, urinary tract bleeding, urine discoloration
- Vascular disorders: Thrombophlebitis of the leg
- Vision disorders: eye irritation, visual disturbances, double vision (diplopia), eye twitching, styes, visual field defect, dry eye (xerophthalmia)

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor or pharmacist.

### **Reporting side effects**

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page ([www.health.gov.il](http://www.health.gov.il)) which links to an online form for reporting side effects. You can also use this link: <https://sideeffects.health.gov.il>

### **5. How to store the medicine?**

Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.

Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.

### **Storage conditions:**

- Do not store above 25°C. Store the bottle in an upright position.
- The medicine can be used for up to 120 days from the time of opening.
- In case of doubt, consult the pharmacist who dispensed the medicine to you.
- Dispose of any unused medicine appropriately. Do not throw away the medicine via household waste or wastewater. Ask the pharmacist how to throw away medicines you no longer need. These steps will help protect the environment.

### **6. Additional information**

In addition to the active ingredient, this medicine also contains:  
peach flavor, saccharin sodium, brilliant blue FCF, acetic acid glacial, propylene glycol.

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

**License holder's name and address:** Tzamal Bio-Pharma Ltd., 20 Hamagshimim St., Petah-Tikva

**Manufacturer's name and address:** CHEPLAPHARM Ltd., Greifswald, Germany

**Revised in May 2021 in accordance with Ministry of Health guidelines.**

**Registration number of the medicine in the Ministry of Health's National Drug Registry:**  
061-31-21476-00

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