

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

The medicine is dispensed with a doctor's prescription only

## **Clonnirit®**

**Active ingredient:**

Each tablet contains: 25 mcg Clonidine hydrochloride.

For the list of the additional ingredients, see section 6. See also 'Important information about some of the medicine's ingredients' in section 2.

**Read the entire leaflet carefully before using this medicine.**

This leaflet contains concise information about the medicine. If you have any further questions, refer to the doctor or pharmacist.

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

### **1. What is the medicine intended for?**

The medicine is intended for preventing migraine attacks and recurring headaches, that are not acute, due to narrowing or dilation of blood vessels. In addition, the medicine is intended for the treatment of flushing for women in menopause.

**Therapeutic group:**

Anti-migraine medicines

### **2. Before using the medicine**

**Do not use the medicine if:**

- You are sensitive (allergic) to the active ingredient or to any of the additional ingredients the medicine contains (for a list of the additional ingredients, see section 6).
- You suffer from a slow heartbeat caused by a heart disease called 'sick sinus syndrome' or from severe heart problems.

**Special warnings regarding the use of the medicine:**

- Use of the medicine may cause dryness in the eyes; this may constitute a problem for patients wearing contact lenses.
- If you are about to undergo surgery (including dental) or any procedure requiring anesthesia, inform the doctor and the anesthesiologist of taking this medicine.
- If you are sensitive to any food or medicine, inform your doctor before taking this medicine.

**Before starting the treatment with Clonnirit tell the doctor if:**

- You suffer or have suffered in the past from Raynaud's disease - a problem with blood circulation to the fingers and toes, or from other problems of blood circulation (including blood circulation to the brain).
- You suffer or have suffered in the past from impaired function of the: heart and/or blood vessels, kidneys.
- You suffer or have suffered in the past from depression.
- You suffer from a nerve disorder that causes a change in feeling in the hands and feet.
- You suffer from constipation.

**If you are taking or have recently taken any other medicines, including non-prescription medicines and nutritional supplements, please tell the doctor or pharmacist.** Especially inform the doctor or pharmacist if you are taking the following medicines (it should be noted that the following list mentions the active ingredients of the medicines. If you are unsure whether you are using one of these medicines, please consult with the doctor or pharmacist):

- Anti-anxiety medicines, sedatives, sleeping medicines and anesthetics for surgery.
- Tricyclic antidepressants and other antidepressants such as mirtazapine.
- Antipsychotics (for the treatment of mental disorders).
- Medicines used to slow the heart rate or to lower blood pressure (beta blockers).

- Diuretics.
- Medicines to treat heart rate disturbances or for heart failure (cardiac glycosides).
- Medicines to treat high blood pressure and medicines of the alpha-blocker group (used for the treatment of high blood pressure, heart or prostate gland problems).
- Medicines that dilate blood vessels (vasodilators).
- Methylphenidate.

**Use of the medicine and alcohol consumption:** Do not drink wines or alcoholic beverages during the treatment period with this medicine. The medicine may cause drowsiness and drinking alcohol may exacerbate this effect.

**Pregnancy, breast-feeding and fertility:**

Pregnancy

There is limited information about the use of Clonnirit during pregnancy. As with all medicines, do not use Clonnirit, especially during the first three months of pregnancy (first trimester), without consulting the doctor, if you are pregnant, think you are pregnant, or are planning a pregnancy. The medicine passes through the placenta and could slow the heart rate of the fetus.

Breastfeeding

The medicine is secreted into the breastmilk. There is insufficient information about the effect of the medicine while breastfeeding and therefore the use of the medicine is not recommended.

Fertility

There is insufficient information about the effect of the medicine on fertility.

**Driving and use of machinery:** Caution! Use of this medicine may impair the ability to drive and cause impairment of alertness, dizziness, drowsiness or disturbances of vision. If you experience these effects - do not drive, operate machinery or take part in any endangering activity requiring alertness.

**Use in children:** This medicine is not intended for children below the age of 18, since there is no data for this population.

**Important information about some of the medicine's ingredients:**

The medicine contains lactose. If you are sensitive to lactose, or if the doctor told you that you have intolerance to certain sugars, inform the doctor before taking this medicine - see section 6.

**3. How to use the medicine?**

Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are not sure.

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

Use this medicine at set intervals as determined by the attending doctor.

**The standard dosage is usually:** Initial dosage of 2 tablets taken together, twice a day. If required, after two weeks, the doctor may increase the dose to 3 tablets taken together, twice a day.

The duration of treatment will be determined by the doctor in accordance with your condition. It may take 2 to 4 weeks before reaching the full effect.

**Do not exceed the recommended dose.**

Swallow the medicine with a glass of water.

Do not chew or crush the tablet!

Do not halve the tablet since there is no scored line.

**Tests and follow-up:** During the treatment period with this medicine, your blood pressure should be monitored.

**If you have accidentally taken a higher dosage:** If you have taken an overdose or if a child has accidentally swallowed the medicine, proceed immediately to a hospital emergency room and bring the medicine package with you. Symptoms of overdose may include: constricted pupils, slow heart rate, hypotension (low blood pressure), low blood pressure upon sitting up or standing up,

hypothermia, sleepiness, coma, respiratory depression, sleep apnea, hypertension (high blood pressure), vomiting, dry mouth.

**If you forgot to take the medicine** at the set time, take the dose as soon as you remember, however, if it is nearly time for the next dose, skip the forgotten dose. Do not take a double dose to make up for a forgotten dose!

Adhere to the treatment as recommended by the doctor.

**If you stop taking the medicine:** Even if your state of health improves, do not stop the treatment with the medicine without consulting your doctor, and even then, only in a gradual manner. Sudden discontinuation of the medicine may cause withdrawal symptoms (especially if you have been using the medicine at a high dosage and/or for a prolonged period), such as agitation, restlessness, palpitations (strong heart beating), a rapid increase in blood pressure, restlessness, tremor, headache and gastrointestinal system symptoms such as nausea. Therefore, it is essential to gradually reduce the dose, according to the doctors's instructions.

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

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

#### 4. Side effects

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

Most of the side effects usually resolve following the period of adaptation to the medicine.

**Refer to the doctor immediately if you experience** symptoms of pseudo-obstruction of the large intestine causing colicky pains, vomiting, and constipation (rare).

Additional side effects:

*Very common side effects (appear in more than one user out of ten):*

dizziness, sedation (fuzziness, drowsiness, unusual tiredness), dizziness when standing up (due to a sharp drop in blood pressure), dry mouth.

*Common side effects (appear in 1-10 users out of 100):*

depression, sleeping problems, headache, constipation, nausea, vomiting, pain below the ear (from the salivary glands), erectile dysfunction, fatigue.

*Uncommon side effects (appear in 1-10 users out of 1,000):*

erroneous perception of reality, hallucinations, nightmares, altered sensation in the hands and feet, slow heartbeats, Raynaud's syndrome (a problem with blood circulation to the fingers and toes), rash, itch, urticaria (nettle rash), general unwell feeling.

*Rare side effects (appear in 1-10 users out of 10,000):*

breast enlargement in men, dry eyes, abnormal and irregular heartbeats, dryness of the nasal mucosa, hair loss, increase in blood sugar level.

*Side effects of unknown frequency (effects whose frequency has not yet been determined):*

confusion, decreased libido, vision problems such as blurred vision, very slow heartbeats.

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

Side effects may be reported to the Ministry of Health by clicking on the link "Report on side effects following medicinal treatment" on the homepage of the Ministry of Health website

([www.health.gov.il](http://www.health.gov.il)) which leads to an online form for reporting side effects, or by entering the link:

<https://sideeffects.health.gov.il/>

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

Avoid poisoning! This medicine, and any other medicine, must be stored in a safe place out of the reach and sight 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) stated on the package. The expiry date refers to the last day of that month.

- Storage conditions: Store below 25°C.

## 6. Additional information

### **In addition to the active ingredient, the medicine also contains:**

Starch corn, lactose, calcium phosphate dibasic, starch soluble, silicon dioxide colloidal, povidone K25, magnesium stearate, indigotine blue (E132).

Each tablet contains approximately 18 mg of lactose.

### **What does the medicine look like and what does the package contain?**

Light blue small round tablets, in blister packs of 30 tablets.

**Registration holder and manufacturer:** Rafa Laboratories Ltd., P.O. Box 405, Jerusalem 9100301.

**Medicine registration number in the National Medicines Registry of the Ministry of Health:**

0445422183

Revised in July 2023 according to MOH's guidelines.

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