

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

The medicine is dispensed with a doctor's prescription only

**Normopresan  
Tablets**

**Active ingredient:**

Each tablet contains: 150 mcg (microgram) 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 the medicine.**

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

This medicine has been prescribed for the treatment of 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 treatment of high blood pressure.

**Therapeutic group:**

Centrally acting alpha-2 ( $\alpha_2$ ) adrenergic agonist and imidazoline receptor agonist.

**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 slow heart rate (bradycardia) due to heart problems.

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

- If you are taking additional medicines that affect the heart rate such as digoxin, calcium channel blockers or beta blockers, your heart rate should be monitored (see also 'Tests and follow up' in section 3). The medicine may affect liver-related blood test results. Tell the doctor that you are taking this medicine before having blood tests.
- Using the medicine may cause dryness in the eyes; this could be a problem for patients wearing contact lenses.
- Inform the doctor that you are treated with this medicine if you are scheduled to undergo any surgery (including dental surgery).
- Dizziness or faintness may occur while taking the medicine, especially when getting up from a lying or sitting position.
- The elderly may be more sensitive to the effect of the medicine.
- Do not stop taking this medicine abruptly without consulting the doctor.
- If you are sensitive to any food or medicine, inform the doctor before taking the medicine.

**Before treatment with Normopresan 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 blood circulation problems (including blood circulation to the brain).
- If you suffer or have suffered in the past from impaired function of the heart and/or blood vessels and of kidney function.
- If you suffer or have suffered in the past from depression.
- If you suffer from polyneuropathy (a nerve disorder causing change of sensation in hands and feet).
- If you suffer from a benign tumor in the adrenal gland (pheochromocytoma).
- If you suffer from low blood pressure when sitting up or standing up.
- If you suffer from constipation.

- If you suffer from diabetes.

**Children and adolescents:**

This medicine is not intended for children under the age of 18, since there is no data for this population.

**Drug interactions**

**If you are taking or have recently taken any other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.** Especially if you are taking:

- Medicines that affect the central nervous system or which may cause drowsiness such as: sedatives, sleeping medicines, antipsychotic medicines used to treat severe mental illnesses such as schizophrenia (for instance chlorpromazine), opioid pain relievers and anesthetics for surgery.
- Tricyclic medicines to treat depression such as imipramine and other medicines to treat depression such as mirtazapine.
- Other medicines for the treatment of high blood pressure or heart problems such as: diuretics (e.g. furosemide), calcium channel blockers (e.g. verapamil, diltiazem), ACE inhibitors (e.g. captopril, lisinopril) and beta blockers (e.g. atenolol).
- Medicines from the alpha blocker group such as prazosin or doxazosin (used for the treatment of high blood pressure, heart or prostate gland problems).
- Vasodilators (e.g., diazoxide, sodium nitroprusside).
- Non-steroidal anti-inflammatory drugs (NSAIDs; e.g. ibuprofen).
- Glycoside group medicines such as digoxin.
- Methylphenidate.

**Use of the medicine and food:** There is no information about the use of the medicine and food.

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

**Pregnancy, breastfeeding and fertility:**Pregnancy

There is limited information on the use of Normopresan during pregnancy. Do not use the medicine without consulting the doctor if you are pregnant, think you are pregnant or are planning a pregnancy. The medicine passes into the placenta and may slow the heart rate of the fetus.

Breastfeeding

The medicine is secreted into the breast milk. There is insufficient information on the effect of the medicine when breastfeeding and therefore its use is not recommended.

Fertility

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

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

**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 an intolerance to certain sugars, inform the doctor before taking this medicine - see section 6.

### 3. How to use this medicine?

Always use the medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are not sure about the dosage and the manner of treatment with the medicine.

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

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

**The standard dosage is usually:** the dose will be adjusted to your condition and response to treatment. It is usually started with a low dosage, and is gradually increased according to the response.

**Do not exceed the recommended dosage.**

#### **How to take the medicine:**

Do not chew or crush the tablet! Swallow the tablet with a glass of water.

The tablet may be halved along the scored line.

#### **How can you contribute to the success of the treatment?**

In addition to taking this medicine, it is recommended that high blood pressure treatment should also include control of weight and food intake, especially refraining from foods with high sodium (salt) content.

#### **Tests and follow-up:**

- During the treatment period with the medicine, your blood pressure should be monitored.
- During prolonged treatment with the medicine, you should undergo periodic eye examinations.
- If you are taking additional medicines that affect the heart rate such as digoxin, calcium channel blockers or beta blockers, your heart rate 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, lethargy (slowness, fatigue, drowsiness), slow heart rate, low blood pressure, hypothermia, sleepiness, coma, respiratory depression, sleep apnea, paradoxical hypertension.

**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 the forgotten dose! You should be careful not to miss any 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 the doctor. This instruction is particularly important for a medicine such as Normopresan. It is essential to gradually reduce the dose, to avoid a recurrent elevation of the blood pressure. In addition, stopping the treatment with the medicine may cause withdrawal symptoms (especially if you have been using the medicine at a high dose and/or for a prolonged period), such as agitation, restlessness, palpitations (strong heart beat), irritability, tremor, headache and gastrointestinal symptoms.

**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 further questions concerning the use of the medicine, consult the doctor or pharmacist.

### 4. Side effects

As with any medicine, the use of Normopresan 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.

Most of the side effects tend to pass following the period of adjustment to the medicine.

**Refer to the doctor immediately if you experience symptoms** of obstruction of the large bowel 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 (drowsiness, fuzziness, 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, pain below the ear (from the salivary glands), vomiting, 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 heart beats, 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 heart beats, dryness of the nasal mucosa, hair loss, increase in the blood sugar level.

*Side effects of unknown frequency (effects whose frequency has not yet been determined):* confusion, decreased libido, blurred vision, very slow heart beats.

Two cases of liver inflammation (hepatitis) have been reported and occasional reports of blood tests indicating liver function impairment and fluid retention (edemas).

**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 closed place out of the reach and sight of children and/or babies, 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:**

Corn starch, calcium phosphate dibasic anhydrous, lactose spray dried, silicon dioxide colloidal 200, starch soluble, povidone 25, stearic acid, indigotine blue (E132).

Each tablet contains about 36 mg lactose.

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

Round light blue tablets with a scored line, and imprinted with N/150, in blister packs of 30 tablets.

**Registration Holder and manufacturer:** Rafa Laboratories Ltd., PO Box 405, Jerusalem 9100301

**Medicine registration number in the National Medicines Registry of the Ministry of Health:**  
043 98 22680

Revised in August 2023 according to MOH's guidelines.

I-047009