Patient Leaflet According to the Pharmacists' Regulations (Preparations) - 1986

This medicine is sold with a doctor's prescription only

Normopresan

Tablets

Active ingredient:

Each tablet contains: 150 mcg (microgram) Clonidine hydrochloride.

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

Read this 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 the treatment of high blood pressure (Hypertension).

Therapeutic group:

Centrally acting alpha-2 (α_2) adrenergic agonist and imidazoline receptor agonist.

2. Before using the medicine

Do not use the medicine if:

- Do not use if you are sensitive (allergic) to the active ingredient or to any of the other ingredients this medicine contains (for a list of inactive ingredients, please see section 6).
- Do not use this medicine if you suffer from slow heart rate (Bradycardia).

Special warnings regarding the use of this 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).
- Using this medicine may cause dryness in the eyes; this may be a problem for patients wearing contact lenses.
- Inform your doctor about taking 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, when standing for a long period of time, during physical exercise or in hot weather.
- Elderly patients may be more sensitive to the effect of the medicine.
- Do not stop using this medicine abruptly without consulting your doctor.
- If you are sensitive to any type of food or medicine, inform your doctor before taking this medicine.

Before starting the treatment with Normopresan tell your 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 circulation to the brain).
- If you suffer or have suffered in the past from impaired function of the: heart and/or blood vessels, kidneys.
- If you suffer or have suffered in the past from depression, polyneuropathy (a nerve disorder), a benign tumor in the adrenal gland (pheochromocytoma), low blood pressure upon sitting up or standing up.
- If you suffer from constipation.

If you are taking or have recently taken any other medicines, including non-prescription medicines and nutrition supplements, please tell your doctor or pharmacist. Especially inform

your 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 your doctor or pharmacist):

- Medicines that affect the central nervous system or which may cause drowsiness (e.g. sedatives, hypnotics, medicines for the treatment of Parkinson's disease, epilepsy or schizophrenia, opioid analgesics, antihistamines and anesthetics for surgery).
- Antidepressants (e.g. tricyclics and MAO inhibitors).
- Other medicines for treatment of high blood pressure (hypertension) or heart problems such as: diuretics (e.g. furosemide), calcium channel blockers (e.g. verapamil, diltiazem), ACE inhibitors (e.g. captopril, lisinopril), beta blockers (e.g. atenolol).
- Medicines of the alpha blocker class such as prazosin or doxazosin (used for the treatment of high blood pressure, heart or prostate problems).
- Vasodilators such as diazoxide, sodium nitroprusside.
- Non-steroidal anti- inflammatory drugs (NSAIDs; e.g. ibuprofen).
- Digoxin.
- Methylphenidate.

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

Pregnancy and breast-feeding:

- If you are pregnant, do not use this medicine without consulting your doctor.
- Use of this medicine during breastfeeding is not recommended (the medicine is secreted into breast milk).

Driving and use of machinery: Use of this medicine may cause impairment of alertness, dizziness 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:
This medicine contains lactose. If you are sensitive to lactose, inform your doctor before taking this medicine - see section 6.

3. How to use this 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:
The dose will be adjusted to your condition and response to treatment. It is usually started with a low dosage, which is gradually increased according to the response.
Do not exceed the recommended dose.
Do not chew or crush the tablet! Swallow the tablet with a glass of water.
The tablet may be cut in half using the score line.

How can you contribute to the success of the treatment?
In addition to taking this medicine, high blood pressure treatment should also include control of weight and food intake, and especially refraining from eating foods with high sodium (salt) content.

Tests and follow-up:

- During the period of treatment 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 other medicines affecting 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 package of the medicine with you.

Symptoms of overdose may include: constricted pupils, lethargy (slowness, fatigue, drowsiness), slow heart rate, hypotension, 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 a forgotten dose! You should ensure not to miss any dose. In addition, make sure that you have a sufficient amount of medicine for weekends, holidays or vacations.

Continue with 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 this medicine without consulting your doctor. This instruction is especially important for a medicine such as Normopresan. It is essential to gradually reduce the dose, in order to avoid a recurrent elevation of blood pressure. In addition, stopping 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 of time), such as agitation, restlessness, palpitations (strong heart beating), 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 any further questions regarding the use of the medicine, consult the doctor or pharmacist.

4. Side effects

Like any medicine, the use of Normopresan may cause side effects in some users. If the side effects persist or they are bothersome or get worse, consult your doctor. 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 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 (sleepiness, 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 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, inflammation of the liver (hepatitis) which may be also reflected in blood tests for liver function, fluid retention (edemas).

In any case you experience side effects that are not mentioned in this leaflet or if there is a change in your general feeling, consult the doctor immediately!

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 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 tablets also contain the following inactive ingredients:
Corn starch, dibasic calcium phosphate, lactose, silicon dioxide colloidal, soluble starch, povidone 25, stearic acid, indigotine blue (E132).
Each tablet contains approximately 36 mg of lactose.

What does the medicine look like and what does the package contain?
Light blue tablets with a score line, in blister packs of 30 tablets.
Registration holder: Rafa Laboratories Ltd., P.O. Box 405, Jerusalem 9100301.
Medicine registration number in the National Medicines Registry of the Ministry of Health:
043 98 22680

This leaflet was checked and approved by the Ministry of Health in March 2015.