PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986 The medicine is dispensed without a doctor's prescription

Rhinoclir - Metered Dose Nasal Spray The active ingredient and its concentration: Oxymetazoline hydrochloride at a concentration of 0.05%.

Inactive ingredients: see section 6.

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 is not usually intended for infants and children below 6 years of age.

You must use the medicine correctly. Consult

the pharmacist if you need further information.

Refer to the doctor if the symptoms worsen.

WHAT IS THE MEDICINE INTENDED FOR?

For temporary relief of nasal congestion, resulting from cold, sinusitis, hay fever or other allergies of the upper respiratory tract.

Therapeutic group: Sympathomimetics. 2. BEFORE USING THE MEDICINE

Do not use the medicine if:

You are sensitive (allergic) to the active ingredient or to any of the other ingredients contained in the medicine

(see section 6). Do not use this medicine concomitantly with monoamine-oxidase inhibitors (MAOI - for treatment of depression) or

within 14 days after completing treatment with them.

· You have had your pituitary gland removed.

You are suffering from inflamed skin or lining of the nose.

Before treatment with the medicine, consult the doctor if you are suffering or have suffered in the past:

from impaired function of the heart and/or blood vessels.

from an overactive thyroid.

from an eye disease (e.g., glaucoma).

from an enlarged prostate.

from diabetes.

Special warnings regarding use of the medicine:

Do not use often without consulting a doctor.

Frequent and prolonged use may cause recurrence of nasal congestion and

- damage to the nasal lining. The preparation contains benzalkonium
- chloride which may cause irritation of the nasal lining.
- Children, in particular, have a tendency to systemically absorb this medicine and
- as a result, there is an increased chance of occurrence of side effects during If you are sensitive to any food or medicine, inform the doctor before using the medicine.

If you are taking, or have recently taken, other medicines, including non-prescription

medicines and nutritional supplements, tell the doctor or pharmacist. It is particularly important to inform the doctor or pharmacist if you are taking:

Tricyclic or monoamine-oxidase inhibitor (MAOI) antidepressants, or within 14 days of completing treatment with them.

Antihypertensives (e.g., methyldopa). for Parkinson's (e.g., Medicines

bromocriptine).

■ Pregnancy and breastfeeding Consult the doctor before commencing treatment with the medicine if you are

pregnant or breastfeeding.

3. HOW SHOULD YOU USE THE MEDICINE? Check with the doctor or pharmacist if you

are uncertain. Do not use the preparation for more than 3 consecutive days, unless prescribed by the doctor.

Refer to the doctor if the signs of the ailment (symptoms) worsen or do not improve after 3 consecutive days.

Instructions for use:

Remove the plastic cover and spray twice in the air before the first use.

The usual dosage is generally 2-3 sprays in each nostril, twice a day, in the morning and in the evening. **Do not exceed the**

recommended dose. Shake well before

Blow your nose gently. With your head upright, spray the medicine into each nostril (while simultaneously blocking)

the other nostril with a finger) as follows: breathe in a few short inhalations while rapidly and sharply squeezing the bottle, in accordance with the dosage. Wait 3-5

minutes. Gently blow your nose again and repeat the procedure if necessary. · Rinse the tip of the spray bottle with hot

water, but take care that water is not drawn into the bottle. Dry with a clean paper tissue and close tightly. To avoid spreading of infection, do not use the same bottle for more than one person. Use the spray correctly. Consult a pharmacist if you need further information.

Do not swallow. For external use only. 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 take medicines in the dark! Check

the label and the dose <u>each time</u> you take medicine. Wear glasses if you need them. If you have further questions regarding use of the medicine, consult a doctor or pharmacist. 4. SIDE EFFECTS

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

While using the medicine, side effects may occur, such as burning, dryness or stinging of the nose or sneezing. These side effects usually disappear within a short time following the period of adaptation to the preparation but if they continue or are bothersome, consult with the doctor. Side effects that require special attention:

Occurring rarely - stop treatment and refer to a doctor: Recurring congestion. Signs of systemic absorption of the medicine: headaches, nervousness,

tremor, fast or strong heartbeats, sleep

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

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 sight and 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. The expiry date refers to the last day of that month. Store below 25°C.
- 6. FURTHER INFORMATION

multiple use.

· In addition to the active ingredient, the medicine also contains:

Benzalkonium chloride, benzyl alcohol, dibasic sodium phosphate, edetate

disodium, carboxymethylcellulose sodium, microcrystalline cellulose, monobasic sodium phosphate, polyethylene glycol, povidone, purified water. Sodium content per dose: 0.124 mg.

· What does the medicine look like and what are the contents of the package:
A 30 ml plastic bottle with a sprayer for

The medicine can be used up to the expiry date, even after opening. Registration holder: Perrigo Israel Agencies

Ltd., 29 Lehi St., Bnei Brak 51200. · Manufacturer: Perrigo Company, Allegan,

Michigan, USA. This leaflet was checked and approved by the Ministry of Health in July 2013.

Registration number of the medicine in the

National Drug Registry of the Ministry of Health: 137-88-31672-00.