

## **Rhinocalm**

**Paracetamol 650 mg, Pseudoephedrine hydrochloride 60 mg and Chlorpheniramine maleate 4mg**

### **Tablets**

#### **1) Generic name:**

Paracetamol, Pseudoephedrine hydrochloride, & Chlorpheniramine maleate

#### **2) Composition:**

Each tablet contains:

##### **Active ingredients:**

Paracetamol 650 mg

Pseudoephedrine HCL 60 mg

chlorpheniramine maleate 4 mg

##### **Inactive ingredients:**

Croscarmellose, povidone K25, magnesium stearate, microcrystalline cellulose (PH 101), microcrystalline cellulose (PH 102)

#### **3) Pharmaceutical form:**

Tablet.

White oblong tablets scored from one side.

#### **4) Mechanism of action:**

Rhinocalm combine the action of its ingredients as follow:

- Paracetamol acts as pain reliever and fever reducer.
- Chlorpheniramine maleate acts as antihistamine.
- Pseudoephedrine hydrochloride acts as nasal decongestant.

#### **5) Indications:**

Rhinocalm is indicated for:

Relieving these symptoms of hay fever and the common cold:

-Runny nose and sneezing.

**-Nasal congestion.**

-Minor aches and pains.

-Headache.

-Sinus congestion and pressure.

Relieving these additional symptoms of hay fever:

-Itching of the nose or throat.

-Itchy, watery eyes.

-Helps clear nasal passages.

**6) Dosage and administration:**

Do not exceed recommended dosage.

Adults and children 12 years and over: Take one tablet 3 times daily, the maximum daily dosage shouldn't exceed 3 tablets/day.

Swallow whole -do not crush, chew or dissolve

Do not take more than 3 tablets in 24 hours.

**7) Contraindications:**

Hypersensitivity to any of the ingredients of Rhinocalm.

Children under 12 years old.

**8) Drug interactions:**

Rhinocalm should not be used with:

-Any other drug containing paracetamol (acetaminophen) (prescription or non-prescription).

-If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

-Monoamine oxidase inhibitors (MAOI) (certain drugs for depression, psychiatric or emotional conditions Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescribed drugs contain a MAOI ,ask a doctor or pharmacist before giving this product.

**9) Special warnings and precautions for use:**

**Ischaemic optic neuropathy:** Ischaemic optic neuropathy has been reported with pseudoephedrine . Pseudoephedrine should be discontinued if sudden loss of vision or decreased visual acuity such as scotoma occurs.

Adverse reactions related to pseudoephedrine :

**Eye disorders:** Frequency unknown: - Ischaemic optic neuropathy.

**Myocardial infraction, stroke, convulsions but also serious skin reaction such as acute generalized exanthematous pustulosis (AGEP)**

**Liver warning:** This product contains paracetamol (acetaminophen). Severe liver damage may occur if you take:

-More than 3 tablets in 24 hours, which is the maximum daily amount.

-With Other drugs containing acetaminophen.

-3 or more alcoholic drinks every day while using this product.

Rhinocalm should not be used to make the child sleepy.

**Ask a doctor before use if you have:**

-Liver disease.

-Heart disease

-Glaucoma.

-Thyroid disease.

-High blood pressure.

-Trouble urinating due to an enlarged prostate gland.

-A breathing problem such as emphysema or chronic bronchitis.

-Diabetes.

**Ask a doctor or pharmacist before use if you are:**

-Taking sedatives or tranquilizers.

-Taking the blood thinning drug warfarin.

**When using this product:**

-Do not use more than directed.

-Excitability may occur, especially in children.

-Alcohol, sedatives, and tranquilizers may increase drowsiness.

-Avoid alcoholic drinks.

-Be careful when driving a motor vehicle or operating machinery.

-Drowsiness may occur.

**Stop use and ask the doctor if:**

- New symptoms occurred.
- You experience nervousness, dizziness or sleepless.
- Pain or nasal congestion gets worse or lasts more than 7 days
- Redness or swelling is present
- Fever gets worse or lasts more than 3 days.

**These could be signs of a serious condition.**

**10) Fertility, pregnancy and lactation:**

Ask a health professional before use.

A large amount of data on pregnant women indicate neither malformative , nor feto/neonatal toxicity. Epidemiological studies on neurodevelopment in children exposed to paracetamol in utero show inconclusive results. If clinically needed, paracetamol can be used during pregnancy however it should be used at the lowest effective dose for the shortest possible time and at the lowest possible frequency.

In case of overdose, get medical help.

**11) Patient instructions:**

Keep out of reach of children.

**12) Packaging and storage:**

Store at a temperature not exceeding 30°C, in dry place.

**Shelf life:** see outer pack.

**Pack:** Carton box containing 2 (AL/ Opaque PVC) strips, each of 10 tablets and an inner leaflet.

**Manufacturer & license holder:**

**Pharma Cure pharmaceutical industries**