Rhino PAROL®

paracetamol, chlorpheniramine maleate
and phenylephrine hydrochloride

GET RID OF A STUFFY OR RUNNY NOSE
PUT AN END TO CONGESTION AND SNEEZING
PUT A STOP TO PAIN AND FEVER

CORYZA – FLU – COLD – RHINITIS – PHARYNGITIS –
SINUSITIS – BRONCHITIS – LARYNGITIS – ALLERGIES

DAFRA PHARMA INTERNATIONAL

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3FIRHINOE-2021

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Setting the standard

www.dafrapharma.com

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paracetamol, chlorpheniramine maleate
and phenylephrine hydrochloride

EUROPEAN GMP

MULTI-ACTION AGAINST COLD AND ALLERGY SYMPTOMS

- Runny nose
- Stuffy nose
- Sinus congestion
- Sneezing
- Pain
- Fever

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RhinoPAROL®

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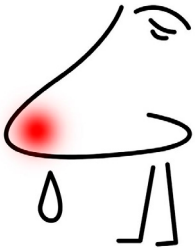

QUALITATIVE AND QUANTITATIVE COMPOSITION: Each tablet contains 650 mg paracetamol, 4 mg chlorpheniramine maleate and 10 mg phenylephrine hydrochloride. Excipients: Povidon, Aerosil, Microcrystalline Cellulose, Maize Starch, Magnesium Stearate, the coating contains colorants Indigotine and Titanium dioxide. Pharmaceutical presentation: 2 blisters, each with 10 tablets.

PHARMACEUTICAL PRESENTATION: A box with two blister, each with 10 tablets.

THERAPEUTIC INDICATIONS: RhinoParol® is used in the treatment of runny or stuffy nose, sinus congestion, sneezing, pain and fever. Paracetamol is an analgesic and antipyretic. Chlorpheniramine is an antihistamine molecule that reduces symptoms of sneezing, itching, watery eyes, and runny nose. Phenylephrine is a decongestant that helps against stuffy nose (nasal congestion). These type of symptoms may occur in following indications: acute respiratory tract infections: coryza, influenza, colds, rhinitis, pharyngitis, sinusitis, bronchitis, laryngitis and allergic diseases of the upper respiratory tract: hay fever, perennial rhinitis, rhinosinusitis.

POSOLOGY AND METHOD OF ADMINISTRATION: The usual dose for adults and children older than 12 years is 1 tablet administered at 6 hour intervals up to 4 times a day.

CONTRA-INDICATIONS: RhinoParol® is contra-indicated in patients with a history of hypersensitivity to any of its active or inactive ingredients. It is also contra-indicated in benign prostatic hyperplasia, bladder neck obstruction, angle closure glaucoma, acute asthma, hyperthyroidism, severe hypertension, cardiac arrhythmias and cerebrovascular disorders.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE: Since active ingredients in the formula are metabolized in the liver and eliminated by urinary excretion, RhinoParol® should be used with caution in patients with advanced liver or kidney disease. Special populations: pediatric and elderly patients may be more sensitive to side effects of the preparation.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES: In some patients who are receiving chlorpheniramine side effects such as drowsiness, dizziness, blurred vision, tremor and excitability may occur. Patients should be warned not to engage in hazardous activities while experiencing these side effects.

INTERACTION WITH OTHER MEDICINAL PRODUCTS: Drug interactions: risk of hepatotoxicity with paracetamol may be increased in chronic alcoholism and in patients on hepatotoxic medication. Alcohol, phenothiazines, tricyclic antidepressants and chlorpheniramine may potentiate the central nervous system depressing effect of each other. Hepatic enzyme inducers (barbiturates, primidone) may accelerate metabolic transformations of paracetamol, thus decreasing its clinical effectiveness. The antimuscarinic action of chlorpheniramine may be potentiated by atropine, amantadine, haloperidol, phenothiazines, procainamide and quinidine. Monoamino oxidase inhibitors (MAOI) inhibit the MAO enzyme that metabolizes phenylephrine with consequent elevation of phenylephrine blood levels, leading to hypertensive crisis. Cyclopropane and halogenated hydrocarbon anesthetics and digital glycosides may sensitize the myocardium to the effects of phenylephrine, increasing the risk of arrhythmias. Chlorpheniramine may mask ototoxic effects of cisplatin, paramomycin, salicylates and vancomycin.

PREGNANCY AND LACTATION: Pregnancy Category C. Safe use of RhinoParol® during pregnancy has not been documented with adequate and well-controlled studies in humans. It should be used in pregnant women only if its expected benefits for the mother justify potential risks to the fetus. Active substances in RhinoParol® pass into human milk. Its use in nursing mothers is not recommended.
UNDESIRABLE EFFECTS: Drowsiness, palpitation, blurred vision, dry mouth, anorexia, irritability, difficult urination, skin allergy, perspiration, tinnitus, tachycardia, photosensitivity, burning in the stomach. IN THE EVENT OF AN UNEXPECTED EFFECT CONSULT YOUR PHYSICIAN.
OVERDOSE: If the patient is seen immediately following ingestion of the drug, the stomach should be evacuated by inducing emesis or gastric lavage. Administration of a cathartic (Milk of Magnesia) may be useful. Depending on the course of the case, general symptomatic and supportive therapy is administered as indicated. Hypotension may be treated with vasopressor agents, however, adrenaline should be avoided for it may aggravate hypotension. Analeptic agents should not be used. They may cause convulsions. Orally administered N-acetylcysteine is the specific antidote for paracetamol overdose.
PHARMACODYNAMIC PROPERTIES: Paracetamol is an effective analgesic and antipyretic agent. Its analgetic effect is due to the inhibition of the prostaglandin synthesis in the central nervous system and to the decreased sensitivity of the peripheral pain receptors. Paracetamol also inhibits the impulse generation and transmission in peripheral nerves carrying pain sensation; formation of pain mediators is also inhibited. Chlorpheniramine has antihistaminic and antimuscarinic actions. It binds to muscarinic receptors at the serous glands in the nasal mucosa, resulting in the inhibition of their secretion (nasal discharge), thus chlorpheniramine eases respiration by abolishing an important cause in the initiation of cough reflex. Phenylephrine is an agonist at the alpha-adrenergic receptors. It is a directly-acting sympathomimetic agent. By producing vasoconstriction in the nasal mucosa, it reduces swelling, edema, oozing and obstruction in the nasal cavity, thus providing a decongestant action.
PHARMACOKINETIC PROPERTIES: Paracetamol is rapidly and completely absorbed following oral administration. However, if taken with a high-carbohydrate meal its absorption decreases. The analgesic effect starts at 3 minutes, reaches a maximum in 1 to 3 hours and lasts for 3 to 4 hours. About 90 to 95% of paracetamol is converted to metabolites in the liver and excreted in the urine. Its half-life is 1 to 4 hours and is prolonged in the elderly, newborns and in patients with liver disease. It can be removed from blood with hemodialysis. Chlorpheniramine: Following oral administration, its action starts in 15 to 60 minutes, reaches a maximum in 3 to 6 hours and eliminated from the body in the form of metabolites via the kidney. It is widely distributed in the body. The half-life is approximately 20 hours. In children, absorption is faster and greater, clearance more rapid and half-life shorter compared to adults. Phenylephrine: Following oral administration its absorption from the gastrointestinal tract is irregular. In addition, it undergoes first-pass metabolism by monoamino oxidases (MAO) in the liver and intestine. Nasal decongestant action of orally administered phenylephrine starts in 15 to 20 minutes and lasts for 2 to 4 hours. Its metabolites and their routes of elimination are not known. Nor it is known whether phenylephrine passes into fetus or human milk.
PHARMACEUTICAL PARTICULARS:
Shelf life: 2 years. Special precautions for storage: Store below 30°C, in the original package, protected from light and humidity. Keep out of reach and sight of children. Legal status: sold without prescription. MANUFACTURER: Atabay Kimya San. ve Tic. A.Ş. Acıbadem Köftüncü Sokak No:1 34718 Kadıköy / Istanbul, Turkey.
MARKETING AUTHORIZATION HOLDER: Dafra Pharma GmbH, Mühlenberg 7, 4052 Basel, Switzerland.