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ClariClear® Nasal Spray 0.05%

Brand of oxymetazoline hydrochloride

DESCRIPTION: Each ml of Clariclear® Nasal Spray contains 0.5 mg (0.05%) oxymetazoline hydrochloride.

Benzalkonium chloride is used as a preservative.

Other inactive ingredients include sodium hydroxide, sodium dihydrogen phosphate dihydrate, disodium edetate, propylene glycol, hydrochloric acid and purified water.

Appearance: Clear, colourless solution with a slight odour, free from foreign matter.

ACTIONS: The sympathomimetic action of oxymetazoline hydrochloride constricts the arteriolar network within the nasal mucosa producing a prolonged decongestant effect.

PHARMACODYNAMIC PROPERTIES: Oxymetazoline hydrochloride is a sympathomimetic agent which exerts a local vasoconstriction action in the nasal mucosa, reducing nasal congestion. Clinical studies have shown that oxymetazoline acts within a few minutes and its effect can last up to 12 hours following treatment.

INDICATIONS: Clariclear® Nasal Spray is indicated for symptomatic relief of nasal and nasal pharyngeal congestion due to the common cold, sinusitis, hay fever or other upper respiratory allergies,

DOSAGE AND ADMINISTRATION: For adults and children six years of age and older: Two or three sprays into each nostril twice daily, morning and evening. With the head upright, place the sprays nozzle into the nostril without completely occluding the nostril. During each administration, the patient should bend his head slightly forward and spray the dose into each nostril by squeezing the bottle rapidly and strongly.

DRUG INTERACTIONS: If significant systemic absorption of oxymetazoline occurs, concomitant use of tricyclic antidepressants, maprotiline, other vasoconstrictive drugs or monoamine oxidase inhibitors (MAOI), may potentiate the pressor effects of oxymetazoline.

ADVERSE REACTIONS: Clariclear® Nasal Spray is generally well tolerated and side effects, should they occur, are usually mild and transient. They include burning, stinging, sneezing or increased nasal discharge.

CONTRAINDICATIONS: Oxymetazoline-containing nasal sprays should not be used:

- in patients with known hypersensitivity to oxymetazoline or other adrenergic agents, or to any component of the medicinal product;
- in patients taking monoamine oxidase inhibitors (MAOIs) or in patients who have taken MAOIs in the previous two weeks;
- in patients with narrow-angle glaucoma;
- in patients after trans-sphenoidal hypophysectomy;
- where there is inflammation of the skin and mucosa of the nasal vestibule and encrustation (rhinitis sicca);
- in patients with acute cardiovascular disease or cardiac asthma;
- in patients with severe high blood pressure.

PRECAUTIONS: Do not exceed the recommended dosage. The product may cause rebound congestion if used for longer than three days. This product should not be used by patients who have heart disease, high blood pressure, thyroid disease, diabetes, or difficulty in urination due to enlargement of the prostate gland without careful clinical consideration. Use of the product by more than one person may spread infection. This product is not recommended for use in children under six years of age. This product must be kept out of the reach of children.

USAGE DURING PREGNANCY AND LACTATION: Since no clinical data on exposed pregnancies are available with oxymetazoline, the safe use of oxymetazoline during pregnancy has not been established. It is also not known if oxymetazoline is excreted into breast milk. Oxymetazoline is not to be used during pregnancy and breast feeding unless the potential benefits outweigh the risks.

OVERDOSAGE INFORMATION: If accidentally ingested, standard methods to remove unabsorbed drug should be considered. There is no specific antidote for oxymetazoline. In children, oxymetazoline may produce profound central nervous system depression.

HOW SUPPLIED: In a nasal pump spray unit

STORAGE: Store below 30°C. Keep out of reach of children.

For the shelf-life, please refer to labels.

Further information can be obtained from the doctor or pharmacist.

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