



OXY-NASE Nasal Spray/ Drops 0.05%w/v
OXY-NASE Paediatric Nasal Spray / Drops 0.025%w/v

NAME AND STRENGTH OF ACTIVE SUBSTANCE:

OXY-NASE Nasal Spray/ Drops 0.05%w/v ~ Oxymetazoline Hydrochloride 0.05%w/v

OXY-NASE Paediatric Nasal Spray/ Drops 0.025%w/v ~ Oxymetazoline Hydrochloride 0.025%w/v

PRODUCT DESCRIPTION: A clear solution. Other ingredients are Benzalkonium Chloride, Citric Acid Anhydrous, Sodium Citrate, Disodium Edetate, Sorbitol Solution 70% and Purified Water.

PHARMACODYNAMICS: Oxymetazoline hydrochloride is a sympathomimetic drug which acts as a topical decongestant by stimulating the L-adrenergic receptors of the vascular smooth muscle, constricting the dilated arteriolar network within the nasal mucosa and reducing blood flow in the engorged edematous nasal area. The constriction results in shrinkage of the engorged mucous membranes, which promotes drainage, improves nasal ventilation and relieves the feeling of stuffiness.

PHARMACOKINETICS : Oxymetazoline hydrochloride is a sympathomimetic amine with L-receptor action. It caused marked vasoconstriction and blanching when applied to nasal and pharyngeal mucosal surfaces. Sufficient absorption may cause central nervous system depression, leading to coma and marked reduction in body temperature especially in infants. Oxymetazoline hydrochloride is a long acting topical nasal decongestant. It acts within a few minutes and the effect up to 12 hours.

INDICATIONS: It is indicated for the relief of nasal congestion.

CONTRAINDICATIONS: Hypersensitivity to any of the ingredients.

DRUG INTERACTIONS: Combinations containing antidepressants, Tricyclic or Maprotiline or Monoamine oxidase inhibitors, depending on the amount present, may also interact with this medication.

ADVERSE EFFECTS: It may occasionally cause local stinging or burning, sneezing and dryness of the mouth and throat. Prolonged use may cause rebound congestion and drug-induced rhinitis.

PRECAUTIONS/WARNINGS: Caution should be observed in patients with hypertension, coronary artery disease, hyperthyroidism or diabetes mellitus or difficulty in urination due to enlargement of the prostate gland. Use with extreme caution in patients who are receiving monoamine oxidase inhibitor therapy.

The dosage of **OXY-NASE Nasal Spray / Drops 0.05%w/v** for children below 6 years of age has not been established.

For children 2 to 6 years of age, **OXY-NASE Paediatric Nasal Spray / Drops 0.025%w/v** is available. Do not exceed the recommended dosage and do not use for longer than 3 days.

The recommended dosage should not be exceeded because symptoms may occur

such as burning, stinging, sneezing or an increase of nasal discharge. It should not be used for more than 3 days. Use of the product dispenser by more than one person may spread infection.

PREGNANCY AND LACTATION: Safety in pregnancy and lactation has not been established. It is not to be used during pregnancy and lactation unless the potential benefits outweigh the risks.

ROUTE OF ADMINISTRATION : Nasal

RECOMMENDED DOSAGE:

OXY-NASE Nasal Spray 0.05%w/v ~ For adults and children 6 years of age and older : 2 or 3 sprays into each nostril twice daily, morning and evening. With the head upright, place the spray nozzle into the nostril without completely occluding the nostril. During each administration, the patient should bend his head slightly forward and press the pump spray quickly and firmly to spray the recommended number of sprays in each nostril. Wipe nozzle clean after use.

OXY-NASE Nasal Drops 0.05%w/v ~ Adults and children over 6 years : 2 to 3 drops in each nostril twice daily; in the morning & evening.

OXY-NASE Paediatric Nasal Spray 0.025%w/v ~ For children 2 to 6 years of age : Administer 2 to 3 spray in each nostril twice daily - morning and evening. With the head upright, place the spray nozzle into the nostril without completely occluding the nostril. During each administration, the patient should bend his head slightly forward and press the pump spray quickly and firmly to spray the recommended number of spray in each nostril. Wipe nozzle clean after use.

OXY-NASE Paediatric Nasal Drops 0.025%w/v ~ Children above 1 year : 1 to 2 drops. Doses to be given twice to three times daily.

Apply up to four times daily until condition improves, then reduce frequency.

SYMPTOMS AND TREATMENT FOR OVERDOSE AND ANTIDOTE(S): Oxymetazoline may produce profound central nervous system depression, leading to coma and marked reduction in body temperature, especially in infants. Consult a physician for more information on the management of overdose.

PACKING: OXY-NASE Nasal Spray 0.05%w/v : 15ml PE bottle.

OXY-NASE Paediatric Nasal Spray 0.025%w/v : 15ml PE bottle.

OXY-NASE Nasal Drops 0.05%w/v : 10ml & 100ml Amber glass bottle.

OXY-NASE Paediatric Nasal Drops 0.025%w/v : 10ml & 100ml Amber glass bottle.

STORAGE: Keep container well closed. Protect from light. Store below 30°C. Keep out of reach of children.

RECOMMENDED SHELF-LIFE: 3 years.

Manufactured by :

HOE Pharmaceuticals Sdn. Bhd.

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42000 Port Klang, Selangor, MALAYSIA.

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