Approved by:
Lee Pui Yee
26/10/2023

After folding L-70 mm & W-25-26 mm
70 mm x 200 mm (Both side print)

Xylocon Nasal Drops 0.05%, 0.025%

Oxymetazoline Hydrochloride USP

NAME OF PRODUCT
Xylocon 0.05% Nasal Drops
Xylocon 0.025% Nasal Drops

NAME AND STRENGTH OF ACTIVE INGREDIENT(S)
Xylocon 0.05% Nasal Drops: Each ml contains Oxymetazoline Hydrochloride USP 0.50 mg.
Xylocon 0.025% Nasal Drops: Each ml contains Oxymetazoline Hydrochloride USP 0.25 mg.

PRODUCT DESCRIPTION
A clear colorless solution having rose-like odor, filled and sealed in plastic container.

PHARMACODYNAMICS
Oxymetazoline is a direct-acting sympathomimetic amine. It acts on alpha-adrenergic receptors in the vessels of the nasal mucosa producing vasoconstriction and decongestion. Onset of action is within minutes and lasts 6-8 hours.

PHARMACOKINETICS
Oxymetazoline enters tissues rapidly and local vasoconstriction is normally achieved within 5-10 minutes of intranasal administration. The full effect lasts for 5-6 hours and then gradually subsides over the next 6 hours. Plasma half-life is 5-8 days with 30% of any absorbed drug being excreted in the urine unchanged and 10% being excreted in the faeces.

INDICATION
Rhinitis acuta, sinusitis, eustachitis and otitis media.

RECOMMENDED DOSAGE
Xylocon 0.025% Nasal Drops
Unless otherwise prescribed, instill 1 - 2 drops of the Xylocon 0.025% into each nostril, 2 - 3 times per day. Xylocon 0.025% should not be used by children younger than 1 year. Unless specifically specified by the doctor, Xylocon 0.025% should only be used for short periods of time.

Xylocon 0.05% Nasal Drops
Unless otherwise prescribed, instill 1 - 2 drops of the Xylocon 0.05% into each nostril, 2 - 3 times per day. Xylocon 0.05% should only be used by adults and children of school age. Unless specifically specified by the doctor, Xylocon 0.05% should only be used for short periods of time.

Permanent use of decongestant rhinological agents may attenuate their effect. The abuse of local rhinological agents may cause mucosal atrophy and reactive hyperaemia with rhinitis medicamentosa. Longer use of oxymetazoline may cause damage to the mucosal epithelium with inhibition of ciliary activity. This may possible result in irreversible damage to the mucosa with rhinitis sicca. Long term use and overdosage must be avoided especially in children. Dosage higher than recommended may only be used under medical supervision.

ROUTE OF ADMINISTRATION
Nasal

CONTRAINDICATION
Xylocon Nasal Drops should not be used:
- By patients taking monoamine oxidase inhibitors (MAOIs) or in patients who have taken MAOIs in the previous two weeks.
- In patients with narrow-angle glaucoma. Xylocon Nasal Drops should not be used by patients after trans- sphenoidal hypophysectomy.
- In case of hypersensitivity to the active substance or to any of the excipients.
- Where there is inflammation of the skin and mucosa of the nasal vestibule and encrustation (rhinitis sicca).
- By patients with acute coronary disease or cardiac asthma.
- Hypertension
- Phaeochromocytoma
- Metabolic disorders (eg. hyperthyroidism, diabetes)

WARNING AND PRECAUTION
- Caution should be exercised in case of hypertension, cardiac diseases including angina, hyperthyroidism, diabetes mellitus and prostatic hypertrophy.
- Do not exceed the recommended dose.
  If symptoms worsen or do not improve after 3 days, physician should re-evaluate clinical situation.
- Xylocon Nasal Drops should be used for a maximum of 7 consecutive days to avoid rebound-effect and drug induced rhinitis.
- The preservative (benzalkonium chloride) contained in Xylocon Nasal Drops can cause swelling of the nasal mucosa, especially during long-term use. If such a reaction (persistent nasal congestion) is suspected, a product for nasal administration which contains no preservative should be used if possible. If such products for nasal administration are not available without preservative, the use of another dosage form should be considered.

INTERACTIONS WITH OTHER MEDICAMENTS
This product should not be used in combination with MAOIs, or for up to 2 weeks after taking MAOIs as there is a risk of interactions leading to hypertension.
This product is known to interact with tricyclic antidepressants with a possible increased risk of hypertension and arrhythmias. The effects of beta-blockers or other antihypertensive drugs e.g. methyl dopa, Bethanidine, Debrisoquine and Guanethidine may be antagonised.
Possible additive cardiovascular toxicity may occur when sympathomimetics are given with anti-parkinsonian drugs such as bromocriptine.

PREGNANCY AND LACTATION
For oxymetazoline no clinical data on exposed pregnancies are available.
Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/foetal development, parturition or postnatal development.
It is not known if oxymetazoline hydrochloride is excreted into breast milk.
The recommended dose should not be exceeded because overdosing can decrease placental blood flow and reduce milk production.
Caution should be exercised during pregnancy and lactation as oxymetazoline may be systemically absorbed.

SIDE EFFECTS

Uncommon	*Respiratory* : sneezing, dryness and irritation in nose, mouth and throat
Rare	*CNS* : anxiety, sedative effect, irritability, sleep disorders in children Cardiovascular : tachycardia, palpitations, increased blood pressure General: reactive hyperaemia, headache, nausea, exanthema and visual disturbances.

Use for longer than recommended may lead to reduced effect and/or rebound congestion.

SYMPTOMS AND TREATMENT OF OVERDOSE
Symptoms of overdose:
Symptoms of moderate or severe overdose can be mydriasis, nausea, cyanosis, fever, spasms, tachycardia, cardiac arrhythmia, cardiac arrest, hypertension, oedema of the lungs, dyspnoea, psychic disturbance. The inhibition of functions of the central nervous system such as somnolence, lowering of the body temperature, bradycardia, shocklike hypotension, apnoea and loss of consciousness is also possible.

Treatment of overdose:
Symptomatic treatment of overdose is required. A nonselective alpha-lytic such as phentolamine may be administered to depress the increased blood pressure, Intubation and artificial respiration may be necessary in serious cases.
In the case of moderate or severe inadvertent oral consumption, the administration of activated carbon (absorbent) and sodium sulphate (laxative) or perhaps gastro-lavage in the case of large amounts should be undertaken.
Further treatment is supportive and symptomatic.
Vasopressor drugs are contraindicated

STORAGE CONDITION
Store below 30°C. Protect from light. Keep out of the reach of children. Use within 28 days after opening at temperature below 30°C.

DOSAGE FORM & PACKAGING AVAILABLE
Nasal Drops;
Polypropylene plastic container (bottle) of 10 ml. 1x 10ml and 6x10ml.

THERAPEUTICAL CODE
R01AA05-oxymetazoline; Belongs to the class of topical sympathomimetic agents used as nasal decongestants.

Manufactured by :
SQUARE PHARMACEUTICALS PLC.
Square Road, Salgaria, Pabna 6600, Bangladesh

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