CURRENT APPROVED PACKAGE INSERT

SCHEDULING STATUS

S1

PROPRIETARY NAME AND DOSAGE FORM

DRIXINE® 0,05 % Nasal Spray and Pump Spray

COMPOSITION

Each ml of DRIXINE 0, 05 % solution contains:

Active ingredients: 0, 5 mg Oxymetazoline hydrochloride.

Inactive ingredients: Disodium edetate, hydrochloric acid, propylene glycol, purified water, sodium dihydrogen phosphate dehydrate, sodium hydroxide.

Preservative: Benzalkonium chloride 0, 02% *m/v.*

PHARMACOLOGICAL CLASSIFICATION

A.16.1 Nasal decongestants

PHARMACOLOGICAL ACTION

Pharmacodynamic properties

Oxymetazoline hydrochloride is a vasoconstrictor that acts directly to reduce the swelling of the nasal membranes. When topically applied, it is effective locally and not absorbed unless swallowed.

Oxymetazoline manifests pharmacologic action through direct activation of α adrenergic receptors in vascular smooth muscle. Oxymetazoline acitivates both α1 and α2 adrenergic receptors.

α-Adrenergic receptor activation results in increased peripheral vascular resistance through arterial vasoconstriction. These actions result in a decreased volume of the nasal mucosa which decrease resistance to airflow.

It acts within a few minutes and the effect lasts for up to 12 hours.

Pharmacokinetic properties

Oxymetazoline hydrochloride is delivered directly to the nasal mucosa, where it exerts a local vasoconstriction effect. Due to its topical, local, and rapid action, oxymetazoline HCl has a very low potential for systemic absorption. However, potential systemic exposure with higher doses and longer durations of use could lead to systemic side effects.

INDICATIONS

For the temporary relief of nasal congestion in colds and influenza, hay fever, allergic rhinitis, other upper respiratory allergies, post-nasal drip and sinusitis.

CONTRAINDICATIONS

Hypersensitivity to oxymetazoline hydrochloride or any of the ingredients.

Use DRIXINE 0, 05% with extreme caution in patients receiving monoamine oxidase inhibitors or within 14 days of stopping such treatment.

DRIXINE 0.05 % should not be used:

- 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 hypertension.

  [SEE WARNING AND SPECIAL PRECAUTIONS]

Porphyria.

WARNINGS AND SPECIAL PRECAUTIONS

DRIXINE 0, 05% is not recommended for children under 6 years of age.

This product should not be used for more than 5 days. If symptoms persist consult a doctor.

Prolonged use or excessive application to the nasal mucosa may produce rebound congestion and rhinorrhoea.

The use of this container by more than one person may spread infection.

Children may be especially sensitive to the effects of these medicines.

Should be used with caution in patients with: Hypertension, hyperthyroidism, cardiovascular disease such as ischaemic heart disease, arrhythmias, tachycardia, occlusive vascular disease, arteriosclerosis, aneurysms, diabetes mellitus, closed-angle glaucoma, prostatic hypertrophy.

SPECIAL PRECAUTIONS:

Do not exceed the recommended dosage.

Prolonged use may cause rebound congestion if used for longer than 3 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.

Caution should be exercised in patients with hypertension or signs of reduced placental perfusion.

Frequent or prolonged use of high doses may reduce placental perfusion

Drixine 0.05 % should be avoided in phaechromocytoma

INTERACTIONS

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

Reversal of the action of anti-hypertensive agents may occur and therefore special care is advisable in patients receiving anti-hypertensive therapy. Interactions with alpha- and beta-blockers may be complex and can produce a hypertensive crisis.
Interactions are possible with guanethidine, reserpine, digoxin and alpha-methyldopa.
DRIXINE 0, 05% should be used with caution in patients undergoing anaesthesia with cyclopropane, halothane or other halogenated anaesthetics as they may induce ventricular fibrillation.
An increased risk of arrhythmias may occur in patients receiving cardiac glycosides, quinidine or tricyclic antidepressants.

PREGNANCY AND LACTATION:

Safety during pregnancy and lactation has not been established.

DOSAGE AND DIRECTIONS FOR USE

Do not administer continuously for longer than 5 days.

For adults and children over 6 years: 1 to 2 sprays into each nostril in the morning and evening, not more often than every 10 to 12 hours. Do not exceed 2 applications in any 24 hour period.

TO USE:

Nasal Spray: Hold bottle upright, insert into each nostril and squeeze the bottle once or twice.

Pump Spray: Place the tip of the pump nozzle into one nostril without completely occluding the nostril. With head bent slightly forward, the patient squeezes the pump bottle 2 or 3 times while sniffing briskly. Treat the other nostril in the same way. When necessary, instillation may be repeated 10 or 15 minutes later.

See illustration:

SIDE EFFECTS

Table 1

The following side-effects have been reported and the frequencies are unknown

System Organ Class (MedDRA)	**Undesirable effect**
Immune system disorders	Hypersensitivity
Metabolism and nutrition disorders	altered metabolism including disturbances of glucose metabolism,
Psychiatric disorders	Nervousness, agitation, anxiety, psychotic states,
Nervous system disorders	dizziness or lightheadedness, trouble in sleeping, drowsiness, trembling, headache, hallucinations (particularly in children), fainting, confusion, tremor
Eye disorders	blurred vision
Cardiac disorders	tachycardia, palpitations, bradycardia, cardiac arrhythmias cardiac arrest, Angina
Vascular disorders	increased blood pressure, reactive hyperaemia, flushing, hypotension

Respiratory, thoracic and mediastinal disorders	nasal burning, nasal stinging, sneezing, increased nasal discharge, increase in stuffy nose, nasal dryness, dry mouth, nasal irritation, throat irritation , rebound congestion, pulmonary oedema. dyspnoea
Gastrointestinal disorders	Nausea and vomiting
Skin and subcutaneous tissue disorders	Rash, sweating
Musculoskeletal and connective tissue disorders	convulsions (particularly in children)
Renal and urinary disorders	Difficulty in micturition, urinary retention
General disorders	Weakness, irritability, cerebral haemorrhage, appetite reduction, hyper salivation

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

Refer to "**SIDE EFFECTS**".

Systemic administration causes sedation, dry mouth and sweating. Alpha-adrenergic blockade may be necessary for severe hypertension.

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, shock like hypotension, apnoea and loss of consciousness is also possible.

Paediatric population

Clinical manifestation includes CNS signs and symptoms: convulsion and coma, hallucinations, bradycardia, apnoea, hypertension changing into hypotension.

Withdrawal or reduction of dosage may be required.

Treatment

A nonselective alphalytic 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 standard methods to remove unabsorbed drugs are indicated.

Further treatment is supportive and symptomatic

IDENTIFICATION

Colourless, watery solution which foams.

PRESENTATION

Plastic LDPE spray bottles of 20 ml and plastic HDPE pump spray bottles of 20 ml.

STORAGE INSTRUCTIONS

Store upright, at or below 25 °C.

Keep out of reach of children.

REFERENCE NUMBER

H1376 (Act 101/1965)

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

27 Wrench Road

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1600

South Africa

Reg. no. 1968/011192/07

DATE OF PUBLICATION OF THIS PACKAGE INSERT

Date on the registration certificate: old medicine.

Date of the recently revised package insert: 07 February 1991.