Professional information for OXYSPRAY MOISTURISING

SCHEDULING STATUS:

S1

1. NAME OF THE MEDICINE

OXYSPRAY MOISTURISING 0,5 mg/mL nasal spray, solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 mL of OXYSPRAY MOISTURISING solution contains 0,5 mg oxymetazoline hydrochloride.

Contains sugar: 43 mg/mL sorbitol.

Excipient with known effect:

Preservative: Benzalkonium chloride 0,033 % *m/v*.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Nasal spray, solution.

Clear, colourless solution, free from visible particles.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

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

4.2 Posology and method of administration

Posology

Adults and children over 6 years:

One to two sprays into each nostril in the morning and evening. Do not exceed 2 applications in any 24 hour period (twice daily every 10 – 12 hours).

Do not exceed the recommended dosage or use for longer than 5 days.

Method of administration

For nasal use only. Avoid spraying into eyes.

- Insert the tip of the pump nozzle in one nostril without completely occluding the nostril.
- With head bent slightly forward, squeeze the pump bottle 1 – 2 times while sniffing briskly and then treat the other nostril in the same way.
- Wipe nozzle clean after each use.

(Instillation may be repeated 10 or 15 minutes later, if necessary.)

4.3 Contraindications

- Hypersensitivity to oxymetazoline hydrochloride, benzalkonium chloride, or any of the ingredients of OXYSPRAY MOISTURISING listed in section 6.1.
- Patients receiving monoamine oxidase inhibitors (MAOIs), or within 14 days of its termination.
- Patients with porphyria.
- Patients with severe hypertension or phaeochromocytoma.
- Patients where there is inflammation of the skin and mucosa of the nasal vestibule and encrustation (rhinitis sicca).
- Patients after transsphenoidal hypophysectomy.

4.4 Special warnings and precautions for use

- OXYSPRAY MOISTURISING is not recommended for children under 6 years of age.
- OXYSPRAY MOISTURISING should not be used for more than 5 days. If symptoms persist, consult a medical practitioner.

- Prolonged use or excessive application of OXYSPRAY MOISTURISING to the nasal mucosa may lead to rebound congestion and medicine-induced rhinitis.
- Use with caution in patients with cardiovascular disorders (especially cardiac dysrhythmias, ischaemic heart disease or hypertension).
- Use with caution in patients with an occlusive vascular disease, who are at increased risk of peripheral ischaemia.
- Caution is advised in patients with hyperthyroidism, who may be at increased risk of effects on the heart (elevated thyroid hormone concentrations may also enhance adrenoceptor sensitivity).
- Diabetic and elderly patients have a high incidence of atherosclerotic disease and may also be at higher risk.
- Use with caution in patients with closed-angle glaucoma.
- Patients with prostate disorders should use OXYSPRAY MOISTURISING with caution as they may be at risk of urinary retention.
- OXYSPRAY MOISTURISING should not be used by more than one person, as it may spread infection.
- Children may be especially sensitive to the effects of OXYSPRAY MOISTURISING and caution is advised when administering to children.
- Use with caution in patients suffering from aneurysms and diabetes mellitus.
- Benzalkonium chloride may cause irritation or swelling inside the nose, especially if used for a long time.

4.5 Interaction with other medicines and other forms of interaction

Since oxymetazoline, as contained in OXYSPRAY MOISTURISING, is absorbed through the mucosa, interactions with other medicines may follow this topical application.

- Severe hypertension may occur when MAOIs (including reversible inhibitors of monoamine oxidase type A (RIMAs)) and OXYSPRAY MOISTURISING are used together (see section 4.3).
- Beta1-agonists and medicines that increase the sensitivity of the myocardium, may

increase cardiac effects. Take special care when using OXYSPRAY MOISTURISING in combination with cardiac glycosides (such as digoxin) and antidysrhythmics (such as quinidine).

- Caution is required when OXYSPRAY MOISTURISING is used in combination with thyroid hormones.
- Use OXYSPRAY MOISTURISING with caution in combination with antihypertensive medicines or medicines that cause hypotension, particularly those whose action involves the sympathetic nervous system.
- Interactions with alpha- and beta-blockers may be complex and can produce a hypertensive crisis.
- The antihypotensive effects of adrenergic neurone blockers (such as reserpine or alpha-methyldopa) may be reversed and may result in hypertension.
- Maprotiline and tricyclic antidepressants block the inactivation of epinephrine (adrenaline) and norepinephrine (noradrenaline) by uptake into the nerve endings and as a result hypertension and dysrhythmias may occur.
- The effect of central nervous system (CNS) stimulants may be potentiated, while the vasoconstrictor and vasopressor effects of alpha-agonists may be enhanced by medicines with similar effects, such as ergot alkaloids or oxytocin.
- Medicines causing potassium loss (such as corticosteroids, potassium depleting diuretics, aminophylline or theophylline) may potentiate beta2-mediated hypokalaemia.
- OXYSPRAY MOISTURISING should be used with caution in patients undergoing anaesthesia with cyclopropane, halothane or other halogenated anaesthetics, as they may induce ventricular fibrillation.
- Inhalation anaesthetics may increase the risk of dysrhythmias when used in combination with OXYSPRAY MOISTURISING.
- Possible additive cardiovascular toxicity may occur when sympathomimetics are given with antiparkinsonian medicines, such as bromocriptine.

4.6 Fertility, pregnancy and lactation

Pregnancy and breastfeeding

Safety during pregnancy and lactation has not been established.

Fertility

No data are available on the effects of OXYSPRAY MOISTURISING on human fertility.

4.7 Effects on ability to drive and use machines

OXYSPRAY MOISTURISING may cause side effects such as dizziness, light-headedness or confusion. Patients should be advised not to drive a vehicle or operate machinery until it is established that their ability to perform such activities is not affected.

4.8 Undesirable effects

Immune system disorders

Frequency unknown: Hypersensitivity.

Metabolism and nutrition disorders

Frequency unknown: Altered metabolism (including disturbances of glucose metabolism).

Psychiatric disorders

Less frequent: Anxiety, irritability, nervousness, restlessness.

Frequency unknown: Agitation, psychotic states, fear.

Nervous system disorders

Less frequent: Headache, insomnia, tremor.

Frequency unknown: Confusion, pain, dizziness, light-headedness, drowsiness, trembling, hallucinations (particularly in children).

Eye disorders

Less frequent: Eye irritation, discomfort or redness.

Frequency unknown: Blurred vision.

Cardiac disorders

Less frequent: Palpitations, tachycardia.

Frequency unknown: Irregular or slow heartbeat, precordial pain, ventricular dysrhythmias, anginal pain, cardiac arrest, bradycardia.

Vascular disorders

Frequency unknown: Vasoconstriction, hypertension, hypotension, cerebral haemorrhage, reactive hyperaemia.

Respiratory, thoracic and mediastinal disorders

Frequent: Sneezing.

Frequency unknown: Troubled breathing, pulmonary oedema, increased nasal discharge, dyspnoea, increase in stuffy nose, nasal dryness, nasal irritation, throat irritation, rebound congestion, medicine-induced rhinitis.

Gastrointestinal disorders

Less frequent: Dryness of the mouth and throat, nausea.

Frequency unknown: Vomiting, reduced appetite, thirst.

Skin and subcutaneous tissue disorders

Frequency unknown: Increased sweating, unusual paleness, piloerection, rash.

Renal and urinary disorders

Frequency unknown: Difficult or painful urination, urinary retention

General disorders and administration site conditions

Frequent: Local stinging, burning, transient irritation.

Less frequent: Flushing

Frequency unknown: Hypersalivation, cold extremities, weakness, fainting, appetite reduction.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of OXYSPRAY MOISTURISING is important. It allows continued monitoring of the benefit/risk balance of OXYSPRAY MOISTURISING. Health care providers are requested to report any suspected adverse reactions via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

4.9 Overdose

See section 4.8.

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 medicines are indicated.

Further treatment is supportive and symptomatic.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and class: A 16.1 Nasal decongestants.

Pharmacotherapeutic group: Decongestants and other nasal preparations for topical use.

Sympathomimetics, plain.

ATC code: R01AB01.

Oxymetazoline hydrochloride is a direct acting sympathomimetic medicine with alpha-adrenergic activity. It is a vasoconstrictor which reduces swelling and congestion when applied to the nasal mucous membranes.

Oxymetazoline hydrochloride acts as local vasoconstrictor within a few minutes, and the effect lasts for up to 12 hours.

5.2 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 hydrochloride 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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzalkonium chloride (50 % solution) 0,033 % *m/v* (as preservative)

Disodium edetate dihydrate

Glycerine

Propylene glycol

Disodium phosphate dihydrate (for pH adjustment)

Monosodium phosphate dihydrate (for pH adjustment)

Sorbitol

Water for injection.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Store at or below 30 °C.

6.5 Nature and contents of container

10 mL solution filled into a 15 mL white HDPE bottle, fitted with a polypropylene metered dose pump with gold colour crimp on fixture, with a white actuator and natural polyethylene dust cap. Each bottle contains 100 metered dose sprays.

20 mL solution filled into a 30 mL white HDPE bottle, fitted with a white polypropylene screw-on metered dose pump, with a white actuator and natural polyethylene dust cap. Each bottle contains 205 metered dose sprays.

One bottle is packed into an outer carton.

6.6 Special precautions for disposal and other handling

Not applicable.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Zydus Healthcare SA (Pty) Ltd

Southdowns Office Park

22 Karee Street

Centurion 0157

Tel: 012 748 6400

8. REGISTRATION NUMBER

OXYSPRAY MOISTURISING: 45/16.1/0232

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

23 March 2015

10. DATE OF REVISION OF THE TEXT

To be allocated.