PROFESSIONAL INFORMATION

SCHEDULING STATUS: S1

1. NAME OF THE MEDICINE

DriNasal Paediatric 0,025 % (Drops and Metered Spray)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml of the solution contains:

Oxymetazoline hydrochloride 0,25 mg

Preservative:

Benzalkonium chloride 0,015 % *m/v*

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Nasal Drops and Metered Spray, solution

Clear, colourless solution, with a faint odour.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

DriNasal Paediatric 0,025 % is indicated for the relief of nasal congestion due to the common cold, sinusitis, allergic rhinitis and hay fever.

Indicated as adjunctive treatment in middle ear infection.

4.2 Posology and method of administration

Posology

DriNasal Paediatric 0,025 % is indicated for children up to the age of 6 years.

Metered Spray:

2 to 3 sprays in each nostril 2 to 3 times a day.

Drops:

2 to 3 drops of the liquid into each nostril 2 to 3 times a day.

DriNasal Paediatric 0,025 % should not be used for a period longer than 5 days.

Method of administration

Nasal administration

Metered Spray:

For best results keep both the head and spray bottle slightly tilted to the back. Remove the cap by pulling. With the middle and forefinger around the bottom of the nozzle and the thumb on the base of the bottle, press once to fill the pump mechanism completely. Insert the nozzle of the spray loosely into the nostril, squeeze the pump spray 2 to 3 times and simultaneously sniff in to ensure an even distribution of the fine spray. Repeat for other nostril.

Drops:

Fill glass dropper unit by placing the open end into the liquid and depressing the rubber teat. Tilt the head back and instill 2 to 3 drops of the liquid into each nostril 2 to 3 times a day.

4.3 Contraindications

- Hypersensitivity to Oxymetazoline hydrochloride or to any of the excipients listed in section 6.1.
- Rhinitis sicca (inflammation of the skin and mucosa of the nasal vestibule and encrustation).
- In patients following a trans-sphenoidal hypophysectomy

4.4 Special warnings and precautions for use

In the following cases, **DriNasal Paediatric 0,025 %** may only be used after carefully weighing the risk-to-benefit ratio:

- Patients treated with monoamine oxidase inhibitors or have taken MAOIs in the previous 2 weeks, or who have been treated with tricyclic antidepressants and other medicines such as stated in 4.5.
- Medicines potentially increasing blood pressure.
- Increased intraocular pressure, especially narrow-angle glaucoma.
- Severe cardiovascular diseases (e.g. coronary heart disease, angina, hypertension, cardiac asthma).
- Phaeochromocytoma.
- Metabolic disorders (e.g. hyperthyroidism, diabetes mellitus, porphyria).
- Hyperplasia of the prostate.
- **Do not exceed the recommended dose.**
- If symptoms worsen or do not improve after 3 days, a medical practitioner should re-evaluate clinical situations.
- **DriNasal Paediatric 0,025 %** should be used for a maximum of 5 consecutive days to avoid a rebound-effect and drug-induced rhinitis.

Long-term use and overdosage of **DriNasal Paediatric 0,025 %** should be avoided.

The efficacy of **DriNasal Paediatric 0,025 %** may be reduced (tachyphylaxis) with long-term use or overdose. This may lead to use of higher doses or to more frequent usage which, in turn, can result in permanent use. If long-term use or overdose occurs, treatment should be discontinued immediately.

Continuous use may cause nasal congestion due to reactive hyperaemia of the nasal mucosa (rebound effect) and chronic swelling of the nasal mucosa (rhinitis medicamentosa) as well as mucosal atrophy or rhinitis sicca. Rebound effects and tachyphylaxis should stop once use of **DriNasal Paediatric 0,025 %** is discontinued.

Medical supervision is indicated in patients with chronic rhinitis.

Dosages higher than recommended may only be used under medical supervision.

DriNasal Paediatric 0,025 % contains 0,15 mg benzalkonium chloride (a preservative) in each millilitre nasal solution which is equivalent to 0,015 % (*m/v*).

4.5 Interaction with other medicines and other forms of interaction

The concomitant use of **DriNasal Paediatric 0,025 %** and certain mood-stimulating medicines with hypertensive effect (e.g. MAO inhibitors and tricyclic antidepressants) may lead to an increase in blood pressure or hypertensive crisis due to their cardiovascular activity.

The efficacy of beta-blocking medicines such as methyldopa, bethanidine, debrisoquine and guanethidine or other anti-hypertensive medicines may be reduced with concomitant use of **DriNasal Paediatric 0,025 %.**

Possible additive cardiovascular toxicity may occur when sympathomimetics are given with antiparkinsonian medicines such as bromocriptine.

4.6 Fertility, pregnancy and lactation

Pregnancy and lactation

DriNasal Paediatric 0,025 % should only be used after consultation with a medical practitioner during pregnancy and lactation.

The recommended dosage must not be exceeded.

Fertility

No data are available on the effects of **DriNasal Paediatric 0,025 %** on human fertility.

4.7 Effects on ability to drive and use machines

No impairment is to be expected if used as recommended.

Systemic effects with involvement of the cardiovascular or central nervous system cannot be excluded after prolonged administration of **DriNasal Paediatric 0,025 %** or intake of oxymetazoline containing cold remedies in doses higher than recommended. In these cases, the ability to drive a vehicle or operate machinery can be impaired.

4.8 Undesirable effects

Tabulated list of adverse reactions	
Immune system disorders	
Frequency unknown	Hypersensitivity reaction (angioedema, rash, pruritis)
Psychiatric disorders	
Frequency unknown	Insomnia, restlessness
Nervous system disorders	
Less frequent	Headache or light-headedness, nervousness, anxiety, irritability
Frequency unknown	Somnolence, sedation, hallucinations, convulsions
Cardiac disorders	
Frequency unknown	Palpitations, tachycardia
Vascular disorders	
Frequency unknown	Hypertension (increased blood pressure)
Respiratory, thoracic and mediastinal disorders	
Frequent	Aqueous nasal secretions, crusted nose

Less frequent	Rebound congestion (increase in runny or stuffy nose)
Frequency unknown	Nasal discomfort (stinging or burning of the nasal mucosa), dryness of the nose, mouth and throat, sneezing, after the effect has worn off increased swelling of the mucosa (reactive hyperaemia), epistaxis
General disorders and administration site conditions	
Frequency unknown	Fatigue, tachyphylaxis (associated with long-term use or overdose). Systemic effects have occurred after local administration.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications:
https://www.sahpra.org.za/Publications/Index/8

4.9 Overdose

Overdosage may occur after nasal or accidental oral administration.

The efficacy of **DriNasal Paediatric 0,025 %** may be reduced (tachyphylaxis) with long-term use or overdose. This may lead to use of higher doses or to more frequent usage which, in turn, can result in permanent use. If long-term use or overdose occurs, treatment should be discontinued immediately.

The clinical picture following intoxication with imidazol-derivatives may be unclear due to the

occurrence of episodes of hyperactivity alternated with episodes of depression of the central nervous system and of the cardiovascular and pulmonary system.

Symptoms

Symptoms of an overdose may be:

Hypertension, tachycardia, palpitations, cardiac dysrhythmia, cardiac arrest, sweating, agitation, convulsion, mydriasis, nausea, vomiting, cyanosis, fever, spasms, circulatory collapse, pulmonary oedema, respiratory disorders, psychic disorders, drowsiness, paleness, miosis, decrease in body temperature, bradycardia, shock-like hypotension, apnoea, loss of consciousness and coma.

In children above 6 years, in particular, overdose often causes dominating central nervous effects with convulsions and coma, bradycardia, apnoea as well as hypertension possibly followed by hypotension.

Therapeutic measures after overdosage

In-house intensive-care therapy is indicated in cases of severe overdose.

Administration of medicinal charcoal (absorbent) or sodium sulfate (laxative) should be performed rapidly.

A non-selective alpha-blocker can be given as antidote. If required, initiate fever lowering measures, anticonvulsive therapy and oxygen ventilation.

Vasopressors are contraindicated.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

A 16.1 Nasal Decongestants

Pharmacotherapeutic group: Sympathomimetics, plain.

ATC code: R01AA05

Mechanism of action

Oxymetazoline hydrochloride is a direct-acting sympathomimetic amine. It acts on alpha-adrenergic receptors in arterioles of the nasal mucosa to produce constriction, resulting in decreased blood flow and decreased nasal congestion.

Application of oxymetazoline into the nostrils leads to decongestion of the inflamed nasal mucosa and thus to a normalisation of nasal breathing.

5.2 Pharmacokinetic properties

Absorption

The effect of oxymetazoline sets in within a few minutes.

The effect of oxymetazoline persists for up to 12 hours.

Relevant absorption of pharmacodynamically effective doses of oxymetazoline following the recommended topical use is regarded as uncommon but cannot be excluded.

The absorption rate is estimated at 3,5 hours. The maximum plasma concentration can be found after 8 to 10 hours.

Elimination

Terminal serum half-life is 35 hours, and the excretion measured in faeces (1,1 % of the applied dose, after 48 hours) and urine (2,1 % of the applied dose, after 96 hours).

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Bezalkonium chloride

Disodium EDTA

Sodium hydroxide

Sodium dihydrogen phosphate dihydrate

Disodium hydrogen phosphate hydrate

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months

6.4 Special precautions for storage

Store at or below 25 ºC. Protect from light.

Keep well closed.

6.5 Nature and contents of container

10 ml Metered spray bottle:

brown glass bottle, containing 10 ml solution, with dispensing pump and cap.

10 ml Dropper bottle:

amber glass bottle, containing 10 ml solution, with glass pipette and cap.

6.6 Special precautions for disposal

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Viatris South Africa (Pty) Ltd

4 Brewery Street

Isando, Johannesburg

1609

8. REGISTRATION NUMBER(S)

27/16.1/0390

9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION

21 January 1993

10. DATE OF REVISION OF THE TEXT

28 April 2024