**SCHEDULING STATUS:** S1

**PROPRIETY NAME (AND DOSAGE FORM):**

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

**COMPOSITION:**
Each 1 ml of the solution contains: Oxymetazoline hydrochloride 0,25 mg.
Preservative: Benzalkonium chloride 0,015% m/v.

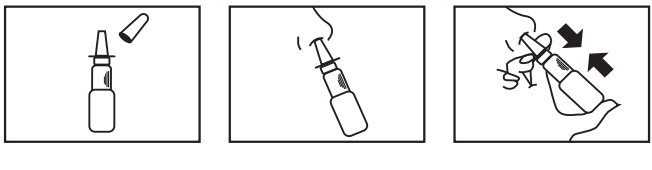
**PHARMACOLOGICAL CLASSIFICATION:**
A 16.1 Nasal Decongestants.

**PHARMACOLOGICAL ACTION:**
**DriNasal Paediatric 0,025 %** is a topical vasconstrictor which exerts a decongestant action on mucous membranes of the nasopharyngeal cavity.

**INDICATIONS:**
**DriNasal Paediatric 0,025 %** is indicated for the relief of nasal congestion due to the common cold, sinusitis, allergic rhinitis and hayfever. Indicated as adjunctive treatment in middle ear infection.

**CONTRA-INDICATIONS:**
Hypersensitivity to any of the ingredients.

**DOSAGE AND DIRECTIONS FOR USE:**
**DriNasal Paediatric 0,025 %** is indicated for children up to the age of six years.
**Metered Spray:**
Two to three sprays in each nostril 2 to 3 times a day.
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 two to three 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 two to three times a day.

**SIDE-EFFECTS AND SPECIAL PRECAUTIONS:**
**DriNasal Paediatric 0,025 %** should be used with care in patients with cardiac disease, hypertension or hyperthyroidism.
It may cause local stinging or burning, sneezing and dryness of the mouth and throat. Prolonged use may cause rebound congestion and drug-induced rhinitis.
**DriNasal Paediatric 0,025 %** should not be used for a period longer than five days. It is not advisable to use **DriNasal Paediatric 0,025 %** more frequently than recommended. If unexpected side-effects appear, consult your doctor immediately.

**KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:**
See "**SIDE-EFFECTS AND SPECIAL PRECAUTION**S". Local gastric irritation and possible systemic sympathomimetic effects may occur, e.g. sweating, tachycardia, drowsiness possibly leading to coma, convulsions and circulatory collapse.
Treatment should be symptomatic and supportive.

**IDENTIFICATION:**
Clear, colourless solution, with a faint odour.

**PRESENTATION:**
10 ml Metered spray bottle.
10 ml Dropper bottle.

**STORAGE INSTRUCTIONS:**
Store below 25 ºC.
Protect from light.
KEEP OUT OF REACH OF CHILDREN.

**REGISTRATION NUMBER:**
27/16.1/0390

**NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:**
Xixia Pharmaceuticals (Pty) Ltd.
Building 6, Greenstone Hill Office Park
Emerald Boulevard
Modderfontein, 1645
Republic of South Africa

**DATE OF PUBLICATION OF THIS PACKAGE INSERT:**
21 January 1993

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**www.mylansa.co.za**

**SKEDULERINGSTATUS:** S1

**EIENDOMSNAAM (EN DOSEERVORM):**

# DriNasal Paediatric 0,025 %
(Druppels en Afgemete Sproei)

**SAMESTELLING:**
Elke 1 ml van die oplossing bevat: Oksimetasolienhidrochloried 0,25 mg.
Preserveermiddel: Bensalkoniumchloried 0,015 % m/v.

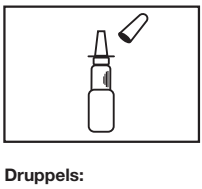
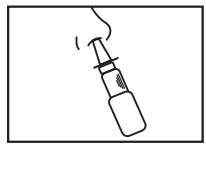
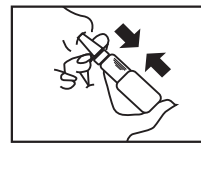
**FARMAKOLOGIESE KLASSIFIKASIE:**
A 16.1 Neusontstoppingsmiddels.

**FARMAKOLOGIESE WERKING:**
**DriNasal Paediatric 0,025 %** is 'n plaaslike vaatvernouer wat 'n ontstuwende werking op die slymvliese van die nasofaringeale holte het.

**INDIKASIES:**
**DriNasal Paediatric 0,025 %** is aangedui vir die verligting van neusontstuwing as gevolg van verkoue, sinusitis, allergiese rinitis en hooikoors. Aangedui as bykomstige behandeling by middeloorinfeksie.

**KONTRA-INDIKASIES:**
Hipersensitiwiteit vir enige van die bestanddele.

**DOSIS EN GEBRUIKSAANWYSINGS:**
**DriNasal Paediatric 0,025 %** is aangedui by kinders tot en met ses jaar oud.
**Afgemete sproei:**
Twee tot drie spuite in elke neusgat 2 tot 3 maal per dag.
Vir beste resultate moet die kop en sproeibottel effens agteroor gehou word. Verwyder die doppie deur te trek. Met die middel en voorvinger om die onderkant van die kop en die duim om die basis van die bottel, druk eenmaal om die pompmeganisme heeltemal te vul. Druk die sproeipunt liggies in die neusgat en druk die sproeimeganisme twee tot drie maal en asem tegelykertyd in om eweredige verspreiding te verseker. Herhaal vir ander neusgat.

**Druppels:**
Vul die glasdruppereenheid deur die oop kant in die vloeistof te plaas en die rubberpunt te druk. Hou die kop agteroor en plaas 2 tot 3 druppels van die vloeistof in elke neusgat twee tot drie maal per dag.

**NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS**
**DriNasal Paediatric 0,025 %** moet versigtig gebruik word by pasiënte met hartvatsiekte, hipertensie of hipertiroïedisme.
Dit kan 'n plaaslike steekgevoel of branderigheid, nies en droogheid van die mond en keel veroorsaak. Langdurige gebruik kan verskynselhernuwing van kongestie en geneesmiddel-geïnduseerde rinitis veroorsaak. **DriNasal Paediatric 0,025 %** behoort nie vir 'n periode van langer as vyf dae gebruik te word nie.
Dit word nie aanbeveel dat **DriNasal Paediatric 0,025 %** meer dikwels gebruik word as aangedui nie. As onverwagte newe-effekte verskyn, moet 'n geneesheer onmiddelik geraadpleeg word.

**BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:**
Sien "**NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS**". Plaaslike gastriese irritasie en moontlike sistemiese simpatomimetiese effekte kan voorkom, bv. sweet, tagikardie, lomerigheid wat moontlik tot koma kan lei, konvulsies en sirkulatoriese ineenstorting. Behandeling behoort simptomaties en ondersteunend te wees.

**IDENTIFIKASIE:**
Helder, kleurlose oplossing, met 'n effense reuk.

**AANBIEDING:**
10 ml Afgemete sproeibottel.
10 ml Druppelbottel.

**BERGINGSAANWYSINGS:**
Berg benede 25 ºC.
Beskerm teen lig.
HOU BUITE BEREIK VAN KINDERS.

**REGISTRASIENOMMER:**
27/16.1/0390

**NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE SERTIFIKAAT VAN REGISTRASIE:**
Xixia Pharmaceuticals (Pty) Ltd
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Modderfontein, 1645
Republiek van Suid-Afrika

**DATUM VAN PUBLIKASIE VAN HIERDIE VOUBILJET:**
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