

**Johnson & Johnson (Pty) Ltd.**

[Sinutab Children Nasal Spray, Xylometazoline hydrochloride 0.5 mg per ml, Solution]

**1.11 SmPC**

**SINUTAB® CHILDREN NASAL SPRAY**

**PROPRIETARY NAME AND DOSAGE FORM**

SINUTAB® CHILDREN NASAL SPRAY (Solution)

**COMPOSITION**

Each 1 ml contains:

Xylometazoline hydrochloride 0,5 mg (0,05 % w/v)

Preservative: Benzalkonium chloride 0,02 % m/v

The other ingredients are disodium edetate, disodium phosphate dihydrate, sodium dihydrogen phosphate dihydrate, sodium chloride, sorbitol solution and purified water.

**PHARMACOLOGICAL CLASSIFICATION**

A: 16.1 Nasal Decongestants

**PHARMACOLOGICAL ACTION**

**Pharmacodynamic properties**

Xylometazoline is a sympathomimetic amine of the imidazoline class with an alpha-adrenergic action. It acts directly on  $\alpha$ -adrenoreceptors but does not act on  $\beta$ - receptors. Xylometazoline has a vasoconstrictive effect and thus reduces the congestion and swelling of the nasal mucosa, thereby improving nasal breathing and discharge of secretion.

When used topically as a nasal decongestant, Xylometazoline acts rapidly and provides long-lasting relief.

Onset of action is usually observed within 5-10 minutes, the decongestant effect being prolonged and lasting for up to 10 hours.

**Pharmacokinetic properties**

Data from pharmacokinetic studies in humans are not available.

**Absorption**

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When used and dosed correctly, the absorption of topically applied xylometazoline into systemic circulation is generally negligible.

**Distribution, metabolism and elimination**

There is scarcely any information available on the distribution, metabolism or secretion of xylometazoline in man.

**INDICATIONS**

SINUTAB® CHILDREN NASAL SPRAY is indicated for relief of nasal congestion accompanying hay fever, allergic rhinitis, colds and sinusitis.

**CONTRA-INDICATIONS**

Contraindicated in children under 2 years of age.

Hypersensitivity to xylometazoline or any of the other ingredients.

The prolonged use of vasoconstrictor agents is not indicated in cases of chronic rhinitis.

Not to be used with antihypertensives of the adrenergic neuron blocking type or monoamine oxidase inhibitors or within 10 days of their discontinuation.

**WARNINGS and SPECIAL PRECAUTIONS**

Prolonged treatment may lead to reactive hyperaemia of the nasal mucosa. resulting in repeated or even continuous use of the medicine (see "SIDE-EFFECTS").

This rebound effect may lead to serious nasal congestion or nasal obstruction during continued use or after discontinuation.

There is minimal systemic absorption with topically applied imidazoline sympathomimetic such as xylometazoline, however use with caution in patients with cardiovascular disorders, hyperthyroidism, diabetic patients and the elderly.

Use with caution in patients with angle-closure glaucoma and those with prostate disorders.

Use only when no safer alternative is available in patients with porphyria.

Not recommended for children under 2 years of age without the intervention of a medical doctor.

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**Effects on ability to drive and use machines**

It is not known if xylometazoline has an effect on the ability to drive or operate machinery.

**Information relating to excipients**

This product contains benzalkonium chloride which is an irritant and could cause skin reactions.

**INTERACTIONS**

Due to the low systemic absorption of xylometazoline when administered intranasally, interactions with medicines administered via another route is considered unlikely.

No interactions studies have been performed.

The concurrent use of xylometazoline and monoamine oxidase inhibitors may cause a hypertensive crisis.

**PREGNANCY AND LACTATION**

**Pregnancy**

Safety and/or efficacy has not been established

**Lactation/Breast feeding**

It is not known if xylometazoline or its metabolites are excreted in human milk. Safety and/or efficacy has not been established

**DOSAGE AND DIRECTIONS FOR USE**

**TOPICAL USE ONLY (INTRANASALLY)**

Do not exceed the recommended dose below.

Children 2 to 12 years:

One spray into each nostril 1 -3 times a day, as required. Maximum daily dose within a 24-hour period: 2 sprays per nostril.

Not recommended for infants less than 2 years of age.

Do not use for more than 7 days.

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Directions on how to use the SINUTAB® CHILDREN NASAL SPRAY:

1. Remove the plastic cap from the nozzle.
2. On first use, press the plunger downwards, and release until a single spray is delivered into the atmosphere.
3. Hold the bottle upright and place nozzle into one nostril.  
Depress the plunger and at the same time breathe in through your nose. Release the plunger and remove nozzle from the nostril. Repeat this procedure for the other nostril.
4. To keep the nozzle clean, wipe the nozzle and replace the plastic cap after use

**SIDE-EFFECTS**

Xylometazoline nasal preparations are generally well tolerated following short-term use and local side-effects are mild and infrequent.

Side-effects that have been reported are:

Psychiatric disorders:

*Frequency unknown:* Hallucinations and paranoia.

Nervous system disorders

*Frequency unknown:* Systemic effects are headache and dizziness, anxiety, fear, restlessness, insomnia, confusion, weakness and irritability may occur with all sympathomimetics.

Cardiac disorders

*Frequency unknown:* Palpitations, tachycardia and arrhythmias

Respiratory, thoracic and mediastinal disorders

*Frequency unknown:* Dyspnoea

Gastrointestinal disorders

General disorders and administration site conditions

*Frequency unknown:* Burning sensation of the nasal mucosal, nasal dryness pain and irritation, and rebound effect with frequent or prolonged use. After local use, transient irritation may occur.

**KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT**

Systemic overdose of xylometazoline may result in a wide range of symptoms that are attributed to cardiac and nervous system stimulation or depression.

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Overdosage or accidental administration by mouth may cause

depression of the central nervous system and marked reduction in body temperature and bradycardia, symptoms of sweating, drowsiness and coma, particularly in children. Hypertension may be followed by rebound hypotension.

Treatment is symptomatic and mainly supportive.

**IDENTIFICATION**

A clear, colourless solution.

**PRESENTATION**

Available in 10 and 15 ml amber glass bottles with a white plastic metered-dose spray pump and a plastic cap.

**STORAGE INSTRUCTIONS**

Store in a cool place (at or below 25 °C).

Protect from light and keep container tightly closed.

KEEP OUT OF REACH OF CHILDREN.

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

Johnson & Johnson (Pty) Ltd.

241 Main Road

RETREAT

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South Africa

NAFDAC Reg. No. XXX-XXX

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## **SINUTAB® CHILDREN NASAL SPRAY**

### **HANDELSNAAM EN DOSERINGSVORM**

SINUTAB® CHILDREN NASAL SPRAY (Solution)

### **SAMESTELLING**

Elke 1 ml bevat:

Xilometasolien-hidrochloried 0,5 mg (0,5 % g/v)

Preserveermiddel: Bensalkoniumchloried 0,02 % g/v

Die ander bestanddele is disodiumedetaat, disodiumfosfaatdihidraat, natriumdihidrogeenfosfaatdihidraat, natriumchloried, sorbitoloplossing en gesuiwerde water.

### **FARMAKOLOGIESE KLASSIFIKASIE**

A: 16.1 Neusontstuwingsmiddels

### **FARMAKOLOGIESE WERKING**

Farmakodinamiese eienskappe

Xilometasolien is 'n simpatomimetiese amien wat aan die imidasolienklas behoort met 'n alfa-adrenergiese werking.

Dit het 'n direkte uitwerking op  $\alpha$ -adrenoreseptore maar nie op  $\beta$ -reseptore nie. Xilometasolien het 'n vatvernouende uitwerking. Dit verminder dus die stuwings en swelling van die neusmukosa en verbeter sodoende asemhaling deur die neus en die afskeiding van sekresie.

Wanneer dit lokaal as neusontstuwingsmiddel gebruik word, werk xilometasolien vinnig en verskaf dit langdurige verligting.

Aanvang van die werking word gewoonlik binne 5-10 minute waargeneem, met die ontstuwings effek wat langdurig is en tot 10 ure duur.

### **Farmakokinetiese eienskappe**

Data van farmakokinetiese studies by mense is nie beskikbaar nie.

### **Absorpsie**

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Wanneer dit korrek gebruik en gedoseer word, is die absorpsie van lokaal toegepaste xilometasolien in die sistemiese sirkulasie gewoonlik gering.

**Verspreiding, metabolisme en eliminasië**

Daar is bykans geen inligting beskikbaar oor die verspreiding, metabolisme en afskeiding van xilometasolien by mense nie.

**INDIKASIES**

SINUTAB®-NEUSSPROEI VIR KINDERS word aangedui as verligting vir neusstuwings wat gepaardgaan met hooikoors, allergiese rinitis, verkoues en sinusitis.

**KONTRAINDIKASIES**

Kontra-indikasië vir kinders jonger as 2 jaar.

Hipersensitiwiteit vir xilometasolien of enige van die ander bestanddele.

Die langdurige gebruik van vatvernouende agense word nie in gevalle van chroniese rinitis aangedui nie.

Moenie in die volgende gevalle gebruik word nie: (1) saam met antihipertensiewe middele wat aan die adrenergiese neuronblokkeringstipe behoort; (2) saam met monoamienoksidaseinhibitors; of (3) binne 10 dae ná staking daarvan.

**WAARSKUWINGS en SPESIALE VOORSORGMAATREËLS**

Langdurige behandeling kan moontlik lei tot reaktiewe hiperemie van die neusmukosa wat kan lei tot herhaalde of selfs voortdurende gebruik van die medisyne (sien "NEWE-EFFEKTE").

Hierdie terugslageffek kan moontlik lei tot ernstige neusstuwings of neusobstruksie tydens voortgesette gebruik of ná staking.

Daar is minimale sistemiese absorpsie met lokaal toegepaste simpatomimetiese imidasolien soos xilometasolien. Gebruik egter met sorg by pasiënte met kardiovaskulêre sturings, hipertiroïdisme en diabetes, sowel as by bejaardes.

Gebruik met sorg by pasiënte met nouhoekgloukoom en diegene met prostaatsturings.

Gebruik slegs by pasiënte met porfirie wanneer geen veiliger alternatief beskikbaar is nie.

Nie aanbeveel vir kinders jonger as 2 jaar sonder die ingryping van 'n mediese dokter nie.

**Uitwerking op die vermoë om te bestuur en om masjiene te gebruik**

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Dit is nie bekend of xilometasolien 'n uitwerking op die vermoë het om te bestuur of met masjinerie te werk nie.

**Inligting met betrekking tot eksipiënte**

Hierdie produk bevat bensalkoniumchloried wat 'n irritant is en velreaksies kan veroorsaak.

**INTERAKSIES**

Weens die lae sistemiese absorpsie van xilometasolien wanneer dit intranasaal toegedien word, word interaksie met medisyne wat elders toegedien word, as onwaarskynlik beskou.

Geen interaksiestudies is gedoen nie.

Die gelyktydige gebruik van xilometasolien en monoamienoksidaseinhibitors kan moontlik 'n hipertensiewe krisis veroorsaak.

**SWANGERSKAP EN LAKTASIE****Swangerskap**

Veiligheid en/of doeltreffendheid is nie vasgestel nie.

**Laktasie/borsvoeding**

Dit is nie bekend of xilometasolien of die metaboliete daarvan in menslike melk afgeskei word nie.

Veiligheid en/of doeltreffendheid is nie vasgestel nie.

**DOSERING EN GEBRUIKSAANWYINGS****SLEGS VIR LOKALE GEBRUIK (INTRANASAAL)**

Moenie die voorgeskrewe dosis oorskry nie.

Kinders 2-12 jaar:

Een spuit in elke neusgat, 1-3 keer per dag, soos vereis.

Maksimum daaglikse dosis binne 'n 24-uur-tydperk: 2 spuite per neusgat.

Word nie aanbeveel vir kinders jonger as 2 jaar nie.

Moenie langer as 7 dae gebruik nie.

Aanwysings vir hoe om die SINUTAB®-NEUSSPROEI VIR KINDERS te gebruik:

1. Haal die plastiekdoppie van die tuit af.



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2. Druk met die eerste gebruikslag die plunjer afwaarts en laat dit uit totdat 'n enkele spuit in die atmosfeer vrygestel word.
3. Hou die bottel regop en plaas die tuit in een neusgat.
4. Druk die plunjer afwaarts en asem tegelykertyd in deur jou neus. Laat die plunjer uit en verwyder die tuit uit die neusgat. Herhaal hierdie prosedure met die ander neusgat.
5. Om die tuit skoon te hou: Vee dit ná gebruik af en sit die plastiekdoppie terug.

**NEWEEFFEKTE**

Xilometasolien-neusvoorbereidings word gewoonlik goed verdra ná korttermyngebruik. Lokale newe-effekte is lig en seldsaam.

Die volgende newe-effekte is gerapporteer:

**Psigiatrisie steurings:**

*Frekwensie onbekend:* Hallusinasies en paranoia.

**Steurings van die senuweestelsel**

*Frekwensie onbekend:* Sistemiese uitwerking is hoofpyn en duiseligheid, angs, vrees, rusteloosheid, slapeloosheid, verwarring, swakheid en prikkelbaarheid. Dit kan moontlik met alle simpatomimetiese middele voorkom.

**Kardiale steurings**

*Frekwensie onbekend:* Palpitاسies, tagikardie en arritmie

**Respiratoriese, torakale en mediastinale steurings**

*Frekwensie onbekend:* Dispnee

**Gastro-intestinale steurings**

*Frekwensie onbekend:* Naarheid, braking en anoreksie

**Algemene steurings en kondisies by die plek van toediening**

*Frekwensie onbekend:* Brandgevoel van die nasale slymvlies; nasale droogheid, pyn en prikkelbaarheid en terugslageffek met gereelde en langdurige gebruik. Kortstondige prikkelbaarheid kan moontlik ná lokale gebruik voorkom.

**BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VIR DIE BEHANDELING DAARVAN**

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Sistemiese oordosering van xilometasolien kan moontlik lei tot 'n wye reeks simptome wat toegeskryf word aan kardiaale en senuweestelselstimulering of depressie.

Oordosering of toevallige toediening per mond kan, veral by kinders, moontlik lei tot onderdrukking van die sentrale senuweestelsel en merkbare vermindering van liggaamstemperatuur en bradikardie, simptome soos sweet, lomerigheid en 'n koma. Hipertensie kan moontlik deur terugslaghipotensie gevolg word.

Behandeling is simptomaties en hoofsaaklik ondersteunend.

**IDENTIFIKASIE**

'n Deursigtige, kleurlose oplossing.

**AANBIEDING**

Beskikbaar in amberkleurige 10 ml-glasbottels met 'n wit plastieksproeipompie met afgemete dosisse en 'n plastiekdoppie.

**BERGINGSINSTRUKSIES**

Stoor in 'n koel plek (25 °C of kouer).

Beskerm teen lig en hou houer deeglik toe.

HOU BUITE BEREIK VAN KINDERS.

**NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT**

Johnson & Johnson (Edms) Bpk.

Hoofstraat 241

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Suid-Afrika