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**This amendment:** Response to Clinical Recommendation.

**Date of original submission:** 31 October 2014

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## PATIENT INFORMATION LEAFLET

### SCHEDULING STATUS

S1

### SINUTAB NASAL SPRAY 0,1 % w/v solution

#### Xylometazoline hydrochloride

Preservative: Benzalkonium chloride 0,02 % w/v.

**Read all of this leaflet carefully because it contains important information for you.**

Sinutab Nasal Spray is available without a doctor's prescription, for you to treat a mild illness.


Nevertheless, you still need to use Sinutab Nasal Spray carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 7 days.

### What is in this leaflet

1. What Sinutab Nasal Spray is and what it is used for.
2. What you need to know before you use Sinutab Nasal Spray.
3. How to use Sinutab Nasal Spray.
4. Possible side effects.
5. How to store Sinutab Nasal Spray.
6. Contents of the pack and other information.

### 1. What Sinutab Nasal Spray is and what it is used for

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Sinutab Nasal Spray contains xylometazoline which helps to open up and clear your nasal passages by reducing the excessive nasal secretions and returning the swollen blood vessels to their normal size.

Sinutab Nasal Spray is for use in your nose to provide relief from nasal congestion (blocked nose) accompanying hay fever, allergies, colds and sinusitis.

## 2. What you need to know before you use Sinutab Nasal Spray


### Do not use Sinutab Nasal Spray:

- If you are hypersensitive (allergic) to xylometazoline hydrochloride or any of the other ingredients of Sinutab Nasal Spray (see **What Sinutab Nasal Spray contains**).
- In children under the age of 12 years.
- For long periods if you suffer from chronic rhinitis (inflammation and swelling of your nasal mucous membranes, causing blocked or runny nose).
- If you are taking medicines for high blood pressure called adrenergic neuron blockers or you stopped taking them within the last 10 days.
- If you are taking medicines for depression called monoamine oxidase inhibitors (MAOIs) or stopped taking them within the last 10 days.
- If you recently had neurosurgery.

### Warnings and precautions

Take special care with Sinutab Nasal Spray:

- If you have high blood pressure.
- If you suffer from cardiovascular disease.
- If you have an overactive thyroid gland (hyperthyroidism).
- If you suffer from narrow angle glaucoma.
- If you have diabetes mellitus.

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- If you have previously had a strong reaction to stimulant medicines, resulting in symptoms such as sleeplessness or dizziness.

Sinutab Nasal Spray should not be used for longer than 7 consecutive days.

### **Other medicines and Sinutab Nasal Spray**

Always tell your health care provider if you are taking any other medicine. This includes complementary or traditional medicines.

Tell your doctor or pharmacist if you are currently using:

- Monoamine oxidase inhibitors (MAOIs) (used to treat depression).
- Tricyclic antidepressants (used to treat depression).
- Medicines for high blood pressure called adrenergic neuron blockers.

### **Pregnancy, breastfeeding and fertility**

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before using Sinutab Nasal Spray.

The safety of Sinutab Nasal Spray in pregnancy and breastfeeding has not been established.

### **Driving and using machines**

Sinutab Nasal Spray can cause side effects, such as drowsiness. Do not drive a vehicle, operate machinery until you know how Sinutab Nasal Spray affects you.

### **Sinutab Nasal Spray contains benzalkonium chloride**

Sinutab Nasal Spray contains 0,2 mg benzalkonium chloride per 1 mL. Benzalkonium chloride may cause irritation or swelling inside the nose, especially if used for a long time.

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### 3. How to use Sinutab Nasal Spray

Do not share medicines with any other person.

#### ***Adults and children over the age of 12 years:***

One spray in each nostril 2 – 3 times a day, as required.

(Maximum daily dose: 3 sprays).

#### ***Children under 12 years of age:***

Not recommended.

**Do not use for more than 7 days.**

**Do not exceed the recommended dosage.**

Always use Sinutab Nasal Spray exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

#### ***Method of administration:***

1. Remove the plastic cap from the nozzle.
2. On first use, press the plunger downwards, and release until a single spray is delivered.
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 clean, wipe the nozzle and replace the plastic cap after use.

If you have the impression that the effect of Sinutab Nasal Spray is too strong or too weak, tell your doctor or pharmacist.

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### **If you use more Sinutab Nasal Spray than you should**

In the event of an overdose or accidental ingestion, consult your doctor or pharmacist. If neither is available contact the nearest hospital or poison centre.

Take this leaflet and the rest of the remaining Sinutab Nasal Spray with you so the doctor will know what you have taken.

### **If you forget to use Sinutab Nasal Spray**

Do not use a double dose to make up for forgotten individual doses.

## **4. Possible side effects**

Sinutab Nasal Spray can have side effects.


Not all side effects reported for Sinutab Nasal Spray are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Sinutab Nasal Spray, please consult your health care provider for advice.

If any of the following happens, stop using Sinutab Nasal Spray and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;
- rash, hives or itching;
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to Sinutab Nasal Spray. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you

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notice any of the following:

- changes in the way your heart beats.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

*Less frequent side effects:*

- burning sensation in your nose or throat;
- irritation or dryness of your nose.

*Side effects with an unknown frequency:*

- visual disturbance;
- difficulty sleeping or sleepiness;
- nausea;
- headache;
- sneezing.


If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

### **Reporting of side effects**

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reactions Reporting Form**”, found online under SAHPRA’s publications: <http://www.sahpra.org.za/Publications/Index/8>.

By reporting side effects, you can help provide more information on the safety of Sinutab Nasal Spray.

## **5. How to store Sinutab Nasal Spray**

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- Store at or below 25 °C.
- Store in a cool place.
- Protect from light and keep container tightly closed.
- Store all medicines out of reach of children.
- Do not use after the expiry date printed on the bottle / carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

## 6. Contents of the pack and other information

### What Sinutab Nasal Spray contains

Each 1 mL solution contains 1 mg xylometazoline hydrochloride (0,1 % w/v).

The other ingredients are benzalkonium chloride, disodium phosphate dihydrate, disodium edetate (E385), purified water, sorbitol (E420), sodium chloride and sodium dihydrogen phosphate dihydrate.

### What Sinutab Nasal Spray looks like and contents of the pack

A clear, colourless solution.

10 mL or 15 mL bottle with metered-dose spray pump.

### Holder of certificate of registration

Johnson & Johnson (Pty) Ltd.

241 Main Road

Retreat

7945

South Africa

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For further information please contact the Johnson & Johnson Call

Centre at telephone

0860 410032

**This leaflet was last revised in**

13 March 2022

**Registration number**

P/16.1/184

**Access to the corresponding Professional Information**

The latest electronic Professional Information may be found at the SAHPRA website:

<https://www.sahpra.org.za/pi-pil-repository/>.

Alternatively, you may directly contact Johnson & Johnson (Pty) Ltd.:

Consumer Contact Centre:

0860 410032 (South Africa Only)

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