Sinutab Adult Nasal Spray

Summary of Product Characteristics Updated 10-Mar-2020 |

1. Name of the medicinal product

Sinutab Adult Nasal Spray

2. Qualitative and quantitative composition

Xylometazoline Hydrochloride 0.1% w/v

For excipients, see section 6.1

3. Pharmaceutical form

Nasal spray, solution

The spray is a clear, colourless solution.

4. Clinical particulars

4.1 Therapeutic indications

For the treatment of nasal congestion, perennial and allergic rhinitis (including hay fever), sinusitis.

4.2 Posology and method of administration

Adults, children over 12 years and the elderly: One application in each nostril 2 or 3 times daily.

Route of administration: Nasal use

4.3 Contraindications

Known hypersensitivity to Sinutab.

Patients with trans-sphenoidal hypophysectomy or surgery exposing the dura mater.

4.4 Special warnings and precautions for use

a

Patients are advised not to take decongestants for more than seven consecutive days. Sinutab, like other preparations belonging to the same class of active substances, should be used only with caution in patients showing a strong reaction to sympathomimetic agents as evidenced by signs of insomnia, dizziness etc.

Caution is recommended in patients with hypertension, cardiovascular disease, hyperthyroidism, narrow angle glaucoma or diabetes mellitus.

Label warnings and precautions

- Do not exceed the stated dose
- Do not use continuously for more than seven consecutive days. If symptoms persist, consult your doctor
- If you are pregnant or taking other medicines or are under a doctor's care, consult your doctor before using Sinutab
- Not to be used for infants or children under 12 years
- Each Sinutab pack should be used by one person only to prevent any cross infection
- For reasons of hygiene do not use this bottle for more than 28 days after first opening it
- Keep medicines out of the reach of children

Additional leaflet warnings and precautions

- Do not use if you are sensitive to any of the ingredients of Sinutab
- Do not use if you have had recent neurosurgery
- Consult your doctor before using Sinutab if you have heart or circulatory disease
- Some patients who have sensitive nasal passages may feel some local discomfort when applying the product.
- Other side effects such as palpitations, nausea and headache are very rare

4.5 Interaction with other medicinal products and other forms of interaction

b

As for all sympathomimetics, a reinforcement of the systemic effects of xylometazoline by concomitant use of monoamine oxidase inhibitors, tricyclic or tetracyclic antidepressants, cannot be excluded, especially in case of overdose.

4.6 Fertility, pregnancy and lactation

a No foetal toxicity or fertility studies have been carried out in animals. In view of its potential systemic vasoconstrictor effect, it is advisable to take the precaution of not using Sinutab during pregnancy.

Label warning: If you are pregnant or taking any other medicines, or are under a doctor's care, consult him before using Sinutab.

b No evidence of any adverse effect on the breast-fed infant. However, it is not known if xylometazoline is excreted in breast milk, therefore caution should be exercised and Sinutab should be used only on the advice of a doctor whilst breastfeeding.

4.7 Effects on ability to drive and use machines

c None

4.8 Undesirable effects

d The following side effects have occasionally been encountered: A burning sensation in the nose and throat, local irritation, nausea, headache and dryness of the nasal mucosa.

Systemic cardiovascular effects have occurred, and this should be kept in mind when giving Sinutab to people with cardiovascular disease. In isolated cases, systemic allergic reactions and transient visual disturbances.

4.9 Overdose

e In rare instances of accidental poisoning in children, the clinical picture has been marked chiefly by signs such as acceleration and irregularity of the pulse, elevated blood pressure and sometimes consciousness clouding.

There is no specific treatment. Appropriate supportive measures should be initiated.

5. Pharmacological properties

5.1 Pharmacodynamic properties

f Sinutab Adult Nasal Spray is a sympathomimetic agent with marked alphaadrenergic activity, and is intended for use in the nose. It constricts the nasal blood vessels, thereby decongesting the mucosa of the nose and neighbouring regions of the pharynx. This enables patients suffering from colds to breathe more easily through the nose. The effect of Sinutab Adult Nasal Spray begins within a few minutes and lasts for up to 10 hours. Sinutab Adult Nasal Spray is generally well tolerated and does not impair the function of ciliated epithelium.

In a double-blind, saline solution (Otrisal) controlled study in patients with common cold, the decongestant effect of Otrivin was significantly superior ($p<0.0001$) to Otrisal saline solution based on rhinomanometry measurement at 1 hour after administration of the study drugs.

5.2 Pharmacokinetic properties

g Systemic absorption may occur following nasal application of xylometazoline hydrochloride solutions. It is not used systemically.

5.3 Preclinical safety data

There are no findings in the preclinical testing which are of relevance to the prescriber.

6. Pharmaceutical particulars

6.1 List of excipients

Benzalkonium chloride

Disodium phosphate dodecahydrate (Sodium phosphate)

Disodium edetate

Sodium dihydrogen phosphate dihydrate (Sodium acid phosphate) Sodium chloride

Purified water

6.2 Incompatibilities

None.

6.3 Shelf life

Unopened: 24 months

After the container is opened for the first time: 28 days

6.4 Special precautions for storage

Do not store above 25°C

6.5 Nature and contents of container

Bottle:	Low density polyethylene
Cap:	High density polyethylene
Spray valve and capillary:	Low density polyethylene
Carton:	Cardboard

Pack size: 10 ml

6.6 Special precautions for disposal and other handling

Keep all medicines out of the reach of children

7. Marketing authorisation holder

GlaxoSmithKline Consumer Healthcare (UK) Trading Limited,

980 Great West Road

Brentford

Middlesex

TW8 9GS

United Kingdom

8. Marketing authorisation number(s)

PL 44673/0149

9. Date of first authorisation/renewal of the authorisation

1st October 1997/19TH August 2010

10. Date of revision of the text

06/03/2020

Company Contact Details

GlaxoSmithKline Consumer Healthcare

Address
980 Great West Road, Brentford, Middlesex, TW8 9GS

Medical Information e-mail
customer.relations@gsk.com

Medical Information Direct Line
0800 783 8881

Customer Care direct line
0800 783 8881