PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

Sinuforce Tablets

COMPLEMENTARY MEDICINE

Homeopathic Medicines

This unregistered medicine has not been evaluated by the South African Health Products Regulatory Authority for its quality, safety or intended use.

SCHEDULING STATUS

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1 NAME OF THE MEDICINE

A.VOGEL SINUFORCE TABLETS

Homeopathic Complex

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Cinnabar (Cinnabaris)	D8	.....50 mg
Hydrastis canadensis L. *(Hydrastis canadensis)*	D6	.....50 mg
Lemna minor L. *(Lemna minor)*	D4	.....50 mg
Luffa operculata (L.) Cogn. *(Luffa operculata)*	D6	.....50 mg
Potassium dichromate *(Kalium bichromicum)*	D6	.....50 mg

Contains sugar: Lactose .....250 mg

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

White, homogenous, round, biconvex tablets with a triangular stamp, odourless with a slightly sweet taste.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

A.VOGEL SINUFORCE TABLETS, a homeopathic medicine for the supportive treatment of nasal congestion and catarrh. In accordance with homeopathic literature, ingredients address symptoms associated with congestion of the nasal passages, such as headache, postnasal drip, runny nose and mucous build-up.

4.2 Posology and method of administration

Posology

Adults and children over 12 years:

Take 2 tablets 3 – 4 times daily.

In acute/severe cases:

Take 2 tablets, hourly, gradually reducing frequency as improvement occurs, or as directed by a doctor, pharmacist or other healthcare provider.

Special populations

Elderly population:

No dosage adjustment is required for this population.

Paediatric population:

Children 6 – 12 years:

Take 1 tablet 3 – 4 times daily.

In acute/severe cases:

Take 1 tablet hourly, gradually reducing frequency as improvement occurs, or as directed by a doctor, pharmacist or other healthcare provider.

Method of administration

For oral use only.
Allow tablets to dissolve in the mouth.
Take 15 minutes before meals.
Discontinue once improvements occurs.

4.3 Contraindications

- A.VOGEL SINUFORCE TABLETS should not be used in patients who have a hypersensitivity to the active substances or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

- If symptoms last longer than 7 days or are associated with fever (above 38 °C), please consult a doctor, pharmacist or other healthcare provider.

Lactose warning:

- A.VOGEL SINUFORCE TABLETS contains lactose which may have an effect on the glycaemic control of patients with diabetes mellitus. Patients with the rare hereditary conditions of galactose intolerance e.g. galactosaemia, Lapp lactase deficiency, glucose-galactose malabsorption or fructose intolerance should not take A.VOGEL SINUFORCE TABLETS.

4.5 Interaction with other medicines and other forms of interaction

None known.

4.6 Fertility, pregnancy and lactation

Women of childbearing potential/Contraception in males and females

No information available.

Pregnancy

No information available.
Although no specific safety studies on the use of A.VOGEL SINUFORCE TABLETS in pregnancy have been conducted, homeopathic remedies are generally considered to be suitable for use during pregnancy, however, please consult your doctor, pharmacist or healthcare provider for further advice.

Breastfeeding

No information available.
Although no specific safety studies on the use of A.VOGEL SINUFORCE TABLETS in breastfeeding have been conducted, homeopathic remedies are generally considered to be suitable for use during breastfeeding, however, please consult your doctor, pharmacist or healthcare provider for further advice.

Fertility

No effect on fertility expected.

4.7 Effects on ability to drive and use machines

A.VOGEL SINUFORCE TABLETS should have no effect on mental and/or physical ability to perform or execute tasks or activities requiring mental alertness, judgment and/or sound coordination and vision.

4.8 Undesirable effects

If symptoms of hypersensitivity occur e.g. rash, urticaria or angioedema of the skin, discontinue use of product, and contact a healthcare professional immediately.

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 Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8

4.9 Overdose

In overdose, side effects can be precipitated and/or be of increased severity (see section 4.8).
Treatment of overdose should be symptomatic and supportive.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Homeopathy D33.2
Has traditionally been used according to homeopathic principles.

5.2 Pharmacokinetic properties

No information available.

5.3 Preclinical safety data

No information available.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose
Magnesium stearate
Pregelatinised starch

Contains sugar: Lactose ..... 250 mg

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store at or below 25 °C.
Protect from light.
Store in the original package/container.

6.5 Nature and contents of container

Amber glass bottles (type III glass), closed with pilfer proof screw caps fitted with a polyethylene liner.

Pack size: 120 tablets

6.6 Special precautions for disposal of a used medicine or waste materials derived from such medicine and other handling of the product

No special requirements.

7 THE HOLDER OF THE CERTIFICATE OF REGISTRATION

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8 REGISTRATION NUMBER(S)/REFERENCE NUMBER

Listing number: 134578

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

To be allocated.

10 DATE OF REVISION OF TEXT

July 2021