PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

Helix Slim

HOMEOPATHIC 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 HELIX SLIM (oral drops)
Helianthus tuberosus L.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml contains:
Helianthus tuberosus L. *(Helianthus tuberosus)* Mother Tincture ..... 1 ml
[HAB 2A: 53 % *v/v* alcohol]

Sugar free.

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Yellow-brown to red-brown liquid with an aromatic odour and taste.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

A.VOGEL HELIX SLIM assists with weight management by regulating blood sugar, appetite and metabolism, and addressing water retention.

This product may assist with weight loss when used with increased physical activity and an energy reduced diet in healthy individuals.

4.2 Posology and method of administration

Posology

Adults and children over 12 years:
Take 15 drops 3 times daily continuously for at least 8 weeks.
For maintenance:
Take 15 drops daily before the main meal.

Special populations

Elderly population:
No dosage adjustment is required for this population.

Paediatric population:
This product is not indicated in patients younger than 12 years.

Method of administration

For oral use only.
Take drops on the tongue, or directly under the tongue, or in a teaspoon of water.
Take 15 minutes before meals.
Do not use continuously for more than 2 months without consulting a registered healthcare provider.
Use continuously for 8 weeks with increased physical activity and an energy reduced diet in healthy individuals to assist with an efficient, healthy weight loss program.

4.3 Contraindications

- A.VOGEL HELIX SLIM 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

- A.VOGEL HELIX SLIM contains alcohol and should be used with caution by individuals with a sensitivity or intolerance to alcohol.

This product is not intended to treat obesity.

Paediatric population

- A.VOGEL HELIX SLIM, (due to its alcohol content) may impact sensitive individuals during daily activities such as learning ability, physical activities, or affect appetite or sleep patterns.
- This product is not indicated in patients younger than 12 years.

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.
The use of A.VOGEL HELIX SLIM is not recommended during pregnancy.
Slimming/weight loss during pregnancy should be undertaken under the guidance of a medical professional.

Breastfeeding

No information available.
The use of A.VOGEL HELIX SLIM is not recommended during breastfeeding.
Slimming/weight loss during breastfeeding should be undertaken under the guidance of a medical professional.

Fertility

Fertility studies have not been performed.
No effect on fertility is expected.

4.7 Effects on ability to drive and use machines

A.VOGEL HELIX SLIM, (due to its alcohol content) may have an effect on mental and/or physical abilities to perform or execute tasks or activities requiring mental alertness, judgment and/or sound coordination and vision in sensitive individuals.

4.8 Undesirable effects

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

Ethanol

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

60 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

Packed in an amber type III glass bottle, with plastic dropper (LDPE) and screw cap (HDPE) with tamper evident seal.

Pack size: 50 ml

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

U 905 (Act 101/1965)

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

To be allocated.

10 DATE OF REVISION OF TEXT

October 2021