PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

MENOPAUSE FORMULA

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 MENOPAUSE FORMULA (oral drops)
Homeopathic Complex

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml contains:

Cimicifuga racemosa (L.) Nutt. (Cimicifuga)	D6 .....0,17 ml
Lachesis species *(Lachesis muta)*	D10 .....0,17 ml
from: *Lachesis melanocephala* Solórzano et Cerdas, *Lachesis stenophrys* Cope, or *Lachesis muta* (L.)	
Sanguinaria canadensis L. *(Sanguinaria canadensis)*	D6 .....0,17 ml
Sepia officinalis L. (Common cuttlefish)	D12 .....0,17 ml
Strychnos ignatii Bergius *(Ignatia amara)*	D6 .....0,17 ml
Vitex agnus-castus L. *(Agnus castus)*	D2 .....0,17 ml

Contains more than 50 % *v/v* alcohol.

Sugar free.

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Clear, colourless to slightly yellow liquid with an aromatic odour and taste.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

A.VOGEL MENOPAUSE FORMULA is a homeopathic medicine which assists with the acute treatment and symptomatic support of symptoms associated with menopause, such as headaches, sleep problems, low libido, hot flushes, as well as mood changes such as anxiety, depression and irritability.

4.2 Posology and method of administration

Posology

Adults (18 years and over):
Take 10 drops 4 times daily.
In acute/severe cases:
Take 10 drops 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:
This product is not indicated in patients younger than 18 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.
Discontinue once improvement occurs.

4.3 Contraindications

- A.VOGEL MENOPAUSE FORMULA 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 Menopause FORMULA contains alcohol and should be used with caution by individuals with a sensitivity or intolerance to alcohol.

If symptoms worsen or do not improve after 30 days during the use of A.VOGEL Menopause FORMULA, a doctor, pharmacist or other healthcare provider should be consulted.

A.VOGEL MENOPAUSE FORMULA contains small quantities of *Vitex agnus-castus* L. (0,17 ml of a homeopathic dilution of 1:100 [10-2] / 1 ml product). Vitex agnus-castus L., in substantially larger doses, should be used with caution and/or under medical supervision when co-administering the following medicines:

- hormone replacement therapy
- oral contraceptives
- progestogens

No interactions are expected with the dosages recommended for A.VOGEL MENOPAUSE FORMULA.
(Bone & Mills, 2013)

Paediatric population

- A.VOGEL MENOPAUSE FORMULA, (due to its alcohol content) may impact sensitive individuals during daily activities such as learning ability, physical activities, or affect appetite or sleep patterns.

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.

Interactions: refer to section 4.4.

Pregnancy

No information available.
Although no specific safety studies on the use of A.VOGEL MENOPAUSE FORMULA in pregnancy have been conducted, the use of A.VOGEL MENOPAUSE FORMULA is not recommended in pregnancy.

Breastfeeding

No information available.
Although no specific safety studies on the use of A.VOGEL MENOPAUSE FORMULA in lactation have been conducted, the use of A.VOGEL MENOPAUSE FORMULA is not recommended in lactation.

Fertility

No effect on fertility is expected.

4.7 Effects on ability to drive and use machines

A.VOGEL MENOPAUSE FORMULA, (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 contract 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

Contains more than 50 % *v/v* alcohol.

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: 30 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 643 (Act 101/1965)

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

To be allocated.

10 DATE OF REVISION OF TEXT

July 2021