PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

Concentration Formula

COMPLEMENTARY MEDICINE

Homeopathic Medicines

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

SCHEDULING STATUS

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1 NAME OF THE MEDICINE

A.VOGEL CONCENTRATION FORMULA (oral drops)
Homeopathic Complex

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml contains:

Asarum europaeum L. (*Asarum europaeum*)	D6	0,09 ml
Avena sativa L. (*Avena sativa*) Mother Tincture [HAB 1A]		0,09 ml
Cypripedium parviflorum Salisb. L. var. *pubescens* (Willd.) O.W. Knight (*Cypripedium pubescens*)	D4	0,09 ml
Delphinium staphisagria L. (Staphisagria)	D6	0,09 ml
Ginkgo biloba L. (*Ginkgo biloba*)	D3	0,09 ml
Helleborus niger L. (*Helleborus niger*)	D6	0,09 ml
Metallic zinc (*Zincum metallicum*)	D12	0,09 ml
Semecarpus anacardium L. (*Anacardium orientale*)	D6	0,09 ml
Vanilla planifolia Jacks. (*Vanilla aromatica*)	D12	0,09 ml
Veratrum album L. (*Veratrum album*)	D6	0,09 ml
Vinca minor L. (*Vinca minor*) Mother Tincture [HAB 2A]		0,09 ml

Contains approximately 50 % *v/v* alcohol.
Sugar free.

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Clear, yellow liquid with an aromatic odour and taste.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

A.VOGEL CONCENTRATION FORMULA is a homeopathic medicine for the supportive treatment of poor concentration and memory. Ingredients address mental and physical overactivity and restlessness, distraction, daydreaming and poor memory recall as well as mental fatigue and associated anxiety.

4.2 Posology and method of administration

Posology

Adults and children over 12 years:
Take 10 drops 4 times daily.

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

Paediatric population:
Children 6 – 12 years:
Take 5 drops 4 times daily.

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 CONCENTRATION 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 CONCENTRATION 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 8 weeks during the use of A.VOGEL CONCENTRAION FORMULA, a doctor, pharmacist or other healthcare provider should be consulted.

Paediatric population

- A.VOGEL CONCENTRATION 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.

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

Breastfeeding
No information available.
Although no specific safety studies on the use of A.VOGEL CONCENTRATION FORMULA in breastfeeding have been conducted, homeopathic remedies are generally considered to be suitable for use during breastfeeding, however please consult a 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 CONCENTRATION 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 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

Contains approximately 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 597 (Act 101/1965)

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
To be allocated.

10 DATE OF REVISION OF TEXT
August 2021