PROFESSIONAL INFORMATION FOR MEDICINES **FOR HUMAN USE**



A.Vogel Circulation 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

NAME OF THE MEDICINE

A.VOGEL CIRCULATION FORMULA (oral drops)

Homeopathic Complex

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml contains:

Ammi visnaga L. Lam. (Ammi visnaga) Mother Tincture		0,14 ml
[HAB 4A]		
Carbo vegetabilis (Carbo vegetabilis)	D12	0,14 ml
Claviceps purpurea (Fr.) Tul. (Secale cornutum)	D6	0,14 ml
Ginkgo biloba L. (Ginkgo biloba)	D2	0,14 ml
Hypericum perforatum L./Hypericum perforatum		
L. ex Herba (Hypericum perforatum)	D6	0,14 ml
Selenicereus grandiflorus (L.) Britton et Rose (Cactus grandiflorus)	D1	0,14 ml
Veratrum album L. (Veratrum album)	D4	0,14 ml

Contains more than 50 % v/v alcohol. Sugar free.

For full list of excipients, see section 6.1.

PHARMACEUTICAL FORM

Clear, light yellow liquid with an aromatic odour and taste.

CLINICAL PARTICULARS

4.1 Therapeutic indications

A.VOGEL CIRCULATION FORMULA is a homeopathic medicine for the supportive treatment of poor peripheral circulation. Ingredients address spasm of smooth muscles in vessel walls and improve peripheral circulation. Specifically indicated for cold, pale, blue and numb extremities (e.g. Raynaud's phenomenon) or stagnation of blood flow and swelling or heaviness linked to poor circulation.

4.2 Posology and method of administration Posology

Adults and children over 12 years:

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

Special populations Elderly population:

No dosage adjustment is required for this population.

Paediatric population:

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

Children 2 - 6 years:

Take 2 drops 4 times daily.

In acute/severe cases: Take the relevant number of drops, as specified above for the child's age category, 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.

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 CIRCULATION FORMULA should not be used in patients who have a hypersensitivity to the active substances or to any of the excipients listed in

4.4 Special warnings and precautions for use

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

A.VOGEL CIRCULATION FORMULA contains very small quantities of *Hypericum perforatum* L., St John's Wort, (0,14 ml of a homeopathic dilution of 1:1 000 000 [10-6] thereof / 1 ml product) and in substantially larger doses Hypericum perforatum L. is contraindicated with:

- Antiplatelets and anticoagulants, e.g., warfarin, phenprocoumon Calcium channel antagonists, e.g., nifedipine, verapamil
- Dinoxin
- Finasteride
- HIV non-nucleoside transcriptase inhibitors, e.g., nevirapine
- HIV protease inhibitors, e.g., indinavir
- Immunosuppressants, e.g., cyclosporin, tacrolimus
- Methadone
- Oncology chemotherapeutics, e.g., irinotecan, imatinib

Use with caution and under medical supervision. No interactions are expected. (Bone and Mills, 2013)

Hypericum perforatum L., St John's Wort, in substantially larger doses, should be used with caution and under medical supervision when co-administering the following medicine, which is not expected to be necessary under the recommended dosages for A.VOGEL CIRCULATION FORMULA:

- Amitriptyline
- Anticonvulsants, e.g., carbamazepine, mephenytoin, phenobarbitone, phenytoin
- Antihistamines, e.g., fexofenadine
- Antiplatelets and anticoagulants, e.g., clopidogrel
- Benzodiazepines, e.g., alprazolam, midazolam, quazepam
- Hypoglycaemic agents, e.g., gliclazide, tolbutamide
- Ivabradine
- Methylphenidate
- Omeorazole
- Oral contraceptives
- Oxvcodone
- SSRIs, e.g., paroxetine, trazodone, sertraline and other serotonergic agents, e.g., nefazodone, venlafaxine
- Statins, e.g., simvastatin
- Talinolol
- Theophylline
- Voriconazole
- Zolpidem

(Bone and Mills, 2013)

Paediatric population

· A.VOGEL CIRCULATION 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 CIRCULATION FORMULA 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 CIRCULATION FORMULA 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 CIRCULATION 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 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 892 (Act 101/1965)

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

To be allocated.

10 DATE OF REVISION OF TEXT

July 2021

14404/PI.07/2021