PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

Anti-Toxin 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 ANTI-TOXIN FORMULA (oral drops)
Homeopathic Complex

2 QUALITIVE AND QUANTITIVE COMPOSITION

Each 1 ml contains:

Allium sativum L. *(Allium sativum)*	D6 .....0,08 ml
Aluminium oxide (Alumina)	D12 .....0,08 ml
Berberis vulgaris L. *(Berberis vulgaris)*	D3 .....0,08 ml
Hedera helix L. *(Hedera helix)*	D3 .....0,08 ml
Lophophytum leandri Eichler *(Flor de piedra)*	D6 .....0,08 ml
Lycopodium clavatum L. (Lycopodium)	D6 .....0,08 ml
Magnesium carbononate *(Magnesium carbonicum)*	D12 .....0,08 ml
Mandragora e radice siccata species *(Mandragora officinarum)* from: *Mandragora officinarum* L. and *Mandragora autumnalis* Bertol.	D6 .....0,08 ml
Okoubaka aubrevillei Pellegr. et Normand *(Okoubaka aubrevillei)*	D3 .....0,08 ml
Phytolacca americana L. *(Phytolacca decandra)*	D3 .....0,08 ml
Tilia species *(Tilia europaea)* from: *Tilia cordata* Mill., *Tilia platiphyllos* Scop., *Tilia x vulgaris* Hayne, separately or as a mixture	D3 .....0,08 ml
Urtica dioica L. *(Urtica dioica)* Mother Tincture [HAB 2A]	.....0,08 ml

Contains more than 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 ANTI-TOXIN FORMULA is a homeopathic medicine to support the body's detoxification process after exposure to toxins (bacterial, viral, metals, poisons, chemicals). Ingredients included support a wide variety of detoxification organs including: digestive tract, liver, gallbladder, kidneys, lymphatic system, and skin.

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.
Use for 6 weeks, repeat up to three times per year if subsequent exposure risk is high.

4.3 Contraindications

- A.VOGEL ANTI-TOXIN 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 ANTI-TOXIN FORMULA contains alcohol and should be used with caution by individuals with a sensitivity or intolerance to alcohol.
- For acute poisoning or toxic reactions see a doctor immediately or contact the nearest hospital or poison control centre.

Paediatric population

- A.VOGEL ANTI-TOXIN 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 ANTI-TOXIN FORMULA in pregnancy have been conducted, homeopathic remedies are generally considered to be suitable for use during pregnancy, however detoxification protocols are generally not recommended during pregnancy, 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 ANTI-TOXIN FORMULA in breastfeeding have been conducted, homeopathic remedies are generally considered to be suitable for use during breastfeeding, however detoxification protocols are generally not recommended during breastfeeding, 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

It is not always possible to predict to what extent A.VOGEL ANTI-TOXIN FORMULA may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which A.VOGEL ANTI-TOXIN FORMULA affects them.

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 over dosage 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 in a cool, dry place.
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
PharmaForce (Pty) Ltd.
130 – 16th Road
Midrand, 1685
South Africa
+27 (0)10 020 2520
www.avogel.co.za

Manufacturer:
CoMED Health (Pty) Ltd.
313 Kuit Street
Pretoria, 0184
South Africa

8 REGISTRATION NUMBER(S)/REFERENCE NUMBER
U 583 (Act 101/1965)

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

10 DATE OF REVISION OF TEXT
November 2020