PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

BREAKOUT 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 BREAKOUT FORMULA (oral drops)
Homeopathic Complex

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml contains:

Amorphous selenium *(Selenium metallicum)*	D12 .....0,08 ml
Arctium species *(Arctium lappa)* Mother Tincture from: *Arctium lappa* L., *Arctium minus* (Hill) Bernh. and *Arctium tormentosum* Mill., separately or as a mixture [HAB 2A]	.....0,08 ml
Aristolochia clematitis L. (Aristolochia)	D30 .....0,08 ml
Centella asiatica (L.) Urb. *(Hydrocotyle asiatica)*	D6 .....0,08 ml
Cetraria islandica (L.) Acharius s.l. *(Cetraria islandica)*	D6 .....0,08 ml
Delphinium staphisagria L. (Staphisagria)	D6 .....0,08 ml
Hepar sulfuris (Hepar sulphur)	D12 .....0,08 ml
Juglans regia L. *(Juglans regia)*	D6 .....0,08 ml
Lycopodium clavatum L. (Lycopodium)	D6 .....0,08 ml
Potassium bromide *(Kalium bromatum)*	D12 .....0,08 ml
Sepia officinalis L. (Common cuttlefish)	D12 .....0,08 ml
Sulfur iodide *(Sulfur iodatum)*	D12 .....0,08 ml
Viola tricolor L. *(Viola tricolor)* Mother Tincture [HAB 2A]	.....0,08 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 BREAKOUT FORMULA is a homeopathic medicine for the supportive treatment of pimples and problem skin in adolescents and adults. In accordance with homeopathic literature ingredients assist the body to address hormones and toxins as contributing factors to the development of pimples, black heads, white heads associated facial flushing and oily 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 10 - 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 BREAKOUT 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 BREAKOUT 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 12 weeks during the use of A.VOGEL BREAKOUT FORMULA, a doctor, pharmacist or other healthcare provider should be consulted.

Paediatric population

- A.VOGEL BREAKOUT 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 BREAKOUT 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 BREAKOUT 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 is expected.

4.7 Effects on ability to drive and use machines

A.VOGEL BREAKOUT 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 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 573 (Act 101/1965)

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

10 DATE OF REVISION OF TEXT
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