

PROFESSIONAL INFORMATION FOR MEDICINES
FOR HUMAN USE



Bladder Irritation 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 BLADDER IRRITATION FORMULA (oral drops)
Homeopathic Complex

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml contains:

<i>Berberis vulgaris</i> L. (<i>Berberis vulgaris</i>)	D3.....0,125 ml
<i>Chimaphila umbellata</i> (L.) W.P.C Barton (<i>Chimaphila umbellata</i>)	D2.....0,125 ml
<i>Chondrodendron</i> Ruiz et Pav. (<i>Pareira brava</i>)	D2.....0,125 ml
<i>Helleborus niger</i> L. (<i>Helleborus niger</i>)	D3.....0,125 ml
<i>Lamium album</i> L. (<i>Lamium album</i>)	D1.....0,125 ml
<i>Lespedeza capitata</i> Michx. (<i>Lespedeza capitata</i>)	D3.....0,125 ml
<i>Solidago virgaurea</i> L. (<i>Solidago virgaurea</i>)	D1.....0,125 ml
<i>Viola tricolor</i> L. (<i>Viola tricolor</i>)	D3.....0,125 ml

Contains more than 60 % v/v alcohol.
Sugar free.

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

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

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

A.VOGEL BLADDER IRRITATION FORMULA is a homeopathic medicine for the supportive treatment of irritable bladder conditions. In accordance with homeopathic literature, ingredients address frequent, uncomfortable or urgent urination, an overactive bladder and urinary discomfort associated with bladder disorders.

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 provider.

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 BLADDER IRRITATION 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 BLADDER IRRITATION FORMULA contains alcohol and should be used with caution by individuals with a sensitivity or intolerance to alcohol.
- If long standing symptoms worsen or do not improve after 2 weeks, a doctor, pharmacist or other healthcare provider should be consulted.
- Recent onset of intense, acute symptoms should be assessed by a healthcare professional.

Paediatric population

- A.VOGEL BLADDER IRRITATION 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 BLADDER IRRITATION 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 BLADDER IRRITATION 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

Fertility studies have not been performed.

No effect on fertility expected.

4.7 Effects on ability to drive and use machines

A.VOGEL BLADDER IRRITATION 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 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 60 % 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 875 (Act 101/1965)

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

To be allocated.

10 DATE OF REVISION OF TEXT

October 2021

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