

PROFESSIONAL INFORMATION FOR MEDICINES  
FOR HUMAN USE



# Rheumatism 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 RHEUMATISM FORMULA** (oral drops)  
Homeopathic Complex

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml contains:

<i>Berberis vulgaris</i> L. ( <i>Berberis vulgaris</i> )	D6	0,1 ml
<i>Bryonia species (Bryonia alba)</i>	D3	0,1 ml
from: <i>Bryonia cretica</i> L. subsp. <i>Dioica</i> (Jacq.) Tutin or <i>Bryonia alba</i> L.		
<i>Cimicifuga racemosa</i> (L.) Nutt. ( <i>Cimicifuga</i> )	D6	0,1 ml
<i>Helonias viridis</i> Ker Gawl. ( <i>Veratrum viride</i> )	D6	0,1 ml
<i>Kalmia latifolia</i> L. ( <i>Kalmia latifolia</i> )	D6	0,1 ml
<i>Ledum palustre</i> L. ( <i>Ledum palustre</i> )	D3	0,1 ml
<i>Phytolacca americana</i> L. ( <i>Phytolacca decandra</i> )	D6	0,1 ml
<i>Rhus toxicodendron</i> L. ( <i>Rhus toxicodendron</i> )	D6	0,1 ml
<i>Ruta graveolens</i> L. ( <i>Ruta graveolens</i> )	D6	0,1 ml
<i>Solidago virgaurea</i> L. ( <i>Solidago virgaurea</i> )	D3	0,1 ml

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

For full list of excipients, see section 6.1.

### 3 PHARMACEUTICAL FORM

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

### 4 CLINICAL PARTICULARS

#### 4.1 Therapeutic indications

A.VOGEL RHEUMATISM FORMULA is a homeopathic medicine for the supportive treatment of rheumatism. In accordance with homeopathic literature, ingredients address symptoms such as mild to moderate pain and discomfort of red and swollen soft tissue within the musculoskeletal system such as muscles, tendons, fibrous tissue as well as nerve pain and rheumatism.

#### 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 RHEUMATISM 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 RHEUMATISM FORMULA contains alcohol and should be used with caution by individuals with a sensitivity or intolerance to alcohol.

### Paediatric population

• A.VOGEL RHEUMATISM 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 RHEUMATISM FORMULA in pregnancy have been conducted, homeopathic remedies are generally considered to be suitable for use during pregnancy, however please consult a doctor, pharmacist or healthcare provider for further advice.

#### Breastfeeding

No information available.

Although no specific safety studies on the use of A.VOGEL RHEUMATISM 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

It is not always possible to predict to what extent A.VOGEL RHEUMATISM 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 RHEUMATISM 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 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 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**

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**8 REGISTRATION NUMBER(S)/REFERENCE NUMBER**

U 653 (Act 101/1965)

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

To be allocated.

**10 DATE OF REVISION OF TEXT**

September 2020

14429/PI.09/2020