PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

Arthritis Formula

COMPLEMENTARY MEDICINE
Homeopathic Medicines
This unregistered medicine has not been evaluated by the SAHPRA for its safety, quality or intended use.

SCHEDULING STATUS:
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1 NAME OF THE MEDICINE
A.VOGEL ARTHRITIS FORMULA (oral drops)
Homeopathic Complex

2 QUALITIVE AND QUANTITIVE COMPOSITION
Each 1 ml contains:
Aranea diadema (Papal-cross spider) D12....0,125 ml
Cimicifuga racemosa (Black cohosh) D6.....0,125 ml
Euphrasia (Eyebright) D6.....0,125 ml
Hedera helix (Common ivy) D5.....0,125 ml
Ledum palustre (Marsh tea) D6.....0,125 ml
Rhododendron (Snow rose) D6.....0,125 ml
Symphytum officinale (Knitbone) D4.....0,125 ml
Viscum album (Mistletoe) D6..... .....0,125 ml

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

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM
Clear, colourless liquid with an aromatic odour and taste.

4 CLINICAL PARTICULARS
4.1 Therapeutic indications
- A.Vogel Arthritis Formula is a homeopathic medicine which assists with the treatment of arthritis and associated symptoms such as pain, inflammation and stiffness of joints including the hands and feet with specific aggravation from exposure to cold and wet weather.

4.2 Posology and method of administration
Posology

Adults and children over 12 years:
Take 10 drops on the tongue, or directly under the tongue, or in a teaspoon of water 4 times daily 15 minutes before meals. Discontinue once improvement occurs.
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 on the tongue, or directly under the tongue, or in a teaspoon of water 4 times daily 15 minutes before meals.
Children 2-6 years: Take 2 drops on the tongue, or directly under the tongue, or in a teaspoon of water 4 times daily 15 minutes before meals.
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.

4.3 Contraindications
- A.Vogel Arthritis Formula should not be used in patients who have a hypersensitivity to the active substance or to any of the excipients.

4.4 Special warnings and precautions for use
- A.Vogel Arthritis Formula contains alcohol and should be used with caution by individuals with a sensitivity or intolerance to alcohol.

Paediatric population
- A.Vogel Arthritis 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 Arthritis Formula in pregnancy have been conducted, homeopathic remedies are generally considered to be suitable for use during pregnancy and breastfeeding, 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 Arthritis Formula in breastfeeding have been conducted, homeopathic remedies are generally considered to be suitable for use during pregnancy and 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 Arthritis 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 professionals 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 Undesirable effects).
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.
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 593 (Act 101/1965)

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

10 DATE OF REVISION OF TEXT
February 2020

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