PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

Prostate 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 PROSTATE FORMULA (oral drops)
Homeopathic Complex

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml contains:

Chimaphila umbellata (L.) W.P.C Barton *(Chimaphila umbellata)*	D3	.....0,14 ml
Clematis recta L. *(Clematis erecta)*	D3	.....0,14 ml
Conium maculatum L. *(Conium maculatum)*	D12	.....0,14 ml
Peumus boldus Molina. *(Boldo fragrans)*	D2	.....0,14 ml
Populus tremuloides Michx *(Populus tremuloides)*	D1	.....0,14 ml
Serenoa repens (W. Bartram) Small *(Sabal serrulata)*	D2	.....0,14 ml
Solidago virgaurea L. *(Solidago virgaurea)*	D1	.....0,14 ml

Contains more than 60 % *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 PROSTATE FORMULA is a homeopathic medicine for the supportive, symptomatic relief of mild disorders of the male lower urinary tract. In accordance with homeopathic literature, ingredients address discomfort and altered urinary patterns in men.

4.2 Posology and method of administration

Posology

Male adults (over 18 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:
Male adolescents 12 - 18 years (Medical supervision required):
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.

This product is not indicated in patients younger than 12 years.

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 PROSTATE 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 PROSTATE FORMULA contains alcohol and should be used with caution by individuals with a sensitivity or intolerance to alcohol.
- Due to *Peumus boldus* content (0,14 ml of a homeopathic dilution of 1:100 [10^{-2}] / 1 ml product) – contains camphor, therefore use with caution in patients with epilepsy or chronic lung conditions. No effect expected.
- For symptoms of acute onset: If symptoms worsen or do not improve after 2 weeks during the use A.VOGEL PROSTATE FORMULA, a doctor, pharmacist or other healthcare provider should be consulted.
- For sub-acute or chronic symptoms: If symptoms worsen or do not improve after 8 weeks during the use A.VOGEL PROSTATE FORMULA, a doctor, pharmacist or other healthcare provider should be consulted.

Paediatric population

- A.VOGEL PROSTATE 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

A.VOGEL PROSTATE FORMULA is not indicated for use in women.
The safety of this product during pregnancy has not been established. In the absence of sufficient data, the use of A.VOGEL PROSTATE FORMULA during pregnancy is not recommended.

Breastfeeding

A.VOGEL PROSTATE FORMULA is not indicated for use in women.
The safety of this product during breastfeeding has not been established. In the absence of sufficient data, the use of A.VOGEL PROSTATE FORMULA during breastfeeding is not recommended.

Fertility

Fertility studies have not been performed, however no negative effect on fertility is expected.

4.7 Effects on ability to drive and use machines

A.VOGEL PROSTATE 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 948 (Act 101/1965)

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

10 DATE OF REVISION OF TEXT
July 2021