PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

Cystoforce

COMPLEMENTARY MEDICINE

Western Herbal Medicine

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 CYSTOFORCE (oral drops)
Western Herbal Medicine

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml contains:

Arctostaphylos uva-ursi (L.) Spreng (Bearberry) ..... 715 mg
[Fresh leaf, 1:4 extract providing dry plant equivalent:
160 - 195 mg herbal drug per ml]

Echinacea purpurea (L.) MOENCH. (Purple cone-flower) ..... 240 mg
[Fresh aerial parts, 1:12 extract providing dry plant equivalent:
20 mg herbal drug per ml]

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

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Clear to opalescent, brown-yellow to brown liquid with an aromatic odour and an aromatic, bitter taste.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

A.VOGEL CYSTOFORCE is a traditional herbal medicinal product used for treatment of bladder discomfort and symptoms of mild recurrent lower urinary tract infections such as burning sensations during urination and/or frequent urination (cystitis) in women.

4.2 Posology and method of administration

Posology

Adults (Women 18 years and over):
Take 15 drops 3 times daily.
In acute/severe cases:
Take 15 drops, up to 5 times a day, gradually reducing frequency as improvement occurs, or as directed by a doctor, pharmacist or other healthcare provider.

This product is not recommended for men, unless under medical supervision (medical advice required).

Special populations
Elderly population:
No dosage adjustment is required for this population.

Paediatric population:
This product is not recommended for patients younger than 18 years, unless under medical supervision (medical advice required).

Method of administration
For oral use only.
Take drops undiluted or diluted in a small volume of water.

4.3 Contraindications

- A.VOGEL CYSTOFORCE should not be used in patients who have a hypersensitivity to the active substances, plants of the *Asteraceae (Compositae)* family or to any of the excipients listed in section 6.1.
- Because of their immunomodulatory activity, *Echinacea* extracts must not be used in cases of progressive systemic disorders (e.g., tuberculosis, sarcoidosis), autoimmune diseases (e.g., collangenoses, multiple sclerosis), immunodeficiencies (e.g., HIV infection, AIDS), immunosuppression (e.g., oncological cytostatic therapy; history of organ or bone marrow transplant), diseases of the white blood cell system (e.g., agranulocytosis, leukaemia) and allergic diathesis (e.g., urticaria, atopic dermatitis, asthma).
- Concomitant use with immunosuppressant medicines.

4.4 Special warnings and precautions for use

- There is a possible risk of anaphylactic reactions in atopic patients. Atopic patients should consult their doctor before using products made of *Echinacea*.
- If complaints of symptoms such as fever, dysuria, spasms, or blood in the urine occur during the use of A.VOGEL CYSTOFORCE, a doctor, pharmacist or other healthcare provider should be consulted.
- If symptoms worsen or do not improve after 7 days during the use of A.VOGEL CYSTOFORCE, a doctor, pharmacist or other healthcare provider should be consulted.
- A.VOGEL CYSTOFORCE contains alcohol and should be used with caution by individuals with a sensitivity or intolerance to alcohol.
- A.VOGEL CYSTOFORCE is not recommended for men, unless under medical supervision (medical advice required).

Paediatric population

- A.VOGEL CYSTOFORCE, (due to its alcohol content) may impact sensitive individuals during daily activities such as learning ability, physical activities, or affect appetite or sleep patterns.
- A.VOGEL CYSTOFORCE is not recommended for patients younger than 18 years, unless under medical supervision (medical advice required).

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
The safety of this product during pregnancy has not been established. In the absence of sufficient data, the use of A.VOGEL CYSTOFORCE during pregnancy is not recommended.

Breastfeeding
The safety of this product during breastfeeding has not been established. In the absence of sufficient data, the use of A.VOGEL CYSTOFORCE during breastfeeding is not recommended.

Fertility
Fertility studies have not been performed.

4.7 Effects on ability to drive and use machines

No adequate studies on the effect on the ability to drive and use machines have been performed.

It is not always possible to predict to what extent A.VOGEL CYSTOFORCE 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 CYSTOFORCE affects them.

A.VOGEL CYSTOFORCE contains alcohol.

4.8 Undesirable effects

Adverse reactions are grouped into the following frequency classifications: Very common (≥ 1/10), common (≥ 1/100 to < 1/10), uncommon (≥ 1/1 000 to < 1/100), rare (≥ 1/10 000 to < 1/1 000), very rare (< 1/10 000), not known (cannot be assessed from the available data)

Tabulated list of adverse reactions

Body System	**Undesirable effect** (Frequency not known)
Gastrointestinal disorders:	Nausea, vomiting and abdominal pain.
Immune system disorders:	Hypersensitivity reactions (rash, urticaria, Stevens-Johnson Syndrome, angioedema of the skin, Quincke oedema, bronchospasm with obstruction, asthma and anaphylactic shock) may occur. *Echinacea* can trigger allergic reactions in atopic patients.

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
None known.
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
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5.2 Pharmacokinetic properties
No information available.

5.3 Preclinical safety data
Tests on reproductive toxicity and carcinogenicity have not been performed with A.VOGEL CYSTOFORCE.

No mutagenic effects of A.VOGEL CYSTOFORCE was detected in Ames' test (with or without metabolic activation).

6 PHARMACEUTICAL PARTICULARS
6.1 List of excipients
Contains more than 50 % *v/v* alcohol.
Purified water.

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
36 months unopened.
Use within 4 months of opening.

6.4 Special precautions for storage
No special storage conditions.
Store at or below 25 °C.
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: 50 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 605 (Act 101/1965)

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

10 DATE OF REVISION OF TEXT
April 2022