Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

A.Vogel Uva-ursi & Echinacea Cystitis oral drops

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 15 drop dose contains:

357.5 mg of tincture from fresh *Arctostaphylos uva-ursi* (L.) Spreng, herba (Bearberry herb) (1:4.0-5.2)
Extraction solvent: Ethanol 43% m/m
and
120 mg of tincture from fresh *Echinacea purpurea* (L.) Moench, herba (Purple Coneflower herb) (1:12-13)
Extraction solvent: Ethanol 57.3% m/m

1 ml is equivalent to 30 drops.

Excipients with known effect:
Each dose (15 drops) contains approximately 213 mg of ethanol (alcohol).

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral drops, solution. (Oral drops)

Clear to opalescent brown-yellow to brown liquid.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

A.Vogel Uva-ursi & Echinacea Cystitis oral drops is a traditional herbal medicinal product used to help relieve minor urinary complaints associated with cystitis in women, such as burning sensation during urination and/or frequent urination, exclusively based on long-standing use.

A.Vogel Uva-ursi & Echinacea Cystitis oral drops is indicated in women aged 18 and over.

4.2 Posology and method of administration

For oral short-term use only.

Adult women: Take 15 drops in a little water 2-5 times daily
Not recommended for children or adolescents under 18 years (see section 4.4 'Special warnings and precautions for use').

Do not take this product for more than 7 days.

If symptoms persist, worsen or do not improve after 4 days, a qualified healthcare professional e.g. a doctor or pharmacist should be consulted.

Due to the nature of the complaint, it is advisable to drink plenty of liquids when treating the symptoms of cystitis.

4.3 Contraindications

Hypersensitivity to the active substance(s), to plants of the Asteraceae (Compositae) family, to Bearberry or to any of the excipients listed in section 6.1.

Because of their immuno-modulatory activity, Echinacea extracts must not be used in cases of progressive systemic disorders (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) and diseases of the white blood cell system (e.g.: agranulocytosis, leukemias).

Patients with:

- Impaired renal function
- Oedema secondary to heart failure or impaired renal function
- Current or previous kidney disorders
- Conditions where a reduced fluid intake is recommended e.g. severe cardiac or renal disease

Pregnancy and lactation (see section 4.6 'Fertility, pregnancy and lactation').

4.4 Special warnings and precautions for use

Do not exceed stated dose.

The use in children and adolescents under 18 years is not recommended because of concerns requiring medical advice.

If complaints or symptoms such as fever, spasms, acute urinary retention, dysuria, urinary incontinence, or blood in urine occur during the use of this product, a qualified healthcare professional e.g. a doctor or pharmacist should be consulted.

There is a possible risk of anaphylactic reactions in atopic patients. Atopic patients should consult their doctor before using Echinacea.

If symptoms persist, worsen or do not improve after 4 days, a qualified healthcare professional e.g. a doctor or pharmacist should be consulted.

The use in men is not recommended because of concerns requiring medical supervision.

Uvae ursi folium may cause a greenish-brown colouration of the urine.

This traditional herbal medicine contains 213 mg of alcohol (ethanol) in each 15 drop dose.
The amount in 15 drops of this medicine is equivalent to less than 6 ml beer or 3 ml wine.
The small amount of alcohol in this medicine will not have any noticeable effects.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

Not to be used concomitantly with immunosuppressant medications.

Contains alcohol and should be avoided in patients taking other medicines known to interact with alcohol (e.g. Metronidazole).

4.6 Fertility, pregnancy and lactation

The safety of this product during pregnancy and lactation has not been established, therefore this product should not be used during pregnancy and lactation (see section 5.3 'Preclinical safety data').

Studies on fertility have not been carried out.

4.7 Effects on ability to drive and use machines

No studies on the effect on the ability to drive and use machines have been performed. This product contains alcohol (See Section 4.4 for details of alcohol content).

4.8 Undesirable effects

Gastrointestinal symptoms (e.g. nausea, vomiting and stomach ache have been reported).

Hypersensitive reactions (rash, urticaria, Stevens-Johnson Syndrome, angioedema of the skin, Quincke edema, bronchospasm with obstruction, asthma and anaphylactic shock) may occur.

Echinacea can trigger allergic reactions in atopic patients. Association with autoimmune diseases (multiple sclerosis, erythema nodosum, immunothrombocytopenia, Evans Syndrome, Sjorgen Syndrome with renal tubular dysfunction) has been reported.

The alkylamides present in A.Vogel Uva-ursi & Echinacea Cystitis oral drops can affect the buccal mucosa which may be experienced as tingling, irritation and numbness in the mouth, this is however considered to be part of the clinical effect.

The frequency of adverse reactions is not known.

If other adverse reactions not mentioned above occur, a qualified healthcare professional e.g. a doctor or pharmacist should be consulted.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system:
HPRA Pharmacovigilance
Website: www.hpra.ie

4.9 Overdose

No case of overdose has been reported.
Overdose of this product may result in alcohol intoxication: the amount of alcohol in a full bottle (21.3 g in 50 ml: equivalent to 2 glasses of wine) may result in intoxication and should be treated accordingly.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended

5.2 Pharmacokinetic properties

Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended

5.3 Preclinical safety data

Reverse mutation assays (Ames test) conducted with Uva-ursi & Echinacea on bacteria indicated that the product was not mutagenic in *Salmonella typhimurium* (strains TA 1535, TA 1537, TA 100 and TA 102) mutation assays with or without metabolic activation. The product was positive in TA98 with or without metabolic activation however this was considered due to the presence of quercetin.

Tests on reproductive toxicity and carcinogenicity have not been performed.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

None

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years

Use within 4 months of opening.

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Amber glass bottles (Type III conforming to Ph.Eur. standards) with a polyolefine two part dropper/dispenser and a polypropylene cap.

Pack size: 50 ml

Amber glass bottles (Type III conforming to Ph.Eur. standards) with a two part dropper (low density polyethylene)/child-resistant closure (high density polyethylene/high density polyethylene).

Pack size: 50 ml

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

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Unit 3d
Killeen Road
Dublin 10
D10 TY20
Ireland

7 REGISTRATION HOLDER

A. Vogel Ireland Limited
48 Upper Drumcondra Road
Dublin 9
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8 MARKETING AUTHORISATION NUMBER

TR2309/021/001

8 REGISTRATION NUMBER(S)

TR2309/021/001

9 DATE OF FIRST REGISTRATION/RENEWAL OF THE REGISTRATION

Date of first authorisation: 26th June 2020

10 DATE OF REVISION OF THE TEXT

November 2023