

PROFESSIONAL INFORMATION FOR MEDICINES
FOR HUMAN USE



Menstruation 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 MENSTRUATION FORMULA (oral drops)

Homeopathic Complex

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml contains:

<i>Aristolochia clematitis</i> (Birthwort) D30.....	0,14 ml
<i>Cimicifuga racemosa</i> (Black cohosh) D6.....	0,14 ml
<i>Cyclamen europaeum</i> (Cyclamen) D6.....	0,14 ml
<i>Hydrastis canadensis</i> (Goldenseal) D6.....	0,14 ml
<i>Lachesis</i> (Bushmaster) D10.....	0,14 ml
<i>Potentilla erecta</i> (Tormentil) D1.....	0,14 ml
<i>Pulsatilla pratensis</i> (Pasque flower) D6.....	0,14 ml

Contains more than 50 % v/v alcohol.

Sugar free.

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

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

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

A.Vogel Menstruation Formula is a homeopathic medicine which assists with the treatment of painful, irregular or heavy periods, abnormal menstrual flow, premenstrual tension and menstrual cycle irregularities.

4.2 Posology and method of administration

Posology

Adults and children over 12 years:

For symptomatic relief during the premenstrual stage (luteal phase) and menstrual period:

Take 10 drops on the tongue every hour in acute cases, reduce dosage to 4 times daily as improvement occurs and discontinue use when recovery is complete.

To assist with regulating the menstrual cycle:

Take 10 drops on the tongue twice daily for 3 menstrual cycles or 90 days.

Special populations

Paediatric population

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

Method of administration

For oral use.

4.3 Contraindications

A.Vogel Menstruation Formula should not be used in patients who have a hypersensitivity to the active substances or to any of the excipients.

4.4 Special warnings and precautions for use

A.Vogel Menstruation Formula contains alcohol and should be used with caution by individuals with a sensitivity or intolerance to alcohol.

4.5 Interaction with other medicines and other forms of interaction

Not recommended for use in conjunction with contraceptives of hormonal origin (oral contraceptive pill, intrauterine devices, or contraceptive injections).

4.6 Fertility, pregnancy and lactation

Women of childbearing potential/Contraception in males and females

No information available.

Pregnancy

No information available.

Not recommended during pregnancy.

Breastfeeding

No information available.

Although no specific safety studies on the use of A.Vogel Menstruation Formula in breastfeeding have been conducted, 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 Menstruation 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

PharmaForce (Pty) Ltd.
130 – 16th Road
Midrand, 1685
South Africa
+27 (0)10 020 2520
www.avogel.co.za

Manufacturer:

CoMED Health (Pty) Ltd.
313 Kuit Street
Pretoria, 0184
South Africa

8 REGISTRATION NUMBER(S)/REFERENCE NUMBER:

U 644 (Act 101/1965)

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

To be allocated.

10 DATE OF REVISION OF TEXT

April 2020

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