

PROFESSIONAL INFORMATION FOR MEDICINES  
FOR HUMAN USE



# Cellulite 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

**S0**

#### 1 NAME OF THE MEDICINE

**A.VOGEL CELLULITE FORMULA** (oral drops)

Homeopathic Complex

#### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml contains:

<i>Aloe ferrox</i> Mill. ( <i>Aloe ferrox</i> )	D6	.....0,09 ml
<i>Cynara scolymus</i> L. ( <i>Cynara scolymus</i> ) Mother Tincture [HAB 3A]		.....0,09 ml
<i>Elymus repens</i> (L.) ( <i>Triticum repens</i> ) Mother Tincture [HAB 3A]		.....0,09 ml
<i>Fucus vesiculosus</i> L. ( <i>Fucus vesiculosus</i> )	D3	.....0,09 ml
<i>Hedera helix</i> L. ( <i>Hedera helix</i> )	D3	.....0,09 ml
<i>Hypericum perforatum</i> L. / <i>Hypericum perforatum</i> L. ex Herba ( <i>Hypericum perforatum</i> ) Mother Tincture [HAB 3A]		.....0,09 ml
<i>Hyssopus officinalis</i> L. ( <i>Hyssopus officinalis</i> )	D3	.....0,09 ml
<i>Ostrea edulis</i> L. ( <i>Calcarea carbonica</i> )	D12	.....0,09 ml
<i>Passiflora incarnata</i> L. ( <i>Passiflora incarnata</i> ) Mother Tincture [HAB 3A]		.....0,09 ml
<i>Verbena officinalis</i> L. ( <i>Verbena officinalis</i> )	D3	.....0,09 ml
<i>Vitis vinifera</i> L. ( <i>Vitis vinifera</i> )	D3	.....0,09 ml

Contains more than 60 % v/v alcohol.

Sugar free.

For full list of excipients, see section 6.1.

#### 3 PHARMACEUTICAL FORM

Yellow-brown, clear liquid with an aromatic odour and taste.

#### 4 CLINICAL PARTICULARS

##### 4.1 Therapeutic indications

A.VOGEL CELLULITE FORMULA is a homeopathic medicine for the supportive treatment of cellulite, management of healthy weight and regulation of appetite. In accordance with homeopathic literature, ingredients promote lymphatic drainage, elimination of excess fluid, improve metabolism and detoxification via the liver and digestive system and address excess appetite.

This product may assist with weight loss when combined with increased physical activity and an energy reduced diet in healthy individuals.

##### 4.2 Posology and method of administration

###### Posology

###### Adults and children over 12 years:

Take 10 drops 4 times daily.

###### Special populations

###### Elderly population:

No dosage adjustment is required for this population.

###### Paediatric population:

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.

Do not use continuously for more than 2 months without consulting a registered healthcare provider.

Use continuously for 8 weeks with increased physical activity and an energy reduced diet in healthy individuals to assist with an efficient, healthy weight loss program.

##### 4.3 Contraindications

• A.VOGEL CELLULITE 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 CELLULITE FORMULA contains alcohol and should be used with caution by individuals with a sensitivity or intolerance to alcohol.

**This product is not intended to treat obesity.**

A.VOGEL CELLULITE FORMULA contains very small quantities of *Hypericum perforatum* L., St John's Wort, (0,09 ml / 1 ml) which, in substantially larger doses, is contraindicated with:

- Antiplatelets and anticoagulants, e.g. warfarin, phenprocoumon
- Calcium channel antagonists, e.g. nifedipine, verapamil
- Digoxin
- Finasteride
- HIV non-nucleoside transcriptase inhibitors, e.g. nevirapine
- HIV protease inhibitors, e.g. indinavir
- Immunosuppressants, e.g. cyclosporin, tacrolimus
- Methadone
- Oncology chemotherapeutics, e.g. irinotecan, imatinib

Use with caution and under medical supervision. No interactions are expected. (Bone and Mills, 2013)

*Hypericum perforatum* L., St John's Wort, in substantially larger doses, should be used with caution and under medical supervision when co-administering the following medicine, which is not expected to be necessary under the recommended dosages for A.VOGEL CELLULITE FORMULA:

- Amitriptyline
- Anticonvulsants, e.g. carbamazepine, mephenytoin, phenobarbitone, phenytoin
- Antihistamines, e.g. fexofenadine
- Antiplatelets and anticoagulants, e.g. clopidogrel
- Benzodiazepines, e.g. alprazolam, midazolam, quazepam
- Hypoglycaemic agents, e.g. gliclazide, tolbutamide
- Ivabradine
- Methylphenidate
- Omeprazole
- Oral contraceptives
- Oxycodone
- SSRIs, e.g. paroxetine, trazodone, sertraline and other serotonergic agents, e.g. nefazodone, venlafaxine
- Statins, e.g. simvastatin
- Talinolol
- Theophylline
- Voriconazole
- Zolpidem

(Bone and Mills, 2013)

Due to *Hyssopus officinalis* content (0,09 ml of a homeopathic dilution of 1:1000 [10<sup>-3</sup>] / 1 ml product) – contains camphor, therefore use with caution in patients with epilepsy or chronic lung conditions. No effect expected.

##### Paediatric population

• A.VOGEL CELLULITE 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.

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

##### 4.5 Interaction with other medicines and other forms of interaction

Refer to section 4.4.

##### 4.6 Fertility, pregnancy and lactation

**Women of childbearing potential/Contraception in males and females**  
No information available.

###### Pregnancy

No information available.

The use of A.VOGEL CELLULITE FORMULA is not recommended during pregnancy. Slimming/weight loss during pregnancy should be undertaken under the guidance of a medical professional.

## Breastfeeding

No information available.

The use of A.VOGEL CELLULITE FORMULA is not recommended during breastfeeding.

Slimming/weight loss during breastfeeding should be undertaken under the guidance of a medical professional. A.VOGEL CELLULITE FORMULA contains very small quantities of *Hypericum perforatum* which should be used with caution in breastfeeding, please consult a doctor, pharmacist or healthcare provider for further advice.

## Fertility

Fertility studies have not been performed.

No effect on fertility expected.

## 4.7 Effects on ability to drive and use machines

A.VOGEL CELLULITE 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

36 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](http://www.avogel.co.za)

## Manufacturer:

CoMED Health (Pty) Ltd.

313 Kuit Street

Pretoria, 0184

South Africa

## 8 REGISTRATION NUMBER(S)/REFERENCE NUMBER

U 886 (Act 101/1965)

## 9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

To be allocated.

## 10 DATE OF REVISION OF TEXT

November 2021

14701/PI.11/2021