PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

URTICALCIN

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 URTICALCIN TABLETS

Homeopathic Complex

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Urtica dioica L. *(Urtica dioica)*	D1 .....10,0 mg
Silicon dioxide (Silicea)	D6 .....2,5 mg
Calcium hydrogen phosphate dihydrate *(Calcarea phosphorica)*	D6 ..... 0,5 mg
Disodium phosphate dodecahydrate *(Natrum phosphoricum)*	D6 ..... 0,5 mg
Ostrea edulis L. *(Calcarea carbonica)*	D4 ..... 0,5 mg

Contains sugar: Lactose ..... 82 mg

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

White, homogenous, biconvex tablets with fine, dark spots and a triangular stamp, with an aromatic odour and a sweet taste.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

A.VOGEL URTICALCIN TABLETS, a homeopathic medicine which assists with the maintenance of healthy calcium levels. Ingredients address healthy absorption and assimilation of calcium and minerals necessary for healthy bones, teeth, hair and nails, and assists the body to manage acidity levels.

4.2 Posology and method of administration

Posology

Adults and children over 12 years:

Take 2 tablets 3 times daily.

Special populations

Elderly population:

No dosage adjustment is required for this population.

Paediatric population:

Children 6 - 12 years:

Take 1 tablet 3 times daily.

Children 2 - 6 years:

Take half a tablet 3 times daily. Crush tablets, if required.

Method of administration

For oral use only.

Allow tablets to dissolve in the mouth.

Take 15 minutes before meals.

4.3 Contraindications

- A.VOGEL URTICALCIN TABLETS 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

- None known
- Do not discontinue the use of prescribed medication without consulting a healthcare professional.

Paediatric population

- A.VOGEL URTICALCIN TABLETS are not indicated for use in patients younger than 2 years.

Lactose warning:

- A.VOGEL URTICALCIN TABLETS contain lactose which may have an effect on the glycaemic control of patients with diabetes mellitus. Patients with the rare hereditary conditions of galactose intolerance e.g. galactosaemia, Lapp lactase deficiency, glucose-galactose malabsorption or fructose intolerance should not take A.VOGEL URTICALCIN TABLETS.

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

No information available.

Although no specific safety studies on the use of A.VOGEL URTICALCIN TABLETS in pregnancy have been conducted, homeopathic remedies are generally considered to be suitable for use during pregnancy, however please consult your doctor, pharmacist or healthcare provider for further advice.

Breastfeeding

No information available.

Although no specific safety studies on the use of A.VOGEL URTICALCIN TABLETS in breastfeeding have been conducted, homeopathic remedies are generally considered to be suitable for use during breastfeeding, however please consult your doctor, pharmacist or healthcare provider for further advice.

Fertility

Fertility studies have not been performed.

No effect on fertility is expected.

4.7 Effects on ability to drive and use machines

A.VOGEL URTICALCIN TABLETS should have no effect on mental and/or physical ability to perform or execute tasks or activities requiring mental alertness, judgment and/or sound coordination and vision.

4.8 Undesirable effects

If symptoms of hypersensitivity occur e.g. rash, urticaria or angioedema of the skin, discontinue use of product, and contract 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

Lactose
Magnesium stearate
Pregelatinised starch

Contains sugar: Lactose .....82 mg

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

60 months.

6.4 Special precautions for storage

Store at or below 25 °C in a cool, dry place.
Protect from light.
Store in the original package/container.

6.5 Nature and contents of container

Amber glass bottles (type III glass), closed with pilfer proof screw caps fitted with a polyethylene liner.

Pack size: 200 tablets, 450 tablets.

Not all pack sizes may be marketed.

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 959 (Act 101/1965)

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

To be allocated.

10 DATE OF REVISION OF TEXT

July 2021