

PROFESSIONAL INFORMATION FOR MEDICINES  
FOR HUMAN USE

**A.Vogel**

# Kelpasan

## 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 KELPASAN** (tablets)

*Macrocystis pyrifera* (Atlantic kelp)

#### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

*Macrocystis pyrifera* (Atlantic kelp) ..... 33,3 mg  
[Powder]

Sugar free.

Approximately 50 µg iodine per tablet.

For full list of excipients, see section 6.1.

#### 3 PHARMACEUTICAL FORM

Beige, with dark spots, round, heterogenous, bevelled tablets with a predetermined breaking point, an aromatic odour and seaweed-like, salty taste.

#### 4 CLINICAL PARTICULARS

##### 4.1 Therapeutic indications

A.VOGEL KELPASAN is a herbal medicine that is mineral and micronutrient dense and a source of iodine. A.VOGEL KELPASAN is used for general wellbeing, support of thyroid function and healthy metabolism.

##### 4.2 Posology and method of administration

###### Posology

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

Take 1 tablet 3 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 with water.

###### Duration of use

Do not take more than 50 days consecutively (1 bottle).

##### 4.3 Contraindications

- A.VOGEL KELPASAN should not be used in patients who have a hypersensitivity to the active substance, *Macrocystis pyrifera* (Atlantic kelp), iodine, or to any of the excipients listed in section 6.1.
- Hyperthyroidism.

##### 4.4 Special warnings and precautions for use

- A.VOGEL KELPASAN contains soya polysaccharides. Patients who are allergic to peanut or soya, should not use A.VOGEL KELPASAN.
- If the condition worsens or does not improve after 50 days / taking 1 bottle, a doctor, pharmacist or other healthcare professional should be consulted.

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

A.VOGEL KELPASAN due to its iodine content should not be used with the following medicines:

- Amiodarone - may cause excessively high iodine levels.
- Antithyroid medicine - could alter the effects of the antithyroid medicine.
- Lithium - may have an additive hypothyroid effect.

Thyroid treatment supplementation with A.VOGEL KELPASAN should be monitored by a healthcare provider.

##### 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 KELPASAN during pregnancy is not recommended, unless under supervision of and on recommendation of a doctor.

###### Breastfeeding

The safety of this product during lactation has not been established. In the absence of sufficient data, the use of A.VOGEL KELPASAN during breastfeeding is not recommended, unless under supervision of and on recommendation of a doctor.

###### Fertility

Fertility studies have not been performed.

##### 4.7 Effects on ability to drive and use machines

A.VOGEL KELPASAN has no known 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

Adverse reactions are grouped into the following frequency classifications: Very common ( $\geq 1/10$ ), common ( $\geq 1/100$  to  $< 1/10$ ), uncommon ( $\geq 1/1\ 000$  to  $< 1/100$ ), rare ( $\geq 1/10\ 000$  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)
Immune system disorders:	If symptoms of hypersensitivity or allergic reactions (itching, rash, urticaria) occur, discontinue use of product, and contact a healthcare professional immediately.
Endocrine disorders:	Hypothyroidism, hyperthyroidism.

###### 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 overdosage 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

No information available.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Magnesium stearate  
Maize starch  
Microcrystalline cellulose  
Potato starch, pregelatinised  
Soya polysaccharides

### **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: 150 tablets

### **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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### **Manufacturer:**

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## **8 REGISTRATION/REFERENCE NUMBER:**

Listing number: 134574

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

To be allocated.

## **10 DATE OF REVISION OF TEXT**

October 2021

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