

PROFESSIONAL INFORMATION FOR MEDICINES
FOR HUMAN USE



COMPLEMENTARY MEDICINE

Health Supplement

This unregistered medicine has not been evaluated by the South African Health Products Regulatory Authority for its quality, safety or intended use. Health supplements are intended only to complement health or supplement the diet.

SCHEDULING STATUS

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1 NAME OF THE MEDICINE

A.VOGEL MOLKOSAN® ORIGINAL (liquid solution)
Health Supplement

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 100 ml solution contains:

Concentrated, pasteurised, deproteinised,
lactofermented whey: L (+) lactic acid7,0 g

Lactose-, gluten-, fat- and sugar-free.

Suitable for vegetarians and those who are lactose intolerant.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

A.VOGEL MOLKOSAN® ORIGINAL is a slightly yellowish clear liquid, with a characteristic sourish odour and taste.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

- A.VOGEL MOLKOSAN® ORIGINAL is made from lactofermented whey, and is a prebiotic food supplement. It assists in promoting better digestive health. It can be taken either alone, before or alongside a probiotic supplement.
- A.VOGEL MOLKOSAN® ORIGINAL is a source of high levels of lactate (L (+) lactic acid) and butyrate.

The beneficial effects of lactate and butyrate are:

- Supports healthy gut bacteria and microbiome.
- Supports gut health and helps prevent disease of the colon.
- Lowers gut pH and protects gut against pathogens.
- Regulates bowel movement and improves gut motility.
- Supports healthy growth of intestinal cells.
- Lactate and butyrate have been shown *in vitro* to have protective anti-cancer effects on colon cells.
- Protects against the effects of gut inflammation.
- Adjunctive and supportive treatment of symptoms of inflammatory bowel disease (IBD) and/or irritable bowel syndrome (IBS), such as diarrhoea, bloating, cramping, flatulence and constipation.
- Supportive / adjunct treatment for NAFLD (Non-alcoholic fatty liver disease) / Fatty liver.
- Supports the intestinal barrier and defence mechanism.
- Adjunctive and supportive treatment in hyperlipidaemia / high cholesterol / abnormal cholesterol values.
- Beneficial supportive therapy during and after antibiotic treatment.
- Beneficial for those who are lactose intolerant as L (+) lactic acid helps break down the protein in milk.
- Support healthy insulin levels.

4.2 Posology and method of administration

Posology

Adults and children over 12 years:

General digestive health maintenance:
10 ml once daily.

Additional support:

20 ml once to twice daily.

Special populations

Elderly population:

No dosage adjustment is required for this population.

Paediatric population

Children 6 – 12 years:

General digestive health maintenance:

5 ml once daily.

Additional support:

5 ml twice daily.

Children under 6 years: Consult a healthcare professional for use in children under 6 years.

Method of administration

For oral use only.

Dilute in water or juice.

Additional support: One month's course is advised. Thereafter return to the maintenance dosage.

4.3 Contraindications

A.VOGEL MOLKOSAN® ORIGINAL should not be used in patients who have a hypersensitivity to any of the active substances or to the excipient listed in section 6.1.

4.4 Special warnings and precautions for use

- A.VOGEL MOLKOSAN® ORIGINAL contains potassium, which should be used with care in patients with high potassium levels and/or those on a potassium restricted diet.
- Due to its acid pH (approximately pH 4,2), people with a peptic ulcer or intolerance to acidity should consult a healthcare professional before use.
- Take the product as indicated. Dilute before use.
- Do not exceed stated dose.

Paediatric population

Consult your healthcare professional.

4.5 Interaction with other medicines and other forms of interaction

No interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

Women of childbearing potential/Contraception in males and females

No information available.

Pregnancy

No effect on pregnancy expected.

Breastfeeding

No effect on breastfeeding expected.

Fertility

No effect on fertility expected.

4.7 Effects on ability to drive and use machines

A.VOGEL MOLKOSAN® ORIGINAL has no or negligible effect on mental and/or physical abilities to perform or execute tasks or activities requiring mental alertness, judgment and/or sound coordination and vision.

4.8 Undesirable effects

Summary of the safety profile

High doses can cause some side effects such as increased bowel movement. The frequency is unknown.

Paediatric population

Frequency, type and severity of adverse reactions in children are expected to be the same as in adults.

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 the 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

Pharmacotherapeutic group and ATC code:

Lactic acid producing organisms, combinations / A07FA51

D34.13 Other (Health Supplement)

Mechanism of action:

A.VOGEL MOLKOSAN® ORIGINAL is a source of high levels of lactate and butyrate

5.2 Pharmacokinetic properties

No information available.

5.3 Preclinical safety data

No information available.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Potassium citrate

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Store at or below room temperature. After opening, store in the fridge for up to 2 months.

Shelf-life: 36 months unopened.

6.4 Special precautions for storage

This product should be stored in a fridge after opening.

6.5 Nature and contents of container

A.VOGEL MOLKOSAN® ORIGINAL is packed in an amber type III glass bottle, with plastic pourer (PE-LD) and screw cap (PE-HD) with a tamper evident seal (PE-LD).

The pack sizes are 200 ml and 500 ml.

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)

To be allocated.

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

To be allocated.

10 DATE OF REVISION OF TEXT

September 2020

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