

PROFESSIONAL INFORMATION FOR



COMPLEMENTARY MEDICINE

Health Supplement

This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

SCHEDULING STATUS

S01

1. NAME OF THE MEDICINE

A.VOGEL MOLKOSAN BERRY, oral solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 100 mL solution contains

Concentrated, pasteurised, deproteinised, lacto-fermented whey:

L (+) lactic acid 7,0 g

Contains sugar as glucose and/or fructose	3 g/100 mL
Contains sweetener as steviol glycoside (from stevia)	0,04 g/100 mL
Contains preservative as potassium sorbate	0,1 % (w/w)
Contains potassium as potassium citrate and sorbate	1,6 g/100 mL
Contains sodium	0,1 g/100 mL

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral solution

A clear, red brown liquid, with a characteristic odour of berries and a characteristic sour taste of berries.

A.VOGEL MOLKOSAN BERRY has a pH of about 4,2.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

A.VOGEL MOLKOSAN BERRY contains lacto-fermented whey, which acts as 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 BERRY is a source of high levels of L (+) lactic acid. Regular use of A.VOGEL MOLKOSAN BERRY supports beneficial bacteria in the gut that produce butyrate, a compound that is widely known for its positive health effects.

The beneficial effects of L (+) lactic acid and butyrate are:

- Supports healthy gut bacteria and microbiome by selectively stimulating the growth of the beneficial gut flora and positively affecting intestinal health.
- Support and maintain gut and colon health.
- Support healthy growth of intestinal cells.
- By lowering gut pH, create an inhospitable environment for pathogens, thereby supporting general gut health.
- Maintain and support gut health and function by regulating/supporting healthy bowel movement and improved gut motility.
- By helping to protect against gut inflammation it supports the symptomatic treatment of inflammatory bowel conditions.
- Adjunctive and supportive treatment of symptoms of irritable bowel conditions, such as diarrhoea, bloating, cramping, flatulence and constipation.
- Supports the intestinal barrier and defence mechanism.
- Supportive in food allergies with compromised gut barrier.
- May help to maintain healthy cholesterol levels.
- Beneficial supportive therapy during and after antibiotic treatment.
- Support the regulation of healthy blood sugar levels.

4.2 Posology and method of administration

Posology

General digestive health maintenance

Adults and children over 12 years: 10 mL once daily.

Children 6 - 12 years: 5 mL once daily.

Additional support

Adults and children over 12 years: 20 mL once to twice daily.

Children 6 - 12 years: 5 mL twice daily.

Take the additional support course for one month. Thereafter return to the maintenance dosage.

Paediatric population

Children under 6 years: Consult a health care provider for use in children under 6 years.

Method of administration

For oral use only.

Dilute before use.

A.VOGEL MOLKOSAN BERRY should be taken in the morning, or the dose can be divided and taken 2 to 4 times per day. Mix the dose, e.g., one teaspoon (5 mL) to four teaspoons (20 mL) in a glass of water or juice.

Shake well before use.

4.3 Contraindications

• Hypersensitivity to lacto-fermented whey, whey or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

- Take A.VOGEL MOLKOSAN BERRY as indicated; do not drink it undiluted
- Do not exceed stated dose.
- Due to its acid pH (approximately pH 4,2), people with a peptic ulcer or intolerance to acidity should consult a health care provider before use.
- If the condition worsens or does not improve after two weeks, a health care provider should be consulted.

Excipients with known effect

Fructose: Patients with hereditary fructose intolerance (HFI) should not take A.VOGEL MOLKOSAN BERRY.

Glucose: Patients with rare glucose-galactose malabsorption should not take A.VOGEL MOLKOSAN BERRY.

Lactose: A.VOGEL MOLKOSAN BERRY contains less than 0,1 g/100 mL lactose, and is essentially lactose free. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take A.VOGEL MOLKOSAN BERRY.

Potassium: A.VOGEL MOLKOSAN BERRY contains 4,1 mmol potassium per 10 mL (that is 80 mg/5 mL, 160 mg/10 mL, 320 mg/20 mL and 640 mg/40 mL). To be taken into consideration by patients with reduced kidney function or patients on a controlled potassium diet.

Sodium: A.VOGEL MOLKOSAN BERRY contains 0,1 g/100 mL sodium (5 mg/5 mL, 10 mg/10 mL, 20 mg/20 mL and 40 mg/40 mL). 40 mL per day is equivalent to 2 % of the WHO recommended maximum daily intake of 2 g sodium for an adult.

4.5 Interaction with other medicines and other forms of interaction

No interactions have been reported.

4.6 Fertility, pregnancy and lactation

Pregnancy

The safety of A.VOGEL MOLKOSAN BERRY during pregnancy has not been established. During pregnancy, A.VOGEL MOLKOSAN BERRY should be taken under the supervision of a medical practitioner.

Breastfeeding

The safety of A.VOGEL MOLKOSAN BERRY during breastfeeding has not been established.

During breastfeeding, A.VOGEL MOLKOSAN BERRY should be taken under the supervision of a medical practitioner.

Fertility

No data on male and female fertility is available.

4.7 Effects on ability to drive and use machines

A.VOGEL MOLKOSAN BERRY has no known influence on mental and/or physical ability to perform or execute tasks or activities requiring mental alertness, judgment and/or sound coordination and vision.

It is not always possible to predict to what extent A.VOGEL MOLKOSAN BERRY may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which A.VOGEL MOLKOSAN BERRY affects them.

4.8 Undesirable effects

a. Tabulated summary of adverse reactions

System Organ Class	Frequency	Adverse reactions
Immune system disorders	Frequency unknown	Hypersensitivity (see section 4.3)
Gastrointestinal disorders	Frequency unknown	Diarrhoea

b. Description of selected adverse reactions

Diarrhoea: High doses can cause increased bowel movement.

c. 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. Health care 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>.

In addition, side-effects can also be reported to info@pharmacorp.co.za.

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

Category and class: D34.13 Other (Health Supplement)

Mechanism of action:

A.VOGEL MOLKOSAN BERRY contains lacto-fermented whey. During the fermentation process substances are produced that are considered food sources (prebiotics) for beneficial gut bacteria. The most important substance is L (+) lactic acid (converted to lactate). Lactic acid supports healthy gut bacteria and the microbiome.

Besides its own direct health benefits, it is also known that lactic acid is further converted to another vital substance, the short-chain fatty acid (SCFA) butyrate in the intestine, which further adds to the list of health benefits of A.VOGEL MOLKOSAN BERRY.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Calcium lactate (E327)

Fruit juice concentrate (aronia berry, pomegranate)

Malic acid (E296)

Natural flavours (pomegranate, vanilla)

Potassium citrate (E332)

Potassium sorbate (preservative agent) (E202)

Steviol glycoside (from stevia) (E960a)

Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Before opening the bottle: 24 months.

After opening the bottle: 1 month.

The opened bottle should be stored in the fridge.

6.4 Special precautions for storage

Store at or below 25 °C.

For storage conditions after opening of the medicine, see section 6.3.

6.5 Nature and contents of container

A.VOGEL MOLKOSAN BERRY 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).

Pack sizes

200 mL

500 mL

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7. HOLDER OF THE CERTIFICATE OF REGISTRATION

PHARMACORP (PTY) LTD

29 Victoria Link

Route 21 Corporate Park

Irene, 0178, RSA

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

January 2024