PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

MOLKOSAN®

COMPLEMENTARY MEDICINE

Health Supplement

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

Health supplements are intended only to complement health or supplement the diet.

SCHEDULING STATUS:

S0

1 NAME OF THE MEDICINE

A.VOGEL MOLKOSAN® ORIGINAL (liquid solution)

2 QUALITIVE AND QUANTITIVE COMPOSITION

Concentrated, pasteurised, deproteinised, lactofermented whey: L (+) lactic acid 7,0 g / 100 ml

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

Liquid solution.
Molkosan is a slightly yellowish clear liquid, with a characteristic sourish odour and taste.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

- Molkosan 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.
- Molkosan 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

General digestive health maintenance:
Adults and children over 12 years: 10 ml once daily in water or juice
Children 6 – 12 years: 5 ml once daily in water or juice

Additional support:
Adults and children over 12 years: 20 ml once to twice daily in water or juice
Children 6 – 12 years: 5 ml twice daily in water or juice
One month's course is advised. Thereafter return to the maintenance dosage.

Special populations
Elderly population:
No dosage adjustment is required for this population.

Paediatric population
Children under 6 years: Consult your healthcare professional.

Method of administration
For oral use.

4.3 Contraindications
Known hypersensitivity to any of the ingredients.

4.4 Special warnings and precautions for use

- Take the product as indicated. Dilute before use.
- Do not exceed stated dose.
- If the condition worsens or does not improve after two weeks, consult a healthcare practitioner.
- Molkosan 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.

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
Molkosan has no or negligible influence 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 movements. 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 professionals 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 Undesirable effects).

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group and ATC code:

Lactic acid producing organisms, combinations/ A07FA51

D34.10 Prebiotic Health Supplement

Mechanism of action:
Molkosan 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

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

Molkosan 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, 500 ml and 1000 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

October 2019

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