

PROFESSIONAL INFORMATION

D 34.12 Multiple Substance Formulation. Complementary Medicine: Health Supplement

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

SCHEDULING STATUS: S0

1. NAME OF THE MEDICINE

LOCAL HEALTH 9-STRAIN PROBIOTIC vegcapsules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vegcapsule contains:

Probiotic Blend Powder ≥5 Billion Colony Forming Units (CFU)

Containing:

- HOWARU® *Lactobacillus acidophilus*
- HOWARU® *Lactobacillus rhamnosus*
- Lactobacillus casei*
- Lactobacillus reuteri*
- Lactobacillus gasseri*
- Lactobacillus salivarius*
- HOWARU® *Bifidobacterium lactis*
- Bifidobacterium bifidum*
- Bifidobacterium longum*

Orafti® Synergy1 (Oligofructose-enriched inulin) 50 mg

Sugar free

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

White to off-white vegcapsules.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

When ingested on a regular basis, probiotics should improve or normalise the microbial balance in the human intestines and thereby improve the functioning of the digestive tract/gut.

4.2 Posology and method of administration

Adults and children 6 years and older: one to two (1-2) vegcapsules daily.

4.3 Contraindications

Hypersensitivity to any of the active substances or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

- Some research suggests that lactobacillus and bifidobacteria preparations may cause pathogenic colonization in patients who are immunocompromised. Pathogenic colonization is more likely to occur in severely immunocompromised patients.
- Patients with short bowel syndrome might be predisposed to pathogenic infection from lactobacillus. This might be due to impaired gut integrity in patients with short-bowel syndrome.
- Three cases of bacteremia caused by lactobacillus species have been reported in adults and adolescent patients with severe active ulcerative colitis.
- Although it is a rare cause of infective endocarditis, patients with valvular heart disease who use probiotics containing lactobacillus may be at an increased risk. Patients with valvular heart disease should discontinue use of probiotics prior to dental surgery or other invasive gastrointestinal procedures.

4.5 Interaction with other medicines and other forms of interaction

- Concomitant use of antibiotics and probiotics might decrease the effectiveness of the probiotic, as probiotics usually contain live and active organisms. Simultaneously taking antibiotics and probiotics might kill a significant number of the organisms. Patients should take antibiotics and probiotics at least two hours apart.
- Lactobacillus and bifidobacteria may cause infection in patients taking medications that suppress the immune system.

4.6 Fertility, pregnancy and lactation

Safety in fertility, pregnancy and lactation has not been established as there is insufficient reliable data available.

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive or use of machinery have been performed. Patients should exercise caution before driving or using machinery until they are reasonably certain that LOCAL HEALTH 9-STRAIN PROBIOTIC does not adversely affect their performance.

4.8 Undesirable effects

Gastrointestinal

Less frequent: abdominal pain, dyspepsia, bloating, diarrhoea.

Dermatological

Less frequent: rash, itching.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization 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 Reactions Reporting Form", found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>.

4.9 Overdose

In the event of an overdose, undesirable effects as listed in 4.8 can be precipitated or be of increased severity.

Treatment of overdose is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

When ingested on a regular basis, probiotics should improve or normalise the microbial balance in the human intestines and thereby improve the functioning of the digestive tract/gut.

5.2 Pharmacokinetic properties

Lactobacilli pass through the gut and attach to the intestinal mucosa where they can persist for at least one week.

Bifidobacteria are not commonly absorbed in the gastrointestinal tract. Bifidobacteria disappear from the faeces within two weeks of discontinuation, suggesting that there is no long-term colonization.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Magnesium stearate, silica, microcrystalline cellulose.

6.2 Incompatibilities

Not applicable

6.3 Shelf Life

24 months

6.4 Special precautions for storage

Store at or below 25 °C.

Store in the original package in order to protect from moisture.

KEEP OUT OF REACH OF CHILDREN.

6.5 Nature and contents of container

30 vegcapsules in a white, PET plastic container and white screwcap lid.

6.6 Special precautions for disposal

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

CJ Distribution

23 Stag Road, Glen Austin, Johannesburg, South Africa

careline@cjdsa.com

011 589 2729

www.localhealth.com

8. REGISTRATION NUMBER

Will be allocated by SAHPRA upon registration.

9. DATE OF FIRST AUTHORISATION

Will be allocated by SAHPRA upon registration.

