

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 vegecapsules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vegecapsule 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 vegecapsules.

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) vegecapsules 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 vegecapsules 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.

PATIENT INFORMATION LEAFLET
SCHEDULING STATUS
S0

LOCAL HEALTH 9-STRAIN PROBIOTIC (vegecapsules)

Each vegecapsule contains:
Probiotic Blend Powder ≥5 Billion Colony Forming Units (CFU)
Containing:
HOWARU® *Lactobacillus acidophilus*
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Lactobacillus casei
Lactobacillus reuteri
Lactobacillus gasseri
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HOWARU® *Bifidobacterium lactis*
Bifidobacterium bifidum
Bifidobacterium longum

Orafti® Synergy1 (Oligofruktose-enrïeëde inulin) 50 mg

Sugar free

Complementary Medicine: Multiple Substance Formulation (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.

Read all of this leaflet carefully because it contains important information for you.

LOCAL HEALTH 9-STRAIN PROBIOTIC is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to use LOCAL HEALTH 9-STRAIN PROBIOTIC carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share LOCAL HEALTH 9-STRAIN PROBIOTIC with any other person.
- Ask your healthcare practitioner or pharmacist if you need more information or advice.

What is in this leaflet

1. What LOCAL HEALTH 9-STRAIN PROBIOTIC is and what it is used for.
2. What you need to know before you use LOCAL HEALTH 9-STRAIN PROBIOTIC.
3. How to use LOCAL HEALTH 9-STRAIN PROBIOTIC.
4. Possible side effects.
5. How to store LOCAL HEALTH 9-STRAIN PROBIOTIC.
6. Contents of the pack and other information.

1. What LOCAL HEALTH 9-STRAIN PROBIOTIC is and what it is used for

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.

2. What you need to know before you use LOCAL HEALTH 9-STRAIN PROBIOTIC

Do not use LOCAL HEALTH 9-STRAIN PROBIOTIC:

- If you are allergic or sensitive to any of the ingredients listed in section 6.

Warnings and precautions

Consult with a healthcare practitioner prior to using LOCAL HEALTH 9-STRAIN PROBIOTIC, especially if you have a medical condition.

Use LOCAL HEALTH 9-STRAIN PROBIOTIC with caution and consult a healthcare practitioner before use:

- If you have immunodeficiency, short bowel syndrome, ulcerative colitis, or valvular heart disease.

Children and adolescents

LOCAL HEALTH 9-STRAIN PROBIOTIC is not recommended for children below the age of 6 years.

Consult a healthcare practitioner prior to use.

Other medicines and LOCAL HEALTH 9-STRAIN PROBIOTIC

Always tell your healthcare practitioner if you are taking any other medicine (this includes complementary or traditional medicines). Not all possible interactions with other medicines may be included in this leaflet. Consult with a healthcare practitioner prior to use. LOCAL HEALTH 9-STRAIN PROBIOTIC may interact with the following medications: antibiotics, immunosuppressants.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare practitioner for advice before using LOCAL HEALTH 9-STRAIN PROBIOTIC.

Driving and using machinery

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.

3. How to use LOCAL HEALTH 9-STRAIN PROBIOTIC

Do not share medicines prescribed to you with any other person. Do not exceed the daily recommended dosage. Always use LOCAL HEALTH 9-STRAIN PROBIOTIC exactly as described in this leaflet or as your healthcare practitioner has instructed. Check with your healthcare practitioner if you are not sure.

Adults and children 6 years and older:

Take one to two (1-2) vegecapsules daily, or as recommended by a healthcare practitioner.

4. Possible side effects

LOCAL HEALTH 9-STRAIN PROBIOTIC can have side effects. Not all side effects reported for LOCAL HEALTH 9-STRAIN PROBIOTIC are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking LOCAL HEALTH 9-STRAIN PROBIOTIC, please consult your doctor, pharmacist or other healthcare practitioner for advice. If any of the following happens, stop using LOCAL HEALTH 9-STRAIN PROBIOTIC and tell your doctor or pharmacist immediately, or go the casualty department at your nearest hospital: swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing, rash or itching, fainting. These are very serious side effects. If you have them, you may have had a serious reaction to LOCAL HEALTH 9-STRAIN PROBIOTIC. You may need urgent medical attention or hospitalisation.

- **Less frequent:** gastrointestinal disturbances including abdominal pain, dyspepsia, bloating, diarrhoea; rash; itching.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you experience side effects, inform your doctor or pharmacist. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications: <http://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of LOCAL HEALTH 9-STRAIN PROBIOTIC.

5. How to store LOCAL HEALTH 9-STRAIN PROBIOTIC

- Protect from moisture and store at or below 25 °C.
- KEEP OUT OF REACH OF CHILDREN.
- Do not use after the expiry date stated on the label.
- Return all unused LOCAL HEALTH 9-STRAIN PROBIOTIC to your pharmacist.
- Do not dispose of unused LOCAL HEALTH 9-STRAIN PROBIOTIC in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What LOCAL HEALTH 9-STRAIN PROBIOTIC contains

Each vegecapsule contains:
Probiotic Blend Powder ≥5 Billion Colony Forming Units (CFU)
Containing:
HOWARU® *Lactobacillus acidophilus*
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HOWARU® *Bifidobacterium lactis*
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Bifidobacterium longum

Orafti® Synergy1 (Oligofruktose-enrïeëde inulin) 50 mg

Other ingredients: magnesium stearate, silica, microcrystalline cellulose.

Sugar free

Presentation and identification of LOCAL HEALTH 9-STRAIN PROBIOTIC

30 white to off-white vegecapsules packed into a white plastic container.

Holder of Certificate of Registration

Manufactured for: CJ Distribution, 23 Stag Road, Glen Austin, Johannesburg, South Africa, 1685
Careline: 011 589 2729; careline@cjsa.com; www.localhealth.co.za

This pamphlet was last revised in

Will be allocated by SAHPRA upon registration.

Registration number

Will be allocated by SAHPRA upon registration.

PASIËNTINLIGTINGSBLAD
SKEDULERINGSSTATUS

S0

LOCAL HEALTH 9-STRAIN PROBIOTIC (vegecapsules)

Elke vegecapsule bevat:
Probiotiese Poeier Mengsel ≥5 Biljoen Kolonievormende Eenhede (KVE)
Bevat:
HOWARU® *Lactobacillus acidophilus*
HOWARU® *Lactobacillus rhamnosus*
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Lactobacillus salivarius
HOWARU® *Bifidobacterium lactis*
Bifidobacterium bifidum
Bifidobacterium longum

Orafti® Synergy1 (Oligofruktose-verrykte inulien) 50 mg

Suikervry

Komplementêre Medisyne: Meervoudige Bestanddeel Formulasie (Gesondheidsaanvulling)

Hierdie ongeregistreerde medisyne is nie deur SAHPRA vir gehalte, veiligheid of beoogde gebruik geëvalueer nie. Gesondheidsaanvullings dien slegs as aanvulling tot gesondheid of dieet.

Lees hierdie inligtingsblad noukeurig deur dit bevat inligting wat belangrik is vir u.

LOCAL HEALTH 9-STRAIN PROBIOTIC is beskikbaar sonder 'n dokter se voorskrif, om u gesondheid te handhaaf. Nietemin moet LOCAL HEALTH 9-STRAIN PROBIOTIC versigtig gebruik word ten einde die beste resultate te verkry.

- Hou hierdie inligtingsblad. Dit kan nodig wees dat u dit weer lees.
- Moenie LOCAL HEALTH 9-STRAIN PROBIOTIC met enige ander persoon deel nie.
- Vra u gesondheidsorgpraktisyn of apteker indien u meer inligting of advies nodig het.

Wat is in hierdie inligtingsblad

1. Wat LOCAL HEALTH 9-STRAIN PROBIOTIC is en waarvoor dit gebruik word.
2. Wat u moet weet voordat u LOCAL HEALTH 9-STRAIN PROBIOTIC gebruik.
3. Hoe om LOCAL HEALTH 9-STRAIN PROBIOTIC te gebruik.
4. Moontlike nuwe-effekte.
5. Berging van LOCAL HEALTH 9-STRAIN PROBIOTIC.
6. Inhoud van die verpakking en ander inligting.

1. Wat LOCAL HEALTH 9-STRAIN PROBIOTIC is en waarvoor dit gebruik word

Wanneer probiotika op 'n gereelde basis ingeneem word, behoort die mikrobiële balans in die derm van die mens verbeter of normaliseer en sodoende die werking van die spysverteringskanaal / dermkanaal verbeter.

2. Wat u moet weet voordat u LOCAL HEALTH 9-STRAIN PROBIOTIC gebruik

Moet nie LOCAL HEALTH 9-STRAIN PROBIOTIC neem nie:

- Indien u allergies of sensitief is vir enige van die bestanddele gelys in afdeling 6.

Waarskuwings en voorsorgmaatreëls

Raadpleeg 'n gesondheidsorgpraktisyn voordat u LOCAL HEALTH 9-STRAIN PROBIOTIC gebruik, veral as u 'n mediese toestand het.

Gebruik LOCAL HEALTH 9-STRAIN PROBIOTIC met omsigtigheid en raadpleeg 'n gesondheidsorgpraktisyn voor gebruik:

- Indien u immuunbrek, kort derm-sindroom, ulseratiewe kolitis of hartklepsiekte het.

Kinders en adollesente

LOCAL HEALTH 9-STRAIN PROBIOTIC word nie aanbeveel vir kinders jonger as 6 jaar nie. Raadpleeg 'n gesondheidsorgpraktisyn voor gebruik.

Die neem van LOCAL HEALTH 9-STRAIN PROBIOTIC en ander medisyne

Lig altyd u gesondheidsorgpraktisyn in indien u enige ander medisyne neem (dit sluit aanvullende of tradisionele medisyne in). Nie alle moontlike interaksies met ander medisyne word in hierdie pamflet ingesluit nie. Raadpleeg 'n gesondheidsorgpraktisyn voor gebruik. LOCAL HEALTH 9-STRAIN PROBIOTIC kan interaksie hê met die volgende medisyne: antibiotika, immuunonderdrukkers.

Swangerskap, borsvoeding en vrugbaarheid

Indien u swanger is of borsvoed, vermoed dat u swanger is of beplan om 'n baba te hê, raadpleeg u dokter, apteker of ander gesondheidsorgpraktisyn vir advies voordat u LOCAL HEALTH 9-STRAIN PROBIOTIC gebruik.

Bestuur en die gebruik van masjinerie

Geen studies is uitgevoer oor die effekte op die vermoë om te bestuur of die gebruik van masjinerie nie. Pasiënte moet versigtig wees voordat hulle bestuur of masjinerie gebruik, totdat hulle redelik seker is dat LOCAL HEALTH 9-STRAIN PROBIOTIC nie hul werkverrigting nadelig beïnvloed nie.

3. Hoe om LOCAL HEALTH 9-STRAIN PROBIOTIC te gebruik

Moenie medisyne wat aan u voorgeskryf is met enige ander persoon deel nie. Moenie die aanbeveelde daaglikse dosis oorskry nie. Gebruik LOCAL HEALTH 9-STRAIN PROBIOTIC presies soos aanbeveel in hierdie inligtingsblad, of soos aanbeveel deur u gesondheidsorgpraktisyn. Raadpleeg u gesondheidsorgpraktisyn indien u nie seker is nie.

Volwassenes en kinders 6 jaar en ouer:

Neem een tot twee (1-2) vegecapsules daaglik, of soos aanbeveel deur 'n gesondheidsorgpraktisyn.

4. Moontlike nuwe-effekte

LOCAL HEALTH 9-STRAIN PROBIOTIC kan nuwe-effekte hê. Nie alle nuwe-effekte vir LOCAL HEALTH 9-STRAIN PROBIOTIC is ingesluit in hierdie inligtingsblad nie. Indien u algemene gesondheid vererger, of as u enige ongewenste reaksies ervaar tydens die gebruik van LOCAL HEALTH 9-STRAIN PROBIOTIC, raadpleeg u dokter, apteker of ander gesondheidsorgpraktisyn vir advies. As een van die volgende gebeur, hou op met die gebruik met LOCAL HEALTH 9-STRAIN PROBIOTIC en raadpleeg u dokter of apteker onmiddellik, of gaan na die ongevalle afdeling van u naaste hospitaal: swelling van jou hande, voete, enkels, gesig, lippe en mond of keel, wat dit moeilik kan maak om te sluk of asem te haal, veluitslag, gejeuk, of floutes. Hierdie is baie ernstige nuwe-effekte. Indien jy dit het, mag jy 'n ernstige allergiese reaksie op LOCAL HEALTH 9-STRAIN PROBIOTIC gehad het. Jy mag dringende mediese bystand of hospitalisasie nodig hê.

- **Minder dikwels:** gastroïntestinale verstourings, insluitend buikpyn, dispepsie, opgeblasenheid, diarree; uitslag; jeuk.

Lig asseblief u dokter of apteker in indien u enige nuwe-effekte opmerk wat nie in hierdie inligtingstuk genoem word nie.

Rapportering van nuwe-effekte

Praat met u dokter of apteker as u nuwe-effekte ervaar. U kan ook nuwe-effekte by SAHPRA aanmeld via die "6.04 Adverse Drug Reactions Reporting Form", wat aanlyn gevind kan word onder SAHPRA se publikasies: <http://www.sahpra.org.za/Publications/Index/8>. Deur nuwe-effekte aan te meld, kan u help om meer inligting te verskaf oor die veiligheid van LOCAL HEALTH 9-STRAIN PROBIOTIC.

5. Berging van LOCAL HEALTH 9-STRAIN PROBIOTIC

- Beskerm teen vog en berg by of onder 25 °C.
- HOU BUIE BEREIK VAN KINDERS.
- Moenie gebruik na die vervaldatum op die etiket nie.
- Neem alle ongebruikte LOCAL HEALTH 9-STRAIN PROBIOTIC na u apteker terug.
- Moenie ongebruikte LOCAL HEALTH 9-STRAIN PROBIOTIC in afvoerpype of rioolsisteme (bv. toilette) weggooi nie.

6. Inhoud van die verpakking en ander inligting

Wat LOCAL HEALTH 9-STRAIN PROBIOTIC bevat

Elke vegecapsule bevat:
Probiotiese Poeier Mengsel ≥5 Biljoen Kolonievormende Eenhede (KVE)
Bevat:
HOWARU® *Lactobacillus acidophilus*
HOWARU® *Lactobacillus rhamnosus*
Lactobacillus casei
Lactobacillus reuteri
Lactobacillus gasseri
Lactobacillus salivarius
HOWARU® *Bifidobacterium lactis*
Bifidobacterium bifidum
Bifidobacterium longum

Orafti® Synergy1 (Oligofruktose-verrykte inulien) 50 mg

Ander bestanddele: magnesiumstearaat, silika, mikrokristallyne sellulose.

Suikervry

Aanbieding en identifikasie van LOCAL HEALTH 9-STRAIN PROBIOTIC

30 wit tot af-wit vegecapsules, verpak in 'n wit plastiekhouer.

Houer van Registrasiesertifikaat

Vervaardig vir: CJ Distribution, 23 Stag Road, Glen Austin, Johannesburg, Suid Afrika, 1685
Sorglyn: 011 589 2729; careline@cjsa.com; www.localhealth.co.za

Hierdie pamflet is laas hiersien in

Sal met registrasie deur SAHPRA toegeken word.

Registrasienuommer

Sal met registrasie deur SAHPRA toegeken word.