40825_PI_P3

BIOGEN
FOR THE RESULTS YOU WANT

SUPREME PROBIOTIC 9-STRAIN

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
BIOGEN SUPREME PROBIOTIC 9-STRAIN

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each vegetarian capsule contains:

Probiotic Blend Powder 10 ≥ Billion Colony Forming Units (CFU)	10 ≥ 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® Syngery1 (Oligofructose-enriched inulin)	50 mg

Sugar free

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM
Vegetarian capsules

4. CLINICAL PARTICULARS

4.1 Therapeutic indications
BIOGEN SUPREME PROBIOTIC 9-STRAIN, may improve or normalise the microbial balance in the human intestines when ingested on a regular basis, and thereby improve the functioning of the digestive tract.

4.2 Posology and method of administration
Adults and children 6 years and older:

Take one to two (1 to 2) capsules daily, or as recommended by your healthcare provider.

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
A healthcare provider must be consulted prior to using BIOGEN SUPREME PROBIOTIC 9-STRAIN, especially in the case where the patient has a medical condition:
- 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
Patients who are pregnant or breastfeeding, think they may be pregnant or are planning to have a baby must consult a healthcare practitioner for advice prior to using BIOGEN SUPREME PROBIOTIC 9-STRAIN.

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 BIOGEN SUPREME PROBIOTIC 9-STRAIN does not adversely affect their performance.

4.8 Undesirable effects
Gastrointestinal
Less frequent: abdominal pain, dyspepsia, bloating, diarrhea.
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.

Preclinical safety data
No clinical data are available on the effects of BIOGEN SUPREME PROBIOTIC 9-STRAIN

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 in a cool, dry place at or below 25 °C. Do not use after expiry date.
Keep the container tightly closed.
Protect from light.
KEEP OUT OF REACH OF CHILDREN.

6.5 Nature and contents of container
30/70 white to off white vegetarian capsules are available in a white plastic container sealed with a white plastic screw cap.

6.6 Special precautions for disposal
No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION
Biogen,
23 Stag Rd,
Glen Austin,
South Africa

8. REGISTRATION NUMBER
Will be allocated by SAHPRA upon registration.

10. DATE OF REVISION OF THE TEXT
Will be allocated by SAHPRA upon registration.