44539 PI P12

BIOGEN
FOR THE RESULTS YOU WANT

BIOGEN JUNIOR PROBIOTIC CHEWS

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 JUNIOR PROBIOTIC CHEWS (chewable tablets)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each chewable tablet contains:

HOWARU® *Lactobacillus acidophilus*	200 Million CFU
HOWARU® *Lactobacillus rhamnosus*	100 Million CFU
Lactobacillus casei	100 Million CFU
Lactobacillus reuteri	100 Million CFU
Lactobacillus gasseri	100 Million CFU
Lactobacillus salivarius Ls-33	100 Million CFU
HOWARU® *Bifidobacterium lactis*	100 Million CFU
Bifidobacterium bifidum	100 Million CFU
Bifidobacterium longum	100 Million CFU
Orafti® Synergy1 (Inulin and Oligofructose)	50 mg

CFU = Colony Forming Units

Contains sugar (0,4 g sorbitol) per tablet.

Contains sweetener (1 mg steviol glycosides) per tablet.

For the full list of excipients, see section **6.1.**

3. PHARMACEUTICAL FORM
Tablets.
Small, oval, white to light pink strawberry-flavoured chewable tablets.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications
BIOGEN JUNIOR PROBIOTIC CHEWS may improve and restore the microbial balance in the intestines and thereby improve the functioning of the digestive tract, when ingested on a regular basis.

4.2 Posology and method of administration
Children 3 years and older: Chew 1 tablet daily, or as recommended by a healthcare provider. Do not exceed the daily recommended dosage.

4.3 Contraindications:
- If you are allergic (hypersensitive) to any of the ingredients listed in section 2 or any of the excipients listed in 6.1.
- Patients with the rare hereditary condition of sorbitol intolerance should not take BIOGEN JUNIOR PROBIOTIC CHEWS.

4.4 Special warnings and precautions for use
- Contains sorbitol, which may have a laxative effect.
- *Lactobacillus reuteri* and *Lactobacillus rhamnosus* might cause pathogenic colonization in patients who are severely immunocompromised.
- *Lactobacillus reuteri* and *Lactobacillus rhamnosus* preparations might cause pathogenic colonization in patients with valvular heart disease. Use should be avoided prior to dental surgery or other invasive gastrointestinal procedures. Endocarditis related to probiotic use is a rare cause of infective endocarditis.
- *Lactobacillus rhamnosus* might cause pathogenic colonization in patients with serious gastrointestinal disorders, such as short bowel syndrome or inflammatory bowel disease.

4.5 Interaction with other medicines and other forms of interaction
- Antibiotics might decrease the effects of probiotics (bifidobacterial and lactobacillus species).
- Advise patients to take antibiotics and BIOGEN JUNIOR PROBIOTIC CHEWS at least 2 hours apart.
- Lactobacillus may increase the risk of infection in patients who are taking immunosuppressants such as cyclosporine, tacrolimus, azathioprine and cancer chemotherapeutic agents like cyclophosphamide and cisplatin.

4.6 Fertility, pregnancy and lactation
Safety in pregnancy and lactation has not been established.

4.7 Effects on ability to drive and use machines
BIOGEN SUPREME PROBIOTIC CHEWS has no known effect on the ability to drive or use machines. However, patients should be careful until they are reasonably certain that BIOGEN SUPREME PROBIOTIC CHEWS does not adversely affect their performance.

4.8 Undesirable effects

Gastrointestinal disorders
Frequency unknown: flatulence, belching, abdominal pain, constipation, bloating, diarrhoea, dyspepsia, nausea, vomiting.

Immune system disorders
Frequency unknown: pathogenic infection.

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 providers are requested to report any suspected adverse drug reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website.

4.9 Overdose
In overdose, side effects can be precipitated and/or be of increased severity (see section 4.8).
In the event of overdose, treatment should be symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
Class and category: Category D 34.12 Multiple Substance Formulation. Complementary Medicine: Health Supplement
Probiotics may improve and restore the microbial balance in the intestines and thereby improve the functioning of the digestive tract, when ingested on a regular basis.

5.2 Pharmacokinetic properties
Pharmacokinetic studies have not been conducted on BIOGEN JUNIOR PROBIOTIC CHEWS.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Silicon dioxide
Sorbitol
Magnesium stearate
Flavouring

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 a dry place away from direct sunlight and moisture.
Store in the original package until required for use.

6.5 Nature and contents of container
30s: 175 ml white plastic container with a white plastic screw-on cap, containing 30 chewable tablets, packed into an outer carton.
10s: blister strip containing 10 chewable tablets, packed into an outer carton.
Pack sizes: 10 / 30 chewable tablets.

6.6 Special precautions for disposal and other handling
No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION
Biogen
23 Stag Road
Glen Austin
South Africa
Tel: 0860 347 243
Email: info@biogen.co.za
Website: www.biogen.co.za

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

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
Will be allocated by SAHPRA upon registration.