

## 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 FOR HER (vegetarian capsules)**

#### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vegetarian capsule contains:

HOWARU® *Lactobacillus rhamnosus*

*Lactobacillus reuteri*

Oraforti® Synergy1 (Oligofructose-enriched inulin)

CFU = Colony Forming Units

Sugar free

2,50 Billion CFU

2,50 Billion CFU

50,00 mg

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

#### 3. PHARMACEUTICAL FORM

Capsules.

Size 0, white vegetable capsules.

#### 4. CLINICAL PARTICULARS

##### 4.1 Therapeutic indications

BIOGEN SUPREME PROBIOTIC FOR HER 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

*Adults and children 12 years and older:*

Take 1-2 capsules daily with food, or as recommended by a healthcare provider. Do not exceed the recommended daily dosage.

##### 4.3 Contraindications:

- Hypersensitivity to any of the active ingredients listed in section 2 or excipients listed in 6.1.

##### 4.4 Special warnings and precautions for use

- *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 SUPREME PROBIOTIC FOR HER 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 FOR HER 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 FOR HER does not adversely affect their performance.

##### 4.8 Undesirable effects

###### Gastrointestinal disorders

*Less frequent:* diarrhoea, constipation.

###### Immune system disorders

*Frequency unknown:* pathological 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

Some preparations of *Lactobacillus rhamnosus* and *Lactobacillus reuteri* may behave as probiotics and colonize the large bowel.

### 6. PHARMACEUTICAL PARTICULARS

#### 6.1 List of excipients

Aerosil

Magnesium stearate

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.

#### 6.5 Nature and contents of container

175 ml white plastic container with a white screw-on cap.

Pack sizes: 30 capsules.

#### 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

Will be allocated by SAHPRA upon registration.

### 10. DATE OF REVISION OF THE TEXT

September 2025