

PROFESSIONAL INFORMATION
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 LACTORASE CHEWABLE TABLETS
2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each chewable tablet contains:

Tolerase® L (pH-stable lactase from <i>Aspergillus oryzae</i>)	100 mg
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Contains sweetener (31 mg Sucralose) per chewable tablet.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Chewable tablets.

4. CLINICAL PARTICULARS
4.1 Therapeutic indications

BIOGEN LACTORASE is indicated for lactose-intolerant patients to assist with the management of digestion of dairy.

4.2 Posology and method of administration

For moderate lactose-intolerance:

Chew 1 tablet on consuming lactose based foods / dairy products.

For severe lactose-intolerance:

Chew 2 tablets on consuming lactose based foods / dairy products.

Dosage can be adjusted according to individual requirements, or as recommended by a healthcare practitioner. Do not exceed 3 tablets at once.

4.3 Contraindications:

- Hypersensitivity to any of the excipients listed in 6.1.

4.4 Special warnings and precautions for use

- The dose of BIOGEN LACTORASE is dependent of the amount of lactose and the size of the meal consumed. In general, a larger meal remains in the stomach for longer and therefore less enzyme is required than when the same amount of lactose is consumed with a light, meal or just a glass of milk.
- BIOGEN LACTORASE is not recommended in children younger than 18 years, as the safety and efficacy in children have not yet been established.
- Use this product in conjunction with food as part of a healthy, balanced diet, not as a substitute for such.
- Tolerance to lactose is variable and individuals with lactose intolerance should seek advice as to the role of this substance in their diet.
- Do not exceed the recommended daily dosage.

4.5 Interaction with other medicines and other forms of interaction

Interactions are not expected. Give your health care provider a list of all the medicines, herbs, non-prescription drugs, or dietary supplements you use.

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 LACTORASE are generally well tolerated and will not affect the ability to drive a vehicle and use machines (see section 4.8).

Caution is advised before driving a vehicle or operating machinery.

4.8 Undesirable effects

In general, side effects have not been reported with the use of lactase. BIOGEN LACTORASE is generally well tolerated.

Immune system disorders:

Frequent: hypersensitivity reactions.

Gastrointestinal disorders:

Frequent: stomach pain, regurgitation, heartburn, nausea, dyspepsia, diarrhoea, constipation.

Skin and subcutaneous tissue disorders:

Frequent: rash; hives; itching; red, swollen, blistered, peeling skin, or swelling of the mouth, face, lips, tongue, or throat.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of BIOGEN LACTORASE is important. It allows continued monitoring of the benefit/risk balance of BIOGEN LACTORASE. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the **Adverse Drug Reaction Reporting Form**, found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>.

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

Category and class: D 34.5 Enzymes.

BIOGEN LACTORASE from Tolerase® L is an acid lactase that converts lactose into glucose and galactose. The enzyme originates from a special strain of the fungus *Aspergillus oryzae*. Its activity at low pH (3.5 – 5.5) makes this lactase particularly effective to digest lactose in the stomach and is therefore ideal for use in dietary supplements as a digestive aid.

6. PHARMACEUTICAL PARTICULARS
6.1 List of excipients

Calcium carbonate, Micro-cellulose, Silicon dioxide, Flavouring, Citric acid anhydrous, Magnesium stearate.

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.

KEEP OUT OF REACH OF CHILDREN.

6.5 Nature and contents of container

175 ml PET Container

Pack sizes: 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

info@biogen.co.za

www.biogen.co.za

Tel: 011 589 2322

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.

10. DATE OF REVISION OF THE TEXT

April 2021.

JOB: BPS_Lactorase_30s		SIZE: 210mm x 344mm	
STOCK: Foil Substrate: <input type="checkbox"/> Clear Substrate: <input type="checkbox"/> White Substrate: <input type="checkbox"/> Paper: <input checked="" type="checkbox"/> Other: <input type="checkbox"/>			
COLOUR:		FINISHING:	
 K		<input type="checkbox"/> Foil / Holographic Foil <input type="checkbox"/> Matte <input type="checkbox"/> Gloss <input type="checkbox"/> Spot UV <input type="checkbox"/> Doming <input type="checkbox"/> Embossing	
PLEASE CHECK CAREFULLY Although we endeavour to proof accurately, we cannot accept responsibility for errors once proofs are signed and accepted by our clients.			

