

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 *Aspergillus oryzae*) 100 mg

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.

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PATIENT INFORMATION LEAFLETSCHEDULING STATUS: SO**LACTORASE CHEWABLE TABLETS**

Each chewable tablet contains:

Tolerase® L (pH-stable lactase from *Aspergillus oryzae*) 100 mg

Contains sweetener (31 mg Sucralose) per chewable tablet.

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.

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

BIOGEN LACTORASE is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to take BIOGEN LACTORASE carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share BIOGEN LACTORASE with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.

What is in this leaflet

1. What BIOGEN LACTORASE is and what it is used for.
2. What you need to know before you take BIOGEN LACTORASE.
3. How to take BIOGEN LACTORASE.
4. Possible side effects.
5. How to store BIOGEN LACTORASE.
6. Contents of the pack and other information.

1. What BIOGEN LACTORASE is and what it is used for

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

2. What you need to know before you take BIOGEN LACTORASE**Do not take BIOGEN LACTORASE:**

- If you are hypersensitive (allergic) to any of the ingredients of BIOGEN LACTORASE (see section 6).

Warnings and precautions**Take special care with BIOGEN LACTORASE:**

- Do not take BIOGEN LACTORASE if you are younger than 18 years, as safety and efficacy 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.

Other medicines and BIOGEN LACTORASE

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Interactions are not expected.

BIOGEN LACTORASE with food and drink

The requirement of a lactase enzyme 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.

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.

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 provider for advice before taking BIOGEN LACTORASE.

Safety of BIOGEN LACTORASE during pregnancy and lactation has not been established. Do not take BIOGEN LACTORASE while pregnant or breastfeeding.

Driving and using machinery

BIOGEN LACTORASE are generally well tolerated and will not affect the ability to drive a vehicle and use machines (see section 4).

Caution is advised before driving a vehicle or operating machinery until the effects of BIOGEN LACTORASE are known.

3. How to take BIOGEN LACTORASE

Do not share your medicines with any other person.

Always take BIOGEN LACTORASE exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

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.

If you take more BIOGEN LACTORASE than you should

In the event of an overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

Take this leaflet and the rest of the BIOGEN LACTORASE with you so the doctor will know what you have taken.

If you forget to take BIOGEN LACTORASE

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

In general, side effects have not been reported with the use of lactase. BIOGEN LACTORASE is generally well tolerated. Should your general health worsen or if you experience any untoward effects while taking BIOGEN LACTORASE, please consult your healthcare provider for advice.

If any of the following happens, stop taking BIOGEN LACTORASE and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to BIOGEN LACTORASE. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Side effects with unknown frequency:

- Stomach pain, regurgitation, heartburn, nausea, dyspepsia, diarrhoea, constipation.
- Rash; hives; itching; red, swollen, blistered, peeling skin, or swelling of the mouth, face, lips, tongue, or throat.

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

Reporting of side effectsIf you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the Adverse Drug Reactions Reporting Form, found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of BIOGEN LACTORASE.**5. How to store BIOGEN LACTORASE**

- Store at or below 25 °C.
- Protect from light and moisture.
- Store all medicines out of reach of children.
- Do not use after the expiry date printed on the container.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information**What BIOGEN LACTORASE contains**

Each chewable tablet contains:

Tolerase® L (pH-stable lactase from *Aspergillus oryzae*) 100 mg

Contains sweetener (31 mg Sucralose) per chewable tablet.

The other ingredients are Calcium carbonate, Micro-cellulose, Silicon dioxide, Flavouring, Citric acid anhydrous, Magnesium stearate.

What BIOGEN LACTORASE looks like and contents of the pack

Small round, white tablet, packed in a 175 ml PET container.

Pack sizes: 30 chewable tablets.

Holder of certificate of registrationBiogen
23 Stag Road, Glen Austin, South Africa
info@biogen.co.za
www.biogen.co.za
Tel: 011 589 2322

This pamphlet was last revised in April 2021.

Registration number
Will be allocated by SAHPRA upon registration.**JOB:** BPS_Lactorase_30s**SIZE:** 210mm x 344mm**STOCK:** Foil Substrate: Clear Substrate: White Substrate: Paper: Other: **COLOUR:****FINISHING:**

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PASIËNTINLIGTINGSBLADSKEDULERINGSTATUS: SO**LACTORASE KOUBARE TABLETTE**

Elke koubare tablet bevat:

Tolerase® L (pH-stabile laktase van *Aspergillus oryzae*)

100 mg

Bevat versetero (31 mg Sukralose) per koubare tablet.

Aanvullende Medisyne: Gesondheidsaanvulling

Hierdie ongeregistreerde medisyne is nie vir gebruik veiligheid en beoogde gebruik deur SAHPRA geëvalueer nie.

Gesondheidsaanvullings diens slegs as aanvulling tot gesondheid of dieet.

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

BIOGEN LACTORASE is beskikbaar sonder 'n dokter se voorskrif, sodat jy jou gesondheid kan onderhou. Jy moet BIOGEN LACTORASE nie temeinlik versigtig neem om die beste resultate te verkry.

- Hou hierdie inligtingsblad. Dit mag nodig wees dat jy dit weer lees.
- Moenie BIOGEN LACTORASE met iemand anders deel nie.
- Vra gerus jou gesondheidsorgverskaffer of apoteker indien jy verdere inligting van advies nodig het.

Wat jy in hierdie inligtingsblad kan kry

1. Wat is BIOGEN LACTORASE en waarvoor word dit gebruik.
2. Wat jy moet weet voor dat jy BIOGEN LACTORASE neem.
3. Hoe om BIOGEN LACTORASE te neem.
4. Moontlike newe-effekte.
5. Hoe om BIOGEN LACTORASE te bêre.
6. Inhoud van die verpakking en ander inligting.

1. Wat is BIOGEN LACTORASE en waarvoor word dit gebruik

BIOGEN LACTORASE word aangedui vir pasiënte wat 'n onverdraagsaamheid teenoor laktose, dit help met die vertering van suwelprodukte.

2. Wat u moet weet voor dat u BIOGEN LACTORASE neem

Moenie BIOGEN LACTORASE neem nie:

- Indien jy hypersensitief (allergies) is vir enige van die bestanddele van BIOGEN LACTORASE (sien afdeling 6).

Waarskuwings en voorsorgmaatreëls

Wees versigtig met BIOGEN LACTORASE:

- Moenie BIOGEN LACTORASE neem as u jonger as 18 jaar is nie, aangesien veiligheid en doeltreffendheid nog nie vasgestel is nie.
- Gebruik hierdie produk saam met voedsel as deel van 'n gesonde, gebalaseerde dieet, nie as 'n plaasvervanger daarvoor nie.
- Verdraagsaamheid teenoor laktose is wisselvallig en individue met 'n laktose-intoleransie moet raad vra oor die rol van hierdie bestanddeel in hul dieet.
- Moenie nie die aanbeveelde dosis oorskry nie.

Ander medisyne en BIOGEN LACTORASE

Sé altyd vir jou gesondheidsorgverskaffer indien jy enige ander medisyne neem. (Dit sluit alle aanvullende of tradisionele medisyne in.)

Interaksies word nie verwag nie.

BIOGEN LACTORASE met kos en drankgoed

Die vereiste van 'n laktose-ensiem hang af van die hoeveelheid laktose en die grootte van die maaltyd. Oor die algemeen bly 'n groter maaltyd langer in die maag en daarom is minder ensieme nodig as dieselfde hoeveelheid laktose saam met 'n ligte maaltyd of net in glas melk geneem was.

Gebruik hierdie produk saam met voedsel as deel van 'n gesonde, gebalaseerde dieet, nie as 'n plaasvervanger daarvoor nie. Verdraagsaamheid teenoor laktose is wisselvallig en individue met laktose-intoleransie moet raad vra oor die rol van hierdie bestanddeel in hul dieet.

Swangerskap, borsvoeding en vrugbaarheid

Indien jy swanger is of jou baba borsvoed, vermoed dat jy swanger mag wees of beplan om swanger te raak, raadpleeg asseblieke jou dokter, apoteker of ander gesondheidsorgverskaffer voordat jy BIOGEN LACTORASE neem.

Dit is nie vasgestel dat BIOGEN LACTORASE veilig is om te gebruik tydens swangerskap en borsvoeding nie. Moenie BIOGEN LACTORASE gebruik indien jy swanger is of jou baba borsvoed nie.

Bestuur en die gebruik van masjinerie

BIOGEN LACTORASE word oor die algemeen goed verdra en beïnvloed nie die vermoë om 'n voertuig te bestuur en masjinerie te gebruik nie (sien afdeling 4).

Wees versigtig voordat u 'n voertuig bestuur of masjinerie gebruik totdat die effekte van BIOGEN LACTORASE bekend is.

3. Hoe om BIOGEN LACTORASE te neem

Moenie jou medisyne met enigemand anders deel nie.

Neem BIOGEN LACTORASE altyd presies soos wat in hierdie inligtingsblad aangedui word, of soos wat jou dokter of apoteker vir u aangegewys het. Vir gerus jou dokter of apoteker indien jy onseker is.

Vir matige laktose-onverdraagsaamheid:

Kou 1 tablet aan die verbruik van laktose-voedsel / suiwelprodukte.

Vir erg laktose-onverdraagsaamheid:

Kou 2 tablette oor die verbruik van laktose-voedsel / suiwelprodukte.

Die dosis kan aangepas word volgens individuele vereistes, of soos aanbeveel deur 'n mediese praktyk. Moenie drie tablette gelukkig oorskry nie.Vir die optimale effek is die minimum behandelingstydperk 3 maande.

Wat om te doen indien jy meer BIOGEN LACTORASE geneem het as wat jy moet

In die geval van 'n oordosis, raadpleeg jou dokter of apoteker. Indien nie een van hulle beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.

Neem hierdie inligtingsblad en die corblywende BIOGEN LACTORASE saam sodat die dokter kan sien wat jy ingeneem het.

Indien jy vergeet om BIOGEN LACTORASE te neem

Moenie 'n dubbele dosis neem om te vergoed vir individuele dosisse wat vergeet is nie.

4. Moontlike newe-effekte

Oor die algemeen is newe-effekte nie met die gebruik van laktase gerapporteer nie. BIOGEN LACTORASE word oor die algemeen goed verdra.

Raadpleeg u gesondheidsorgverskaffer vir advies indien u algemene gesondheid vererger of as u enige ongewenste effekteervaar tydens die gebruik van BIOGEN LACTORASE.

Indien jy enige van die volgende ondervind, hou op om BIOGEN LACTORASE te neem en sê dadelik vir jou dokter of gaan na die ongevalle-afdeling by jou naaste hospitaal:

- Swelling van die hande, voete, enkels, gesig, lippe, mond of keel, wat probleme kan veroorsaak met slik en asemhaling.
- Uitslag of gejuk.
- Floute.

Dit is alles baie ernstige newe-effekte. As u dit het, het u moontlik 'n ernstige allergiese reaksie op BIOGEN LACTORASE gehad. U benodig moontlik dringende mediese hulp of hospitalisasie.

Vertel u dokter as u een van die volgende opmerk:

Newe-effekte met onbekende frekwensie:

- Maagpyn, herhaling, soorbrand, naaheid, dispepsie, diarree, hardlywigheid.
- Uitslag; korwe; jeuk; rooi, geswelle, geblaasde, afskilferende vel of swelling van die mond, gesig, lippe, tong of keel.

As u enige newe-effekte opmerk wat nie in hierdie pamphlet genoem word nie, moet u u dokter of apoteker daarvan in kennis stel.

Rapportering van newe-effekteIndien jy newe-effekte ondervind, bespreek dit met jou dokter of apoteker. Jy kan ook newe-effekte aan SAHPRA rapporteer via die vorm om ongurende geneesmiddelreaksies te rapporteer, wat aanlyn by SAHPRA se publikasies beskikbaar is: <http://www.sahpra.org.za/Publications/Index/8>.

Deur newe-effekte te rapporteer kan jy help om meer inligting rakende die veiligheid van BIOGEN LACTORASE te verskaf.

5. Hoe om BIOGEN LACTORASE te bêre

- Bêre by of onder 25 °C.
- Beskerm teen lig en vog.
- Bêre alle medisyne buite bereik van kinders.
- Moenie gebruik nie dalk