

PATIENT INFORMATION LEAFLET
SCHEDULING STATUS: [S0]

BIOGEN PROBIOTIC CHEWS (Strawberry Flavoured Chewable tablets).
Each chewable tablet contains:

 HOWARU® *Lactobacillus acidophilus*, HOWARU® *Lactobacillus rhamnosus*, *Lactobacillus casei*, *Lactobacillus reuteri*, *Lactobacillus gasseri*, *Lactobacillus salivarius* Ls-33, HOWARU® *Bifidobacterium lactis*, *Bifidobacterium bifidu*, *Bifidobacterium longum* and Orafti® Synergy1.

Contains sugar (0,4 g Sorbitol) per chewable tablet.

Contains sweetener (1 mg steviol glycosides) per chewable tablet.

D 34.9 Probiotics 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 PROBIOTIC CHEWS is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to take BIOGEN PROBIOTIC CHEWS carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share BIOGEN PROBIOTIC CHEWS 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 PROBIOTIC CHEWS is and what it is used for.
2. What you need to know before you take BIOGEN PROBIOTIC CHEWS.
3. How to take BIOGEN PROBIOTIC CHEWS.
4. Possible side effects.
5. How to store BIOGEN PROBIOTIC CHEWS.
6. Contents of the pack and other information.

1. What BIOGEN PROBIOTIC CHEWS is and what it is used for

BIOGEN 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.

2. What you need to know before you take BIOGEN PROBIOTIC CHEWS
Do not take Probiotic Junior Chews:

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

Warnings and precautions

Take special care with BIOGEN PROBIOTIC CHEWS:

- Use this product in conjunction with food as part of a healthy, balanced diet, not as a substitute for such.
- BIOGEN PROBIOTIC CHEWS contains sorbitol.
- If you have been told that you have an intolerance to some sugars, you should not take BIOGEN PROBIOTIC CHEWS.
- May have a laxative effect.
- Might cause gastrointestinal reactions.
- Do not exceed the recommended daily dosage.

Other medicines and BIOGEN PROBIOTIC CHEWS

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

Antibiotics might decrease the effects of probiotics (bifidobacterial and lactobacillus species).

Advise patients to take antibiotics and this product at least 2 hours apart. Avoid taking probiotics (bifidobacterial and lactobacillus species) during digestive tract surgery, as it might contribute to infection.

Lactobacillus could cause infection in patients with short bowel syndrome, who are immunocompromised, or who are taking immunosuppressants such as cyclosporine, tacrolimus, azathioprine and cancer chemotherapeutic agents like cyclophosphamide and cisplatin.

BIOGEN PROBIOTIC CHEWS with food and drink

Use this product in conjunction with food as part of a healthy, balanced diet, not as a substitute for such.

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 PROBIOTIC CHEWS.

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

Driving and using machinery

BIOGEN PROBIOTIC CHEWS 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 PROBIOTIC CHEWS are known.

3. How to take BIOGEN PROBIOTIC CHEWS

Do not share your medicines with any other person.

Always take BIOGEN PROBIOTIC CHEWS 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.

Children ages 3 years and older:

Chew 1 chew tablet daily, or as recommended by a healthcare practitioner.

If you take more BIOGEN PROBIOTIC CHEWS 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 PROBIOTIC CHEWS with you so the doctor will know what you have taken.

If you forget to take BIOGEN PROBIOTIC CHEWS

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

4. Possible side effects

BIOGEN PROBIOTIC CHEWS can have side effects.

Not all side effects reported for BIOGEN PROBIOTIC CHEWS are included in this leaflet. Should your general health worsen or if you experience any untowards effects while taking BIOGEN PROBIOTIC CHEWS, please consult your healthcare provider for advice.

Side effects associated with BIOGEN PROBIOTIC CHEWS:

- Frequent:* Diarrhoea, dry mouth, vomiting, and abdominal pain or discomfort.
Frequency unknown: Rash or itching.

Should your general health worsen or if you experience any untoward effects while taking BIOGEN PROBIOTIC CHEWS, please consult your healthcare provider for advice.

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

Reporting of side effects

 If 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: <http://www.sahpra.org.za/Publications/Index/8>.

By reporting side effects, you can help provide more information on the safety of BIOGEN PROBIOTIC CHEWS.

5. How to store BIOGEN PROBIOTIC CHEWS

- 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 PROBIOTIC CHEWS contains
Each chewable tablet contains:

 HOWARU® *Lactobacillus acidophilus*

 HOWARU® *Lactobacillus rhamnosus*
Lactobacillus casei
Lactobacillus reuteri
Lactobacillus gasseri
Lactobacillus salivarius Ls-33

 HOWARU® *Bifidobacterium lactis*
Bifidobacterium bifidum
Bifidobacterium longum

Orafti® Synergy1 (Inulin and Oligofructose)

CFU = Colony Forming Units

Contains sugar (0,4 g Sorbitol) per chewable tablet.

Contains sweetener (1 mg Steviol glycosides) per chewable tablet.

The other ingredients are Fumed silica, Sorbitol, Magnesium stearate, Flavouring.

What BIOGEN PROBIOTIC CHEWS looks like and contents of the pack

Small oval, white to light pink chewable tablet.

Pack sizes: 10's/30's.

Chewable tablets in a 175 ml PET container packed in a unit carton.

Chewable tablets in blisters packed in a unit carton.

Holder of certificate of registration

 Biogen,
 23 Stag Rd,
 Glen Austin,
 South Africa.

This pamphlet was last revised in

September 2022.

Registration number

Will be allocated by SAHPRA upon registration.

PASIËNTINLIGTINGSBLAD
SKEDULERINGSTATUS: [S0]

BIOGEN PROBIOTIC CHEWS (Aarbei gekeurde Koubare tablette).
Elke koubare tablet bevat:

 HOWARU® *Lactobacillus acidophilus*, HOWARU® *Lactobacillus rhamnosus*, *Lactobacillus casei*, *Lactobacillus reuteri*, *Lactobacillus gasseri*, *Lactobacillus salivarius* Ls-33, HOWARU® *Bifidobacterium lactis*, *Bifidobacterium bifidu*, *Bifidobacterium longum* and Orafti® Synergy1.

Bevat suiker (0,4 g sorbitol) per koubare tablet.

Bevat versoeter (1 mg Steviol glikosiede) per koubare tablet.

D 34.9 Probiotika Aanvullende Medisyne: Gesondheidsaanvulling

Hierdie ongeregistreerde medisyne is nie vir gehalte, veiligheid of beoogde gebruik deur SAHPRA geëvalueer nie. Gesondheidsaanvullings dien slegs as aanvulling tot gesondheid of dieet.

Lees hierdie hele inligtingsblad aandagtig deur want dit bevat inligting wat belangrik is vir jou.

BIOGEN PROBIOTIC CHEWS is beskikbaar sonder 'n dokter se voorskrif, sodat jy jou gesondheid kan onderhou. Jy moet BIOGEN PROBIOTIC CHEWS nietermin steeds versigtig neem om die beste resultate te verkry.

- Hou hierdie inligtingsblad. Dit mag nodig wees dat jy dit weer lees.
- Moenie BIOGEN PROBIOTIC CHEWS met enigiemand anders deel nie.
- Vra gerus jou gesondheidsorgverskaffer of apteker indien jy verdere inligting of advies nodig het.

Wat is in hierdie inligtingsblad

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

1. Wat is BIOGEN PROBIOTIC CHEWS en waarvoor word dit gebruik

BIOGEN PROBIOTIC CHEWS kan die mikrobie se balans in die ingewande verbeter en herstel, en sodoende die werking van die spysverteringskanaal verbeter as dit gereeld ingeneem word.

2. Wat jy moet weet voordat jy BIOGEN PROBIOTIC CHEWS neem
Moenie BIOGEN PROBIOTIC CHEWS neem nie:

- Indien jy hipersensitief (allergies) is vir enige van die bestanddele van BIOGEN PROBIOTIC CHEWS (sien afdeling 6).

Waarskuwings en voorsorgmaatreëls

Wees versigtig met BIOGEN PROBIOTIC CHEWS :

- Gebruik hierdie produk saam met voedsel as deel van 'n gesonde, gebalanseerde dieet, nie as 'n plaasvervanger daarvoor nie.
- BIOGEN PROBIOTIC CHEWS bevat sorbitol.
- As u gesê is dat u sommige suikers nie goed verdra nie, moet u nie BIOGEN PROBIOTIC CHEWS neem nie.
- Kan 'n laksasemiddel hê.
- Kan gastro-intestinale reaksies veroorsaak.
- Moet nie die aanbevole daaglikse dosis oorskry nie.

Ander medisyne en BIOGEN PROBIOTIC CHEWS

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

Antibiotika kan die gevolge van probiotika (bifidobakteriële en lactobacillus spesies) verminder.

Beveel pasiënte aan om antibiotika en hierdie middel met minstens 2 uur uittekaar te neem. Vermoed probiotika (bifidobakteriese en lactobacillus spesies) tydens spysverterings-operasies, dit mag bydra tot infeksie.

Lactobacillus kan infeksie veroorsaak by pasiënte met kort-dermsindroom, wat se immuun onder, is, en wat immuunonderdrukkers neem soos siklosporien, takrolimus, azatioprien- en kankerchemoterapeutiese middels soos siklofosfamied en cisplatin.

BIOGEN PROBIOTIC CHEWS saam met kos en drinkgoed

Gebruik hierdie produk saam met voedsel as deel van 'n gesonde, gebalanseerde dieet, nie as 'n plaasvervanger daarvoor nie.

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 asseblief jou dokter, apteker of ander gesondheidsorgverskaffer voordat jy BIOGEN PROBIOTIC CHEWS neem.

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

Bestuur en die gebruik van masjiene

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

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

3. Hoe om BIOGEN PROBIOTIC CHEWS te neem

Moenie jou medisyne met enigiemand anders deel nie.

Neem BIOGEN PROBIOTIC CHEWS altyd presies soos wat in hierdie inligtingsblad aangedui word, of soos wat jou dokter of apteker vir jou aangewys het. Vra gerus jou dokter of apteker indien jy onseker is.

Kinders 3 jaar en ouer:

Kou 1 koutablet daaglik, of soos aanbeveel deur 'n mediese praktisyn.

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

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

Neem hierdie inligtingsblad en die oorblywende BIOGEN PROBIOTIC CHEWS saam sodat die dokter kan sien wat jy ingeneem het.

Indien jy vergeet om BIOGEN PROBIOTIC CHEWS te neem

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

4. Moontlike newe-effekte

BIOGEN PROBIOTIC CHEWS kan newe-effekte hê.

Nie alle newe-effekte wat aangemeld is vir BIOGEN PROBIOTIC CHEWS is in hierdie voulijet ingesluit nie. Indien u algemene gesondheid vererger, of as u ongewenste gevolge ervaar tydens die gebruik van BIOGEN PROBIOTIC CHEWS, raadpleeg u gesondheidsorgverker vir advies.

Newe-effekte geassosieer met BIOGEN PROBIOTIC CHEWS:

- Algemeen:* Diarree, droë mond, braking, en buikpyn of ongemak.
Frekwensie onbekend: Uitslag of jeuk.

Raadpleeg u dokter, apteker of ander geneesheer vir advies indien u algemene gesondheid vererger of as u enige ongewenste effekte ervaar terwyl BIOGEN PROBIOTIC CHEWS neem.

As u enige newe-effekte opmerk wat nie in hierdie inligtingstuk genoem word nie, moet u dokter of apteker daarvan in kennis ste

Rapportering van newe-effekte

 Indien jy newe-effekte ondervind, bespreek dit met jou dokter of apteker. Jy kan ook newe-effekte aan SAHPRA rapporteer via die vorm om ongunstige 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 PROBIOTIC CHEWS te verskaf.

5. Hoe om BIOGEN PROBIOTIC CHEWStE bêre

- Bêre by of onder 25 °C.
- Beskerm teen lig en vog.
- Bêre alle medisyne buite bereik van kinders.
- Moenie gebruik ná die vervaldatum wat op die produk gedruk is nie.
- Neem alle ongebruikte medisyne terug na jou apteker.
- Moenie ongebruikte medisyne in dreine en rioolsisteme (bv. toilette) weggooi nie.

6. Inhoud van die pak en ander inligting
Wat BIOGEN PROBIOTIC CHEWS bevat
Elke koubare tablet bevat:

 HOWARU® *Lactobacillus acidophilus*

 HOWARU® *Lactobacillus rhamnosus*
Lactobacillus casei
Lactobacillus reuteri
Lactobacillus gasseri
Lactobacillus salivarius Ls-33

 HOWARU® *Bifidobacterium lactis*
Bifidobacterium bifidum
Bifidobacterium longum

Orafti® Synergy1 (Inulien en Oligofruktose)

KVE = Kolonievormende Eenhede

Bevat suiker (0,4 g sorbitol) per koubare tablet.

Bevat versoeter (1 mg Steviol glikosiede) per koubare tablet.

Die ander bestanddele is Silikondioksied, Sorbitol, Magnesiumstearaat, Geurmiddel.

Hoe BIOGEN PROBIOTIC CHEWS lyk en inhoud van die verpakking

Klein ovaal, wit to ligpink koubare tablette.

Verpakkingsgroottes: 10's/30's.

Koubaretablette in 'n 175 ml PET houer gepak in 'n karton boksie.

Koubaretablette in 'n blister gepak in 'n karton boksie.

Houer van die registrasiesertifikaat


 Biogen,
 23 Stag weg,
 Glen Austin,
 Suid Afrika.

Hierdie inligtingsblad is laas hersien in

September 2022.

Registrasienuommer

Sal met registrasie deur SAHPRA toegeken word.

JOB: BPS_Probiotic Chews_10s		SIZE: 246mm x 341mm	
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"/> Dorrning <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.			