

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S0

SYMBIO-D

Lactobacillus acidophilus, lactobacillus reuteri, streptococcus thermophilus, lactococcus lactis, enterococcus faecium, bacillus subtilis, lactobacillus casei, bifidobacterium longum, bromelain, dicalcium phosphate dihydrate, folic acid, pyridoxine hydrochloride (vitamin B₆), riboflavin (vitamin B₂), thiamine hydrochloride (vitamin B₁), cholecalciferol (vitamin D₃).

Contains sweetener: Each enteric-coated tablet contains 200 mg sorbitol (E420).

Salmon oil blend [providing eicosapentaenoic acid (EPA), docosahexaenoic acid (DHA) and alpha-tocopherol acetate (vitamin E)].

Sugar free.

COMPLEMENTARY MEDICINE: COMBINATION PRODUCT

This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

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

SYMBIO-D is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to use SYMBIO-D carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your healthcare provider or pharmacist if you need more information or advice.

What is in this leaflet

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

1. What SYMBIO-D is, and what it is used for

SYMBIO-D is an 8-strain probiotic with added omega-3. SYMBIO-D may assist to promote and maintain gut health, support cognitive health and/or brain function, and also maintain and support cardiovascular health.

2. What you need to know before you take SYMBIO-D

Do not take SYMBIO-D:

- if you are hypersensitive (allergic) to fish (and shellfish) or any of the other ingredients of SYMBIO-D (see **What SYMBIO-D contains**).

Warnings and precautions

SYMBIO-D contains Salmon Oil. If you have a known hypersensitivity/allergy to fish (and shellfish), do not take SYMBIO-D.

Other medicines and SYMBIO-D:

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

SYMBIO-D with food and drink

See section 3 (**How to take SYMBIO-D**).

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 this medicine.

Safety and efficacy of SYMBIO-D during pregnancy and breastfeeding have not been established. Do not use this medicine if you are pregnant or breastfeeding your baby. There is no evidence that SYMBIO-D will cause harm to you or your baby during pregnancy or breastfeeding.

Driving and using machines

Safety and efficacy when driving or operating machines have not been established. Do not drive a vehicle, operate machines, or do anything else that requires your attention until you know how SYMBIO-D affects you.

SYMBIO-D contains sorbitol (E420):

SYMBIO-D contains sorbitol, which is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars, talk to your doctor before you (or your child) take or receive this medicine.

Sorbitol may cause gastrointestinal discomfort and a mild laxative effect.

SYMBIO-D contains Salmon Oil:

SYMBIO-D contains Salmon Oil. If you have a known hypersensitivity/allergy to fish (and shellfish), do not take SYMBIO-D.

3. How to take SYMBIO-D

Do not share your medicines with any other person.

Always take SYMBIO-D 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.

The usual dose is:

Adults and children from 12 years of age: Take 1 enteric-coated tablet and 1 softgel capsule daily.

If you have the impression that the effect of SYMBIO-D is too strong or too weak, tell your doctor or pharmacist.

Do not exceed the recommended dosage.

SYMBIO-D can be taken with or without food.

SYMBIO-D is for oral use only and should be swallowed with sufficient liquid.

If you take more SYMBIO-D than you should

In the event of 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 remaining SYMBIO-D with you so the doctor will know what you have taken.

4. Possible side effects

SYMBIO-D can have side effects.

Not all side effects reported for SYMBIO-D are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking SYMBIO-D, please consult your healthcare provider for advice.

If any of the following happens, stop taking SYMBIO-D 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 SYMBIO-D. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- chest pain;
- angina;

- changes in the way your heart beats, for example, if you notice it beating faster;
- difficulty breathing.

These are all serious side effects. You may need urgent medical attention.

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 “6.04 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 SYMBIO-D.

5. How to store SYMBIO-D

- Store all medicines out of reach of children.
- Store at or below 25 °C in a cool, dry place, protected from light (enteric-coated tablet).
- Store in a refrigerator after opening, as the product is not encapsulated (softgel capsule).
- Do not store in a bathroom.
- Do not use after the expiry date printed on the carton.
- Store in the original packaging.
- 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 SYMBIO-D contains

Each enteric-coated tablet contains:

The active substances are:

<i>Lactobacillus acidophilus</i>	9.5 x 10 ⁸ CFU* (9,5 mg)
<i>Lactobacillus reuteri</i>	6 x 10 ⁸ CFU* (3 mg)
<i>Streptococcus thermophilus</i>	6.5 x 10 ⁸ CFU* (6,5 mg)
<i>Lactococcus lactis</i>	6 x 10 ⁸ CFU* (2 mg)
<i>Enterococcus faecium</i>	9.6 x 10 ⁷ CFU* (0,32 mg)
<i>Bacillus subtilis</i>	6.3 x 10 ⁷ CFU* (0,63 mg)
<i>Lactobacillus casei</i>	6.3 x 10 ⁷ CFU* (0,21 mg)
<i>Bifidobacterium longum</i>	5 x 10 ⁸ CFU* (10 mg)
Bromelain	100 µg
Dicalcium Phosphate dihydrate	625 mg
providing calcium (elemental)	118 mg
providing phosphorus (elemental)	92 mg
Folic acid	200 µg
Pyridoxine Hydrochloride	10,4 mg
providing pyridoxine (Vitamin B ₆)	8,5 mg
Riboflavin (Vitamin B ₂)	5,5 mg
Thiamine Hydrochloride	7,1 mg
providing thiamine (Vitamin B ₁)	5,5 mg
Cholecalciferol (Vitamin D ₃)	10 µg (400 I.U.)

*CFU – Colony-Forming Unit

The other ingredients are magnesium stearate (E572), microcrystalline cellulose (E460), Opadry enteric white (coating).

Contains sweetener: Each enteric-coated tablet contains 200 mg sorbitol (E420).

Each Omega-3 softgel capsule contains:

Salmon Oil Blend	1 000 mg
providing Eicosapentaenoic acid (EPA)	120 mg
providing Docosahexaenoic acid (DHA)	80 mg
Alpha-tocopherol acetate (Vitamin E)	5 mg

The other ingredient is gelatine capsule (bovine).

Sugar free.

What SYMBIO-D looks like and contents of the pack

30 enteric-coated probiotic tablets in an amber glass bottle with a silver lid, packed inside a carton. The tablets are white to off-white in colour.

30 Omega-3 softgel capsules in an amber glass bottle with a gold lid, packed inside a carton. The softgel capsules contain a yellowish oil.

Holder of Certificate of Registration

Brunel Laboratoria (Pty) Ltd

1 Van Tonder Street

Sunderland Ridge

Centurion

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This leaflet was last revised in

Will be allocated by SAHPRA upon registration.

Registration number

Will be allocated by SAHPRA upon registration.

Access to the corresponding Professional Information

The Professional Information for SYMBIO-D is available on <https://www.brunel.co.za/professional-information/> or can be requested from the contact details above.

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PASIËNTINLIGTINGSBLAD

SKEDULERINGSSTATUS

S0

SYMBIO-D

Lactobacillus acidophilus, lactobacillus reuteri, streptococcus thermophilus, lactococcus lactis, enterococcus faecium, bacillus subtilis, lactobacillus casei, bifidobacterium longum, bromelien, dikalsiumfosfaatdihidraat, foliensuur, piridoksien hidrokloried (vitamien B₆), riboflavin (vitamien B₂), tiamien hidrokloried (vitamien B₁), cholekalsiferol (vitamien D₃).

Bevat versoeter: Elke enteries-bedekte tablet bevat 200 mg sorbitol (E420).

Salmolie mengsel [lewer eikosapentanoësuur (EPA), dokosaheksanoësuur (DHA) en alfa-tokoferol asetaat (vitamien E)].
Suikervry.

KOMPLEMENTÊRE MEDISYNE: KOMBINASIEPRODUK

Hierdie ongeregistreerde medisyne is nie deur die SAHPRA geëvalueer vir sy gehalte, veiligheid of beoogde gebruik nie.

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

SYMBIO-D is beskikbaar sonder 'n dokter se voorskrif, vir jou om jou gesondheid te onderhou. Nietemin, moet jy SYMBIO-D versigtig gebruik om die beste resultate daaruit te kry.

- Hou hierdie inligtingsblad. Dit mag nodig wees dat jy dit weer lees.
- Vra gerus jou gesondheidsorgverskaffer of apteker indien jy verdere inligting of advies nodig het.

Wat is in hierdie inligtingsblad

1. Wat SYMBIO-D is, en waarvoor dit gebruik word.
2. Wat jy moet weet voordat jy SYMBIO-D neem.
3. Hoe om SYMBIO-D te neem.
4. Moontlike nuwe-effekte.
5. Hoe om SYMBIO-D te bêre.
6. Inhoud van die verpakking en ander inligting.

1. Wat SYMBIO-D is, en waarvoor dit gebruik word

SYMBIO-D is 'n 8-stam probiotika met bygevoegde omega-3. SYMBIO-D kan help om dermgesondheid te bevorder en te onderhou, kognitiewe gesondheid en/of breinfunksie en kardiovaskulêre gesondheid te ondersteun.

2. Wat jy moet weet voordat jy SYMBIO-D neem

Moet nie SYMBIO-D neem:

- indien jy hipersensitief (allergies) is vir vis (en skulpvis) of vir enige van die ander bestanddele van SYMBIO-D nie (sien **Wat SYMBIO-D bevat**).

Waarskuwings en voorsorgmaatreëls

SYMBIO-D bevat Salmolie. Indien jy hipersensitief (allergies) is vir vis (en skulpvis), moet nie SYMBIO-D neem nie.

Ander medisyne en SYMBIO-D

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

SYMBIO-D met eet- en drinkgoed

Sien afdeling 3 (**Hoe om SYMBIO-D te neem**).

Swangerskap, borsvoeding en vrugbaarheid

Indien jy swanger is of jou baba borsvoed, dink dat jy swanger mag wees of beplan om swanger te raak, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer voordat jy die medisyne neem.

Die veiligheid en effektiwiteit van SYMBIO-D tydens swangerskap en borsvoeding is nie vasgestel nie. Moet nie hierdie medisyne gebruik as jy swanger is of jou baba borsvoed nie.

Bestuur en die gebruik van masjiene

Veiligheid en doeltreffendheid wanneer jy bestuur of masjiene gebruik, is nie vasgestel nie. Moet nie 'n voertuig bestuur, masjiene gebruik of enigiets anders doen wat jou aandag verg totdat jy weet hoe SYMBIO-D jou affekteer nie.

SYMBIO-D bevat sorbitol (E420):

SYMBIO-D bevat sorbitol wat 'n bron is van fruktose. Indien jou dokter jou ingelig het dat jy (of jou kind) onverdraagsaam vir sommige suikers is, kontak jou dokter voordat jy (of jou kind) SYMBIO-D gebruik. Sorbitol kan gastrointestinale ongemak, en 'n matige lakserende effek, veroorsaak.

SYMBIO-D bevat Salmolie:

SYMBIO-D bevat Salmolie. Indien jy hipersensitief (allergies) is vir vis (en skulpvis), moet nie SYMBIO-D neem nie.

3. Hoe om SYMBIO-D te neem

Moet nie jou medisyne met enige ander persoon deel nie.

Neem SYMBIO-D altyd presies soos aangedui in hierdie inligtingsblad, of soos jou dokter of apteker vir jou verduidelik het. Vra gerus jou dokter of apteker indien jy onseker is.

Die gewone dosis is:

Volwasse en kinders vanaf 12-jarige ouderdom: Neem 1 enteries-bedekte tablet en 1 sagtejel kapsule daaglik.

Indien jy die indruk kry dat die uitwerking van SYMBIO-D te sterk of te swak is, bespreek dit met jou dokter of apteker.

Moet nie die aanbevole dosis oorskry nie.

SYMBIO-D kan met of sonder kos geneem word.

SYMBIO-D is slegs vir orale gebruik, en moet met genoegsame vloeistof afgesluk word.

As jy meer SYMBIO-D neem as wat jy moet

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

Neem hierdie inligtingsblad en die houer met die oorblywende SYMBIO-D saam met jou sodat die dokter kan sien wat jy geneem het.

4. Moontlike neue-effekte

SYMBIO-D kan neue-effekte hê.

Nie alle neue-effekte wat vir SYMBIO-D gerapporteer is, word in hierdie inligtingsblad ingesluit nie. Indien jou algemene gesondheid verswak of indien jy enige ongunstige effekte ondervind terwyl jy SYMBIO-D neem, raadpleeg asseblief jou gesondheidsorgverskaffer.

Indien enige van die volgende gebeur, hou op om SYMBIO-D te neem en sê dadelik vir jou dokter, of gaan na die ongevalle-afdeling van jou naaste hospitaal:

- swelling van jou hande, voete, enkels, gesig, lippe, mond of keel, wat probleme kan veroorsaak met sluk en asemhaling;
- uitslag of gejeuk;
- floute.

Hierdie is baie ernstige neue-effekte. Indien jy enige daarvan ondervind, mag jy 'n ernstige allergiese reaksie op SYMBIO-D gehad het. Jy mag dringend mediese bystand of hospitalisasie benodig.

Vertel jou dokter onmiddellik of gaan na die ongevalle-afdeling by jou naaste hospitaal as jy een van die volgende opmerk:

- borspyn;
- angina;
- veranderinge in die manier waarop jou hart klop, byvoorbeeld as jy sien dat dit vinniger klop;
- asemhalingsprobleme;

Hierdie is ernstige neue-effekte. Jy kan dringend mediese hulp benodig.

Indien jy enige nuwe-effekte opmerk wat nie in hierdie inligtingsblad genoem word nie, sê asseblief vir jou dokter of apteker daarvan.

Aanmelding van nuwe-effekte

Indien jy nuwe-effekte ondervind, bespreek dit met jou dokter of apteker. Jy kan ook nuwe-effekte aan SAHPRA rapporteer via die “**6.04 Adverse Drug Reaction Reporting Form**”, wat aanlyn by SAHPRA se publikasies beskikbaar is: <http://www.sahpra.org.za/Publications/Index/8>. Deur nuwe-effekte te rapporteer kan jy help om meer inligting rakende die veiligheid van SYMBIO-D te verskaf.

5. Hoe om SYMBIO-D te bêre

- Bêre alle medisyne buite die bereik van kinders.
- Bêre teen of onder 25 °C in 'n koel, droë plek, en beskerm teen lig (enteries-bedekte tablet).
- Bêre in die yskas nadat die houër oopgemaak is. Die produk is nie ge-enkapsuleer nie (sagtejel kapsule).
- Moet nie in die badkamer bêre nie.
- Moet nie gebruik word na die vervaldatum wat op die karton gedruk is nie.
- Bêre in die oorspronklike verpakking.
- Neem alle ongebruikte medisyne terug na jou apteker.
- Moet nie ongebruikte medisyne in dreine en rioelstelsels (bv. toilette) weggooi nie.

6. Inhoud van die verpakking en ander inligting

Wat SYMBIO-D bevat

Elke enteries-bedekte tablet bevat:

Die aktiewe bestanddele is:

<i>Lactobacillus acidophilus</i>	9.5 x 10 ⁸ KVE* (9,5 mg)
<i>Lactobacillus reuteri</i>	6 x 10 ⁸ KVE* (3 mg)
<i>Streptococcus thermophilus</i>	6.5 x 10 ⁸ KVE* (6,5 mg)
<i>Lactococcus lactis</i>	6 x 10 ⁸ KVE* (2 mg)
<i>Enterococcus faecium</i>	9.6 x 10 ⁷ KVE* (0,32 mg)
<i>Bacillus subtilis</i>	6.3 x 10 ⁷ KVE* (0,63 mg)
<i>Lactobacillus casei</i>	6.3 x 10 ⁷ KVE* (0,21 mg)
<i>Bifidobacterium longum</i>	5 x 10 ⁸ KVE* (10 mg)
Bromelien.....	100 µg
Dikalsiumfosfaatdihidraat	625 mg
lewer kalsium (elementaal).....	118 mg
lewer fosfor (elementaal).....	92 mg
Foliensuur.....	200 µg
Piridoksien Hidrochloried	10,4 mg
lewer piridoksien (Vitamiën B ₆)	8,5 mg
Riboflaviën (Vitamiën B ₂).....	5,5 mg
Tiamien Hidrochloried	7,1 mg
lewer tiamien (Vitamiën B ₁)	5,5 mg
Cholekalsiferol (Vitamiën D ₃)	10 µg (400 I.U.)

*KVE – Kolonie-Vormende Eenheid

Die ander bestanddele is magnesiumstearaat (E572), mikrokristallynsellulose (E460), Opadry enteriese wit (kleurstof).

Bevat versoeter: Elke enteries-bedekte tablet bevat 200 mg sorbitol (E420).

Elke Omega-3 sagtejel kapsule bevat:

Salmolie mengsel.....	1 000 mg
lewer Eikosapentanoësuur (EPA)	120 mg
lewer Dokosaheksanoësuur (DHA).....	80 mg
Alfa-tokoferol asetaat (Vitamiën E).....	5 mg

Die ander bestanddeel is gelatien kapsule (bees).

Suikervry.

Hoe SYMBIO-D lyk en die inhoud van die verpakking

30 enteries-bedeekte probiotika tablette in 'n amber glas houer met 'n silwer skroefprop, verpak in 'n karton. Die tablette is wit tot naaswit in kleur.

30 Omega-3 sagtejel kapsules in 'n amber glas houer met 'n goue skroefprop, verpak in 'n karton. Die sagtejel kapsules bevat 'n gelerige olie.

Houer van die Registrasiesertifikaat

Brunel Laboratoria (Edms) Bpk
Van Tonderstraat 1
Sunderland Ridge
Centurion
0157
info@brunel.co.za

Hierdie inligtingsblad is hersien in

Sal met registrasie deur SAHPRA aangedui word.

Registrasienuommer

Sal met registrasie deur SAHPRA toegeken word.

Toegang tot die ooreenstemmende Professionele Inligtingsblad

Die Professionele Inligtingsblad vir SYMBIO-D is beskikbaar by <https://www.brunel.co.za/professional-information/> of dit kan aangevra word deur die kontakbesonderhede hier bo te gebruik.

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