

**SCHEDULING STATUS [S0]****PRO-B INFANT DROPS****PHARMACEUTICAL CLASSIFICATION:**

Complimentary Medicine Cat D: Health Supplement 34.9 Probiotics

**Pro-B Infant** is a health supplement and as such has not been evaluated by the SAHPRA. This unregistered medicine is not intended to diagnose, treat, cure, or prevent any disease. Health supplements are only intended to supplement the diet or to complement health.

**READ ALL OF THIS LEAFLET CAREFULLY BECAUSE IT  
CONTAINS IMPORTANT INFORMATION FOR YOU**

Available without a doctor's prescription.

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

**ACTIVE INGREDIENTS PER 5 DROPS**

<b>Probiotics:</b>	
Lactobacillus Rhamnosus Howaru®	500 million CFU's*
Bifidobacterium Lactis Howaru®	500 million CFU's*
<b>Total Probiotics</b>	1 billion CFU's*

\*CFU's = Colony Forming Units

**BEFORE YOU TAKE PRO-B INFANT:**

- If you are taking other supplements, read the label, since these supplements may contain the same ingredients.
- Do not take if you are hypersensitive to any of the active or inactive ingredients.
- Tell your healthcare provider if you are taking any other medicines, this includes complementary or traditional medicines.

**WHAT PRO-B INFANT IS USED FOR:**

Formulated for infants from birth to help maintain intestinal flora balance and combat imbalances caused by diarrhoea, lactose intolerance, irritable bowel syndrome, constipation and oral thrush while strengthening the body's natural defence.

**PREGNANCY AND BREASTFEEDING:**

If you are pregnant or breastfeeding, please consult your doctor, pharmacist, or other healthcare professional for advice before taking this medicine.

**DIRECTIONS:**

Infants: Take five (5) drops daily.

Do not exceed the daily recommended dose.

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

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

**POSSIBLE SIDE-EFFECTS:**

Gastrointestinal upset: Nausea, abdominal pain, constipation, diarrhoea, vomiting, poor appetite.

Not all side effects reported are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, discontinue use immediately and please consult your doctor or pharmacist for advice.

**HOW TO STORE AND DISPOSE PRO-B INFANT:**

Store all medicines out of reach of children.

Store at or below 25°C in a cool, dry place.

Keep the container tightly closed.

Do not use this medicine after the expiry date shown on the label.

Return all unused or expired medicine to your pharmacist for safe disposal.

**PRESENTATION:**

5ml Suspension Bottle

**IDENTIFICATION:**

Amber glass bottle containing fruity clear liquid.

**NAME AND BUSINESS ADDRESS OF THE APPLICANT:**

BFC Pharmaceuticals cc

P.O Box 1581

Kloof

3640

South Africa

**DATE OF PUBLICATION**

October 2024

**SKEDULERINGSTATUS [S0]****DATUM VAN PUBLIKASIE**

Oktober 2024

**PRO-B INFANT DRUPPELS****FARMASEUTIESE KLASIFIKASIE:**

Komplementêre Medisyne Kat D: Gesondheidsaanvulling 34.9 Probiotika

**Pro-B Infant** is 'n gesondheidsaanvulling en is nie deur die SAHPRA geëvalueer nie. Hierdie ongeregistreerde medisyne is nie bedoel om enige siekte te diagnoseer, behandel, genees of voorkom nie. Gesondheidsaanvullings is slegs bedoel om die dieet of gesondheid aan te vul.

**LEES HIERDIE HELE BLAD NOUKEURIG DEUR OMDAT DIT BELANGRIKE INLIGTING VIR U BEVAT**

Beskikbaar sonder 'n doktersvoorskrif.

- Hou hierdie blad. Dit mag nodig wees dat u dit weer moet lees.
- Moenie met enige ander persoon deel nie.
- Vra vir u gesondheidsorgverskaffer of apteker as u meer inligting of advies benodig.

**AKTIEWE BESTANDDELE PER 5 DRUPPELS**

<b>Probiotika:</b>	
Lactobacillus Rhamnosus Howaru®	500 miljoen CFU's*
Bifidobacterium Lactis Howaru®	500 miljoen CFU's*
<b>Totale Probiotika</b>	1 miljard CFU's*

\*CFU's = Kolonievormende Eenhede

**VOORDAT U PRO-B INFANT GEBRUIK:**

- As u ander aanvullings gebruik, lees die inligtingsblad, aangesien hierdie aanvulling moontlik dieselfde bestanddele kan bevat.
- Moenie gebruik as u oorsensitief is vir enige van die aktiewe of onaktiewe bestanddele nie.
- Laat u gesondheidsorgverskaffer weet as u ander medisyne gebruik, dit sluit komplementêre of tradisionele medisyne in.

**WAARVOOR PRO-B INFANT GEBRUIK WORD:**

Geformuleer vir babas vanaf geboorte om te help om dermflora balans te handhaaf en wanbalanse te bestry wat veroorsaak word deur diarree, laktose intoleransie, prikkelbare derm-sindroom, hardlywigheid en mondsproei, terwyl dit die liggaam se natuurlike verdediging versterk.

**SWANGERSKAP EN BORSVOEDING:**

Indien u swanger is of borsvoed, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat u hierdie medisyne gebruik.

**GEBRUIKSAANWYSINGS:**

Babas: Neem vyf (5) druppels daagliks.  
Moenie die daaglikske aanbevole dosis oorskry nie.

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

Moenie 'n dubbele dosis drink om vir vergete individuele dosisse op te maak nie.

**MOONLIKE NEWE-EFFEKTE:**

Gastro-intestinale ongemak: Naarheid, braking, maagpyn, hardlywigheid of diarree, swak eetlus.

Nie alle newe-effekte wat aangemeld is, is in hierdie inligtingsblad ingesluit nie. Indien u algemene gesondheidstoestand vererger of as u enige ongewenste effekte ervaar terwyl u hierdie medisyne gebruik, moet u onmiddellik die gebruik stop en asseblief u doktor of apteker raadpleeg vir advies.

**HOE OM PRO-B INFANT TE STOOR EN WEG TE GOOI:**

Bêre alle medisyne buite die bereik van kinders.

Bêre dit by of onder 25°C in 'n koel, droë plek.

Hou diehouer stewig toegesluit.

Moenie die medisyne gebruik na die vervaldatum nie.

Gee alle ongebruikte of vervalde medisyne terug aan u apteker vir veilige verwydering.

**AANBIEDING:**

5ml Suspensie Bottel

**IDENTIFIKASIE:**

Amber glasbottel wat helder vrugtig vloeistof bevat

**NAAM EN BESIGHEIDSADRES VAN DIE AANSOEKER:**

BFC Pharmaceuticals cc

Posbus 1581

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3640

Suid-Afrika