

SCHEDULING STATUS [S0]3640
South Africa**PRO-B KIDS AND ADULT DROPS****DATE OF PUBLICATION**
October 2024**PHARMACEUTICAL CLASSIFICATION:**

Complimentary Medicine Cat D: Health Supplement 34.9 Probiotics

PRO-B Kids and Adult 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 5ML

Probiotics:	
Lactobacillus Salivarius	200 million CFU's*
Lactobacillus Rhamnosus Howaru®	200 million CFU's*
Bifidobacterium Lactis Howaru®	200 million CFU's*
Bifidobacterium Bifidum	200 million CFU's*
Bifidobacterium Longum	100 million CFU's*
Saccharomyces Boulardii	100 million CFU's*
Total Probiotics	1 billion CFU's*

*CFU's = Colony Forming Units

BEFORE YOU TAKE PRO-B KIDS AND ADULT:

- 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 KIDS AND ADULT IS USED FOR:

Formulated 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. For use in conjunction with antibiotic therapy.

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:

Adults & children from 6 years old: Take five (5ml) millilitres 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 KIDS AND ADULT:

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:

40ml 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

SKEDULERINGSTATUS [S0]**PRO-B KIDS AND ADULT DRUPPELS****FARMASEUTIESE KLASSIFIKASIE:**

Komplementêre Medisyne Kat D: Gesondheidsaanvulling 34.9 Probiotika

PRO-B Kids and Adult 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 5ML

Probiotika:	
Lactobacillus Salivarius Ls-33	200 miljoen CFU's*
Lactobacillus Rhamnosus Howaru®	200 miljoen CFU's*
Bifidobacterium Lactis Howaru®	200 miljoen CFU's*
Bifidobacterium Bifidum BB-02	200 miljoen CFU's*
Bifidobacterium Longum BL-05	100 miljoen CFU's*
Saccharomyces Boulardi	100 miljoen CFU's*
Totale Probiotika	1 miljard CFU's*

*CFU's = Kolonievormende Eenhede

VOORDAT U PRO-B KIDS AND ADULT 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 KIDS AND ADULT GEBRUIK WORD:

Geformuleer om die balans van die dermflora te help handhaaf en wanbalanse wat veroorsaak word deur diarree, laktose intoleransie, prikkelbare derm sindroom, hardlywigheid en mondsproei te bekamp, terwyl dit die liggaam se natuurlike verdediging versterk. Vir gebruik in kombinasie met antibiotika terapie..

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:

Volwassenes en kinders 6 jaar en ouer: Neem vyf milliliter (5ml) 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 vergelete 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 effekteervaar terwyl u hierdie medisyne gebruik, moet u onmiddellik die gebruik stop en asseblief u doktor of apteker raadpleeg vir advies.

HOE OM PRO-B KIDS AND ADULT 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 die houer stewig toegesluit.

Moenie die medisyne gebruik na die vervaldatum nie.

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

AANBIEDING:

40ml Suspensie Bottel

NAAM EN BESIGHEIDSADRES VAN DIE AANSOEKER:

BFC Pharmaceuticals cc
Posbus 1581
Kloof
3640
Suid-Afrika

DATUM VAN PUBLIKASIE

Oktober 2024