

SCHEDULING STATUS: **S0**

Probiflora Probiotic Infant Drops 3 Strain - Regular

1 billion CFU, drops

Bifidobacterium lactis, Lactobacillus rhamnosus, Lactobacillus salivarius

Sugar free

Category D: Complementary Medicine

Health Supplements: 34.9 Probiotics

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

Probiflora Probiotic Infant Drops 3 Strain - Regular is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to use **Probiflora Probiotic Infant Drops 3 Strain - Regular** carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share **Probiflora Probiotic Infant Drops 3 Strain - Regular** with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.

What is in this leaflet

1. What **Probiflora Probiotic Infant Drops 3 Strain - Regular** is and what it is used for.
2. What you need to know before you give **Probiflora Probiotic Infant Drops 3 Strain - Regular**
3. How to give **Probiflora Probiotic Infant Drops 3 Strain - Regular**
4. Possible side effects
5. How to store **Probiflora Probiotic Infant Drops 3 Strain - Regular**
6. Contents of the pack and other information.

1. What Probiflora Probiotic Infant Drops 3 Strain - Regular is and what it is used for
Probiflora Probiotic Infant Drops 3 Strain - Regular is a probiotic.

When ingested on a regular basis, probiotics should improve or normalise the microbial balance in the human intestines and thereby improve the functioning of the digestive tract/gut.

2. What you need to know before you give Probiflora Probiotic Infant Drops 3 Strain - Regular

Do not give Probiflora Probiotic Infant Drops 3 Strain - Regular:

- If your child is hypersensitive (allergic) to *Bifidobacterium lactis*, *Lactobacillus rhamnosus*, *Lactobacillus salivarius* or any of the other ingredients of **Probiflora Probiotic Infant Drops 3 Strain - Regular** (listed in section 6).

Warnings and Precautions

Take special care with **Probiflora Probiotic Infant Drops 3 Strain - Regular**:

- Consult a healthcare provider before giving your child **Probiflora Adult Everyday Flora Balance (2 Strain)** if your child has fever, vomiting, bloody diarrhoea or severe stomach pain.
- Stop giving your child **Probiflora Probiotic Infant Drops 3 Strain - Regular** and consult a healthcare provider if symptoms of upset stomach (e.g. diarrhoea) occur or worsen.

Other medicines and Probiflora Probiotic Infant Drops 3 Strain - Regular

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

- Antibiotic medicines (used to treat bacterial infections) may decrease the effectiveness of **Probiflora Probiotic Infant Drops 3 Strain - Regular** if taken at the same time. Give your child **Probiflora Probiotic Infant Drops 3 Strain - Regular** at least 2 hours before or after the antibiotic medicines.

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 **Probiflora Probiotic Infant Drops 3 Strain - Regular**.

Safety in fertility, pregnancy and lactation has not been established.

Driving and using machines

It is not always possible to predict to what extent **Probiflora Probiotic Infant Drops 3 Strain - Regular** may interfere with your child's daily activities. Ensure that your child does not engage in the above activities until you are aware of the measure to which Probiflora Probiotic Infant Drops 3 Strain - Regular affects them.

3. How to take Probiflora Probiotic Infant Drops 3 Strain - Regular

Do not share medicines prescribed for your child with any other person.

Always use **Probiflora Probiotic Infant Drops 3 Strain - Regular** 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:

Infants aged 0-1 years old:

Give 4 drops daily or as recommended by a healthcare practitioner.

Shake well before use.

Invert or hold bottle at 45° angle to form drops. Can be dropped directly into the mouth or allow drops to collect in a spoon first and then give entire dose orally at once.

Give at least 2 hours before or after antibiotics.

A varied diet is the most effective and safe way to achieve good nutrition, health, body composition as well as mental and physical performance.

If you give your child more Probiflora Probiotic Infant Drops 3 Strain - Regular than you should

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

If you forget to give your child Probiflora Probiotic Infant Drops 3 Strain - Regular

Do not give your child a double dose to make up for forgotten individual doses.

4. Possible Side Effects

Probiflora Probiotic Infant Drops 3 Strain - Regular can have side effects.

Not all side effects reported for **Probiflora Probiotic Infant Drops 3 Strain - Regular** are included in this leaflet. Should your child's general health worsen or if your child experiences any untoward effects while taking **Probiflora Probiotic Infant Drops 3 Strain - Regular**, please consult your healthcare provider for advice.

Probiflora Probiotic Infant Drops 3 Strain - Regular is generally well tolerated.

Tell your doctor if you notice any of the following:

Less frequent side effects:

- worsening diarrhoea,
- abdominal (stomach) pain,
- constipation,
- gas.

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, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org)

found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of **Probiflora Probiotic Infant Drops 3 Strain - Regular**.

5. How to store Probiflora Probiotic Infant Drops 3 Strain - Regular

Store all medicines out of reach of children.

- Store in a cool, dry place at or below 25 °C.
- Store away from direct sunlight and moisture.
- Do not use after the expiry date stated on the carton / bottle.
- Return all unused medicine to your pharmacist for proper disposal.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What Probiflora Probiotic Infant Drops 3 Strain - Regular contains:

The active substances are:

4 drops (0,167 ml) contain:	
<i>Bifidobacterium lactis</i>	400 million CFU
<i>Lactobacillus rhamnosus</i>	300 million CFU
<i>Lactobacillus salivarius</i>	300 million CFU

CFU - Colony forming units

The other ingredients are: Caprylic/capric triglyceride and colloidal silicon dioxide.

What Probiflora Probiotic Infant Drops 3 Strain - Regular looks like and contents of the pack

Oil containing white to cream-coloured suspended granules.

10 ml amber glass bottles with a red dropper insert and a white cap, containing 5 ml of oil, equivalent to 30 doses, enclosed in a carton.

Holder of Certificate of Registration

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Customer Care: 0860 ADCOCK/232625

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SKEDULERINGSSTATUS: **S0**

PROBIFLORA JUNIOR EVERYDAY FLORA BALANCE (3 Strain)

1 biljoen KVE, koubare tablette

Lactobacillus helveticus R-52 ME, *Lactobacillus rhamnosus* R-11 ME, *Bifidobacterium longum* R-175 ME

Bevat suiker: Sorbitol 259 mg en Xilitol 65 mg.

Kategorie D: Komplementêre medisyne

Gesondheidsaanvullings: 34.9 Probiotika

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

Lees hierdie hele biljet noukeurig, want dit bevat belangrike inligting vir u

Probiflora Junior Everyday Flora Balance (3 Strain) is beskikbaar sonder 'n doktersvoorskrif, sodat u kind se gesondheid daarmee onderhou kan word. Nietemin moet u steeds **Probiflora Junior Everyday Flora Balance (3 Strain)** versigtig gebruik om die beste resultate daaruit te verkry.

- Hou hierdie biljet. U sal dit dalk weer moet lees.
- Moenie **Probiflora Junior Everyday Flora Balance (3 Strain)** met enige ander persoon deel nie.
- Vra u gesondheidsorgverskaffer of apteker indien u meer inligting of advies nodig.

Wat in hierdie biljet is

1. Wat **Probiflora Junior Everyday Flora Balance (3 Strain)** is en waarvoor dit gebruik word.
2. Wat u moet weet voordat u **Probiflora Junior Everyday Flora Balance (3 Strain)** gee
3. Hoe om **Probiflora Junior Everyday Flora Balance (3 Strain)** te gee
4. Moontlike neue-effekte
5. Hoe om **Probiflora Junior Everyday Flora Balance (3 Strain)** te bêre
6. Inhoud van die verpakking en ander inligting.

1. Wat Probiflora Junior Everyday Flora Balance (3 Strain) is en waarvoor dit gebruik word
Probiflora Junior Everyday Flora Balance (3 Strain) is 'n probiotika.

Wanneer dit gereeld ingeneem word, behoort probiotika die mikrobiese balans in die menslike ingewande te verbeter of te normaliseer en sodoende die funksionering van die spysverteringskanaal/ingewande verbeter.

2. Wat u moet weet voordat u **Probiflora Junior Everyday Flora Balance (3 Strain)** aan u kind gee

Moenie Probiflora Junior Everyday Flora Balance (3 Strain) aan u kind gee nie:

- Indien u kind hipersensitief (allergies) is vir *Lactobacillus helveticus*, *Lactobacillus rhamnosus*, *Bifidobacterium longum*, soja of enige van die ander bestanddele van **Probiflora Junior Everyday Flora Balance (3 Strain)** (gelys in afdeling 6).

Waarskuwings en voorsorgmaatreëls

Wees veral versigtig met **Probiflora Junior Everyday Flora Balance (3 Strain)**:

- Raadpleeg 'n gesondheidsorgverskaffer voordat u **Probiflora Junior Everyday Flora Balance (3 Strain)** aan u kind gee as u kind koorsig is, braak, bloedige diarree of erge maagpyn het.
- Staak die gebruik van **Probiflora Junior Everyday Flora Balance (3 Strain)** en raadpleeg 'n gesondheidsorgverskaffer indien simptome van 'n omgekeerde maag (bv. diarree) voorkom of vererger.

Ander medisyne en Probiflora Junior Everyday Flora Balance (3 Strain)

Lig altyd u gesondheidsorgverskaffer in indien u kind enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisyne in.)

- Antibiotiese medisyne (wat gebruik word om bakteriële infeksies te behandel) kan die doeltreffendheid van **Probiflora Junior Everyday Flora Balance (3 Strain)** verminder indien dit tegelykertyd geneem word. U moet **Probiflora Junior Everyday Flora Balance (3 Strain)** ten minste 2 uur voor of ná die antibiotiese medisyne aan u kind gee.

Swangerskap, borsvoeding en vrugbaarheid

Indien u swanger is of borsvoed, dink u is dalk swanger, of van plan is om 'n baba te hê, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat u **Probiflora Junior Everyday Flora Balance (3 Strain)** neem.

Veiligheid in vrugbaarheid, swangerskap en laktasie is nie vasgestel nie.

Bestuur en gebruik van masjinerie

Dit is nie altyd moontlik om te voorspel in watter mate **Probiflora Junior Everyday Flora Balance (3 Strain)** met u kind se daaglikse aktiwiteite kan inmeng nie. Maak seker dat u kind nie aan bogenoemde aktiwiteite deelneem voordat u bewus is van die mate waartoe **Probiflora Junior Everyday Flora Balance (3 Strain)** hulle beïnvloed nie.

Probiflora Junior Everyday Flora Balance (3 Strain) bevat:

- **Sorbitol** 259 mg in elke dosis-eenheid, wat gelykstaande is aan 259 mg per koubare tablet. Sorbitol is 'n bron van fruktose. Indien u dokter u ingelig het dat u (of u kind) 'n onverdraagsaamheid teenoor sommige suikers het of indien u gediagnoseer is met oorerflike fruktose-intoleransie (OFI), 'n seldsame genetiese afwyking waarin 'n persoon nie fruktose kan afbreek nie, raadpleeg u dokter voordat u (of u kind) **Probiflora Junior Everyday Flora Balance (3 Strain)** neem of ontvang.
- **Laktose**. Indien u dokter u ingelig het dat u kind 'n onverdraagsaamheid teenoor sommige suikers het, kontak u dokter voordat u **Probiflora Junior Everyday Flora Balance (3 Strain)** toedien.
- **Soja**. Indien u kind allergies is vir soja, moet u nie **Probiflora Junior Everyday Flora Balance (3 Strain)** aan hom/haar gee nie.

3. Hoe om Probiflora Junior Everyday Flora Balance (3 Strain) aan u kind te gee

Moenie medisyne wat aan u kind voorgeskryf is, met enige ander persoon deel nie.

Gee altyd **Probiflora Junior Everyday Flora Balance (3 Strain)** aan u kind presies soos beskryf in hierdie biljet of soos u dokter of apteker aan u verduidelik het. Raadpleeg u dokter of apteker indien u nie seker is nie.

Die algemene dosis is:

Kinders 2 jaar en ouer: Kou 1 tablet daaglik.

Dosis kan verhoog word tot 2 koubare tablette per dag indien nodig of soos voorgeskryf deur u gesondheidsorg kundige.

Gee ten minste 2 uur voor of ná antibiotika.

'n Gebalanseerde dieet is die mees doeltreffende en veilige manier om goeie voeding, gesondheid, liggaamsamestelling sowel as verstandelike en fisiese prestasie te bereik.

Indien u meer Probiflora Junior Everyday Flora Balance (3 Strain) neem as wat u moes

In die geval van oordosering, raadpleeg u dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifhulpentrum.

Indien u vergeet om Probiflora Junior Everyday Flora Balance (3 Strain) aan u kind te gee

Moenie 'n dubbele dosis aan u kind gee om op te maak vir vergete individuele dosisse nie.

4. Moontlike newe-effekte

Probiflora Junior Everyday Flora Balance (3 Strain) kan newe-effekte hê.

Nie alle newe-effekte wat vir **Probiflora Junior Everyday Flora Balance (3 Strain)** aangemeld is, word by hierdie biljet ingesluit nie. Indien u kind se algemene gesondheid verswak of indien u

ongewenste gevolge ervaar terwyl **Probiflora Junior Everyday Flora Balance (3 Strain)** geneem word, raadpleeg u gesondheidsorgverskaffer vir advies.

Probiflora Junior Everyday Flora Balance (3 Strain) word oor die algemeen goed verdra. Indien enige van die volgende gebeur, staak dit om **Probiflora Junior Everyday Flora Balance (3 Strain)** aan u kind te gee en raadpleeg u dokter dadelik, óf gaan na die ongevalle-afdeling by u naaste hospitaal:

- swelling van lippe en mond of keel, wat probleme met sluk of asemhaling kan veroorsaak, veluitslag of jeukerigheid en/of galbulte of floute.

Hierdie is alles baie ernstige newe-effekte. Indien u kind dit ervaar, het hy/sy moontlik 'n ernstige allergiese reaksie op **Probiflora Junior Everyday Flora Balance (3 Strain)** gehad. U kind het dalk dringende mediese hulp of hospitalisasie nodig.

Lig u dokter in indien u enige van die volgende opmerk:

Minder gereelde newe-effekte:

- verergerende diarree,
- buikpyn (maagpyn),
- hardlywigheid,
- winderigheid.

Indien u enige newe-effekte opmerk wat nie in hierdie biljet genoem word nie, stel asseblief u dokter of apteker in kennis.

Aanmelding van newe-effekte

Indien u newe-effekte ervaar, raadpleeg u dokter, apteker of verpleegkundige. U kan ook newe-effekte by SAHPRA aanmeld via die Med Safety Toep (Medsafety X SAHPRA) en elektroniese aanmeldingsplatform (who-umc.org) wat op SAHPRA se webwerf gevind kan word. Deur newe-effekte aan te meld, kan u help om meer inligting te verskaf oor die veiligheid van **Probiflora Junior Everyday Flora Balance (3 Strain)**.

5. Hoe om Probiflora Junior Everyday Flora Balance (3 strain) te bêre

Bêre alle medisyne buite bereik van kinders.

- Bêre op 'n koel, droë plek teen of benede 25 °C.
- Bêre weg van direkte sonlig en vogtigheid.
- Moenie gebruik ná die vervaldatum wat op die kartonboksie/bottel vermeld word nie.
- Neem alle ongebruikte medisyne terug na u apteker vir behoorlike wegdoening.
- Moenie ongebruikte medisyne in afvoerpype en rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van die verpakking en ander inligting

Wat Probiflora Junior Everyday Flora Balance (3 Strain) bevat:

Die aktiewe betsanddele is:

Elke koubare tablet bevat:	
<i>Lactobacillus helveticus</i> R-52 ME	1 biljoen KVE*
<i>Lactobacillus rhamnosus</i> R-11 ME	
<i>Bifidiobacterium longum</i> R-175 ME	

* Kolonievormende eenhede

Die ander bestanddele is: Sitroensuur, driuwegeursel, gliserielbehenaat, maltodekstrien, mikrokristallyne sellulose, aartappelstysel, sorbitol en xilitol.

Hoe Probiflora Junior Everyday Flora Balance (3 Strain) lyk en die inhoud van die verpakking

Sirkelvormige, bikonvekse en pers-gevlekte koubare tablette.

Stulpverpakking wat 10 of 30 tablette bevat, verpak in 'n buitenste kartonboksie.

Nie alle verpakkingsgroottes mag dalk bemark word nie.

Houer van Sertifikaat van Registrasie:

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Kliëntediens: 0860 ADCOCK/232625

Hierdie biljet is mees onlangs hersien op:

30 September 2024

Registrasienommer:

Moet toegeken word

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