

## PATIENT INFORMATION LEAFLET

### SCHEDULING STATUS: S6

Category D: Complementary medicine.

Discipline: Health Supplement

34.9 Probiotics

PROPRIETARY NAME, STRENGTH, PHARMACEUTICAL FORM -

## ULTRAFLOA® BABY PROBIOTIC, 5,56 ml

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

- **ULTRAFLOA® BABY PROBIOTIC** is available without a doctor's prescription.
- Nevertheless, you still need to use **ULTRAFLOA® BABY PROBIOTIC** carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share **ULTRAFLOA® BABY PROBIOTIC** with any other person.
- Ask your pharmacist or healthcare professional if you need more information or advice.

### WHAT IS IN THIS LEAFLET

- What **ULTRAFLOA® BABY PROBIOTIC** is and what it is used for.
- What you need to know before you take **ULTRAFLOA® BABY PROBIOTIC**.
- How to take **ULTRAFLOA® BABY PROBIOTIC**.
- Possible side effects.
- How to store **ULTRAFLOA® BABY PROBIOTIC**.
- Contents of the pack and other information.

### WHAT ULTRAFLOA® BABY PROBIOTIC CONTAINS

Each dose (6 drops, 0,27 ml) of **ULTRAFLOA® BABY PROBIOTIC** contains the following actives:

A Probiotic Blend of:	1 Billion CFU
<i>Lactocaseibacillus rhamnosus</i> LGG®	0,67 Billion CFU
<i>Bifidobacterium lactis</i> BB-12®	0,33 Billion CFU

**Inactive Ingredients:** Maltodextrin, sunflower seed oil (*Helianthus annuus*).

**Contains sugar (4 mg sucrose per 6 drops).**

**This product is suitable for Vegetarians and is Gluten free.**

### WHAT ULTRAFLOA® BABY PROBIOTIC IS AND WHAT IT IS USED FOR

**ULTRAFLOA® BABY PROBIOTIC** offers 1 billion organisms, specifically formulated for the healthy intestinal flora of babies and young children.

### BEFORE YOU TAKE ULTRAFLOA® BABY PROBIOTIC

If your child is taking any chronic medication, do not use this product without consulting your healthcare professional. Do not take **ULTRAFLOA® BABY PROBIOTIC** if your child is hypersensitive (allergic) to any of the ingredients. If your child has allergies, be sure to check with your healthcare professional before taking this supplement. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking **ULTRAFLOA® BABY PROBIOTIC**. **This medicine has not been evaluated by the SAHPRA for quality, safety, or intended use.**

### PREGNANCY AND BREASTFEEDING

Safety during pregnancy and breastfeeding has not been established, consult with your healthcare professional before use. If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult with your healthcare professional before taking this supplement.

### DRIVING AND USING MACHINES

Although this medicine is intended for use by children, it is not always possible to predict to what extent **ULTRAFLOA® BABY PROBIOTIC** may interfere with the daily activities of a patient. Patients should ensure that they do not engage in activities relating to requiring mental alertness, judgement and/or sound co-ordination and vision e.g. driving, riding, flying, sailing, operating machines/equipment, until they are aware of the measure to which **ULTRAFLOA® BABY PROBIOTIC** may affect you.

### TAKING OTHER MEDICINES WITH ULTRAFLOA® BABY PROBIOTIC

Complementary medicine products contain ingredients which may interact with some medication. If you are taking any chronic medication, do not use this product without consulting your healthcare professional. Taking antibiotics along with **ULTRAFLOA® BABY PROBIOTIC** can reduce the effects of the medicine. To avoid this interaction, take **ULTRAFLOA® BABY PROBIOTIC** at least 2 hours before or after antibiotics.

### IMPORTANT INFORMATION ABOUT SOME OF THE INGREDIENTS OF ULTRAFLOA® BABY PROBIOTIC

**ULTRAFLOA® BABY PROBIOTIC** contains sucrose which may have an effect on the control of your child's blood sugar if they have diabetes mellitus.

### HOW TO TAKE ULTRAFLOA® BABY PROBIOTIC

- Do not share medicines prescribed for you with any other person.
- Always take **ULTRAFLOA® BABY PROBIOTIC** exactly as described in this leaflet, or as your doctor, healthcare professional has instructed you.
- You should check with your doctor, pharmacist or healthcare professional if you are unsure.



### Directions for use:

**Children 1 – 2 years:** Give 6 drops into a spoon, milk or food once daily, or as directed by your healthcare practitioner. **Shake well before use. Do not take more than the recommended dose.**

**Do not take more than the recommended dose.**

### IF YOU TAKE MORE ULTRAFLOA® BABY PROBIOTIC THAN YOU SHOULD

In the event of overdosage, consult your doctor, pharmacist. Should none of these be available, contact the nearest hospital or poison control centre.

### IF YOU FORGET TO TAKE ULTRAFLOA® BABY PROBIOTIC

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

### POSSIBLE SIDE EFFECTS

**ULTRAFLOA® BABY PROBIOTIC** may have side effects.

Should you have any of the following diagnosed conditions, consult with your healthcare professional before use: Weakened immune system, Yeast allergy.

If you are taking the following medication, please consult with your healthcare professional before taking: Antibiotic medicine (broad-spectrum), Corticosteroid treatment. If any of the following happens, stop using **ULTRAFLOA® BABY PROBIOTIC** and tell your doctor or go to the casualty department at your nearest hospital:

- Allergic reactions— rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing.

These are all very serious effects. If you have them, you may have had a serious reaction to **ULTRAFLOA® BABY PROBIOTIC**. You may need urgent medical attention or hospitalisation. Side effects that usually do not require medical attention (report to your healthcare professional if they continue):

- Stomach discomfort, diarrhoea, bloating, flatulence.

Not all side effects and interactions reported for **ULTRAFLOA® BABY PROBIOTIC** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice. If you notice any side effects not mentioned in this leaflet, please inform your doctor, pharmacist or healthcare professional.

### REPORTING OF SIDE EFFECTS

If you experience side effects, talk to your doctor, pharmacist or other healthcare professional. You can also report side effects to SAHPRA via "6.04 Adverse Drug Reaction 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 **ULTRAFLOA® BABY PROBIOTIC**.

### STORAGE AND DISPOSING OF ULTRAFLOA® BABY PROBIOTIC

Store all medicines out of the reach of children.

Store in a cool, dark place, below 25 °C.

Protect from direct sunlight and heat.

Store in the original packaging.

Do not use after the expiry date stated on the bottle.

Do not use **ULTRAFLOA® BABY PROBIOTIC** if you notice visible signs of deterioration.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

### PRESENTATION OF ULTRAFLOA® BABY PROBIOTIC

Presented in a 10 ml dark brown glass bottle with a dropper, packed in an outer carton.

**Pack size:** 5,56 ml liquid.

### IDENTIFICATION OF ULTRAFLOA® BABY PROBIOTIC

A light-yellow liquid with a neutral flavour.

**REGISTRATION NUMBER** - To be allocated by SAHPRA upon registration.

### ACCESS TO THE CORRESPONDING PROFESSIONAL INFORMATION

Scan QR code.

### THIS LEAFLET WAS LAST REVISED ON

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### NAME AND ADDRESS OF REGISTRATION HOLDER

Distributed by:

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# PASIEËNT INLIGTINGSBLAD

## SKEDULERINGSSTATUS: [50]

Kategorie D: Komplementêre medisyne.

Disipline: Gesondheidsaanvulling  
34.9 Probiotika

HANDELSNAAM EN DOSEERVORM,

## ULTRAFLOORA® BABY PROBIOTIC, 5,56 ml

LEES HIERDIE INLIGTINGSBLAD NOUKEURIG, WANT DIT BEVAT BELANGRIKE INLIGTING VIR U

- **ULTRAFLOORA® BABY PROBIOTIC** is beskikbaar sonder doktersvoorskrif.
- U moet steeds **ULTRAFLOORA® BABY PROBIOTIC** versigtig gebruik om die beste resultate daaruit te kry.
- Hou hierdie inligtingsblad. Misken moet u dit weer lees.
- Moenie **ULTRAFLOORA® BABY PROBIOTIC** met enige ander persoon deel nie.
- Vra jou apteker of gesondheidsorgpraktisyn of jy meer inligting of advies benodig.

### WAT IS IN HIERDIE INLIGTINGSBLAD

- Wat **ULTRAFLOORA® BABY PROBIOTIC** is en waarvoor dit gebruik word.
- Wat jy moet weet voordat jy **ULTRAFLOORA® BABY PROBIOTIC** neem.
- Hoe om **ULTRAFLOORA® BABY PROBIOTIC** te neem.
- Moontlike nuwe-effekte.
- Hoe om **ULTRAFLOORA® BABY PROBIOTIC** te bêre.
- Inhoud van die pak en ander inligting

### WAT ULTRAFLOORA® BABY PROBIOTIC BEVAT

Elke een (6 druppels, 0,27 ml) **ULTRAFLOORA® BABY PROBIOTIC** bevat die volgende aktiewe:

• 'n Probiotiese mengsel van:	1 Biljoen KVE
<i>Lactisacibacillus rhamnosus</i> LGG®	0,67 Biljoen KVE
<i>Bifidobacterium lactis</i> BB-12®	0,33 Biljoen KVE

**Onaktiewe bestanddele:** Maltodekstrien, sonneblomsaadolie (*Helianthus annuus*).

**Bevat suiker (4 mg sukrose per 6 druppels).** Hierdie produk is geskik vir vegetariërs en glutenvry

### WAT IS ULTRAFLOORA® BABY PROBIOTIC EN WAARVOOR WORD DIT GEBRUIK

**ULTRAFLOORA® BABY PROBIOTIC** bied 1 biljoen organismes, spesifiek formuleer vir die gesonde dermflora van babas en jong kinders.

### VOORDAT JY ULTRAFLOORA® BABY PROBIOTIC NEEM

As jy kind enige chroniese medisyne neem, moenie hierdie produk gebruik sonder om jou gesondheidsorgpraktisyn te raadpleeg nie. Moenie **ULTRAFLOORA® BABY PROBIOTIC** neem as u kind hipersensitief (allergies) is vir enige van die bestanddele nie. As jy allergieë het, maak seker dat jy met jou gesondheidsorgpraktisyn gaan praat voordat jy hierdie aanvulling neem. As u dokter vir u gesê het dat u 'n onverdraagsaamheid teenoor sommige suikers het, kontak u dokter voordat u **ULTRAFLOORA® BABY PROBIOTIC** neem. Hierdie medisyne is nie deur SAHPRA geëvalueer vir kwaliteit, veiligheid of beoogde gebruik nie.

### SWANGERSKAP EN BORSVOEDING

Moenie hierdie swangerskap en borsvoeding is nie vasgestel nie, raadpleeg u gesondheidsorgpraktisyn vir gebruik. As jy swanger is of borsvoed, dink jy kan swanger wees of beplan om 'n babat te hê, raadpleeg asseblief jou gesondheidsorgpraktisyn voordat jy hierdie medisyne neem.

### BESTUUR EN GEBRUIK VAN MASIËNE

Alhoewel hierdie medisyne bedoel is vir gebruik deur kinders, dit is nie altyd moontlik om te voorspel in watter mate **ULTRAFLOORA® BABY PROBIOTIC** die daaglikse aktiwiteite van 'n pasiënt kan belemmer nie. Pasiënte moet seker maak dat hulle nie betrokke raak by aktiwiteite wat verband hou met die verste van verstandelike waaksaamheid, oordeel en/of gesonde koördinasie en visie nie, byvoorbeeld bestuur, ry, vlieg, seil, bedryfsmasjiene/toerusting, totdat hulle bewus is van die mate waartoe **ULTRAFLOORA® BABY PROBIOTIC** jou beïnvloed.

### NEEM ANDER MEDISYNE SAAM MET ULTRAFLOORA® BABY PROBIOTIC

Komplementêre medisyne produkte bevat bestanddele wat met sommige medisyne 'n interaksie kan hê. As jy enige chroniese medisyne gebruik, moenie hierdie produk gebruik sonder om jou mediese praktisyn te raadpleeg nie. Die neem van antibiotika saam met **ULTRAFLOORA® BABY PROBIOTIC** kan die effekte van die medisyne verminder. Om hierdie interaksie te vermy, neem **ULTRAFLOORA® BABY PROBIOTIC** ten minste 2 ure voor of na antibiotika.

### HOE OM ULTRAFLOORA® BABY PROBIOTIC TE NEEM

Moenie medisyne wat vir u voorgeskryf is, met enige ander persoon deel nie. Neem altyd **ULTRAFLOORA® BABY PROBIOTIC** presies soos beskryf in hierdie inligtingsblad, of soos u dokter, of gesondheidsorgpraktisyn u opdrag gegee het. Raadpleeg jou dokter, apteker of gesondheidsorgpraktisyn as jy onseker is.

### BELANGRIKE INLIGTING OOR DIE BESTANDELE VAN ULTRAFLOORA® BABY PROBIOTIC

**ULTRAFLOORA® BABY PROBIOTIC** bevat sukrose wat 'n uitwerking kan hê op die beheer van jou kind se bloedsuiker as hulle diabetes mellitus het.

#### Aanwysings vir gebruik:

**Kinders 1 – 2 jaar:** Gee een keer per dag 6 druppels in 'n lepel, melk of kos, of soos voorgeskryf deur jou gesondheidspraktisyn. Skud goed voor gebruik. Moenie meer as die aanbevole dosis neem nie.

**AS JY MEER ULTRAFLOORA® BABY PROBIOTIC NEEM AS WAT JY MOET** In die geval van oordosering, raadpleeg u dokter, apteker. Indien nie een hiervan beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.

### AS JY VERGEET OM ULTRAFLOORA® BABY PROBIOTIC TE NEEM

Moenie 'n dubbele dosis neem om op te maak vir 'n dosis wat vergelees is nie.

### MOONTLIKE NUWE-EFFEKTE

**ULTRAFLOORA® BABY PROBIOTIC** kan nuwe-effekte hê. Indien jy enige van die volgende gedagnoseerde toestande het, raadpleeg jou gesondheidsorgpraktisyn voor gebruik: Verswakte immuunstelsel, Gisallergie. As jy die volgende medikasie neem, raadpleeg asseblief jou gesondheidsorgpraktisyn voordat jy neem: Antibiotiese medisyne (breespektrum), kortikosteroïedbehandeling.

As enige van die volgende gebeur, hou op om **ULTRAFLOORA® BABY PROBIOTIC** te gebruik en vertel jou dokter of gaan na die ongevallende afdeling by jou naaste hospitaal:

- Allergiese reaksies - uitslag, jeuk / swelling (veral van die gesig / tong / keel), erge duiseligheid, probleme met asemhaling, veranderinge in bui, verminderde eetlus.

Dit is alles baie ernstige gevolge. As jy dit het, het jy dalk 'n ernstige reaksie op **ULTRAFLOORA® BABY PROBIOTIC** gehad. Jy sal dalk dringende mediese hulp of hospitalisasie nodig hê.

Nuwe-effekte wat gewoonlik nie mediese hulp benodig nie (rapporteer aan jou gesondheidsorgpraktisyn as hulle voortduur):

- Maagongemak, diarree, opgeblasenheid, winderigheid.

Nie alle nuwe-effekte en interaksies wat vir **ULTRAFLOORA® BABY PROBIOTIC** gerapporteer word, is by hierdie inligtingsblad ingesluit nie.

Indien jou algemene gesondheid vererger of as jy enige nadelige effekte ervaar tydens die gebruik van hierdie medisyne, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgpraktisyn vir raad. As jy enige nuwe-effekte sien wat nie in hierdie inligtingsblad genoem word nie, stel asseblief jou dokter, apteker of gesondheidsorgpraktisyn in kennis.

### AANMELDING VAN NUWE-EFFEKTE

As jy nuwe-effekte ervaar, praat met jou dokter, apteker of ander gesondheidsorgpraktisyn. U kan ook nuwe-effekte aan SAHPRA rapporteer via "6.04 Adverse Drug Reaction Reporting Form", wat aanyl gevind word onder SAHPRA se publikasies: <https://www.sahpra.org.za/Publications/Index/8>. Deur nuwe-effekte aan te meld, kan u help om meer inligting te verskaf oor die veiligheid van **ULTRAFLOORA® BABY PROBIOTIC**.

### HOË OM ULTRAFLOORA® BABY PROBIOTIC TE BEREÏ

Bêre alle medisyne buite bereik van kinders.

Bêre in 'n koel, donker plek, onder 25 °C.

Beskerm teen direkte sonlig en hitte.

Bêre in die oorspronklike verpakking.

Moet nie gebruik word na die vervaldatum wat op die bottel aangedui word nie.

Moenie **ULTRAFLOORA® BABY PROBIOTIC** gebruik as u sigbare tekens van agteruitgang opmerk nie.

Moenie gebruikte medisyne in dreine of rioolstelsels (bv. toilette) weggooi nie.

### AANBIEDING VAN ULTRAFLOORA® BABY PROBIOTIC

Aangebied in 'n 10 ml donkerbruin glasbottel met 'n drupper, verpak in 'n buitekarton.

**Pak grootte:** 5,56 ml vloeistof.

### IDENTIFIKASIE VAN ULTRAFLOORA® BABY PROBIOTIC

'n Liggeel vloeistof met 'n neutrale geur.

**REGISTRASIE NOMMER** - Om deur SAHPRA toegeen te word by registrasie.

### TOEGANG TOT DIE OOREENSTEMMENDE PROFESSIONELE INLIGTING

Skandeer QR-kode..

### HIERDIE INLIGTINGSBLAD IS LAAS HERSIEN OP

05 November 2024

### NAAM EN ADRES VAN REGISTRASIEHOUEUR

Versprei deur:

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