

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S0

Category D: Complementary medicine.

Discipline: Health Supplement

34.12 Multiple substance formulation

PROPRIETARY NAME, STRENGTH, PHARMACEUTICAL FORM -

ULTRAFLOA® KID'S PROBIOTIC,

30 & 60 Chewable Tablets

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

- **ULTRAFLOA® KID'S PROBIOTIC** is available without a doctor's prescription.
- Nevertheless, you still need to use **ULTRAFLOA® KID'S PROBIOTIC** carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share **ULTRAFLOA® KID'S 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® KID'S PROBIOTIC** is and what it is used for.
- What you need to know before you take **ULTRAFLOA® KID'S PROBIOTIC**.
- How to take **ULTRAFLOA® KID'S PROBIOTIC**.
- Possible side effects.
- How to store **ULTRAFLOA® KID'S PROBIOTIC**.
- Contents of the pack and other information.

WHAT ULTRAFLOA® KID'S PROBIOTIC CONTAINS

Each one (1) tablet of **ULTRAFLOA® KID'S PROBIOTIC** contains the following actives:

A Probiotic combination of:	5 Billion CFU
<i>Lactobacillus acidophilus</i> NCFM®	2,5 Billion CFU
<i>Bifidobacterium lactis</i> Bi-07®	2,5 Billion CFU
Vitamin D (as Cholecalciferol)	1 µg (40 I.U.)

Inactive Ingredients: Hydroxypropylcellulose, magnesium salts of fatty acids, malic acid, microcrystalline cellulose, polyvinylpyrrolidone, raspberry flavour, red beet powder (*Beta vulgaris* L.), (colourant), silicon dioxide.

Contains sugar (137,24 mg mannitol, 125,22 mg fructose and 67,18 mg xylitol per tablet)

This product is Gluten Free.

WHAT ULTRAFLOA® KID'S PROBIOTIC IS AND WHAT IT IS USED FOR

ULTRAFLOA® KID'S PROBIOTIC features a combination of 5 billion organisms per tablet, providing daily support for gut health and immunity.

BEFORE YOU TAKE ULTRAFLOA® KID'S PROBIOTIC

If your child is taking any chronic medication, do not use this product without consulting your healthcare professional. Do not give **ULTRAFLOA® KID'S 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® KID'S PROBIOTIC**.

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

PREGNANCY AND BREASTFEEDING

Although this product is formulated specifically for children, 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

Even though this product is formulation for children, it is not always possible to predict to what extent **ULTRAFLOA® KID'S 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® KID'S PROBIOTIC** may affect your child.

TAKING OTHER MEDICINES WITH ULTRAFLOA® KID'S PROBIOTIC

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

IMPORTANT INFORMATION ABOUT SOME OF THE INGREDIENTS OF

ULTRAFLOA® KID'S PROBIOTIC

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

HOW TO TAKE ULTRAFLOA® KID'S PROBIOTIC

- Do not share medicines prescribed for your child with any other person.
- Always take **ULTRAFLOA® KID'S 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 3 to 12 years: Chew one (1) to two (2) tablets per day or as directed by your healthcare professional.

Do not take more than the recommended dose.

IF YOU TAKE MORE ULTRAFLOA® KID'S PROBIOTIC THAN YOU SHOULD In the event of overdose, consult your doctor, pharmacist. Should none of these be available, contact the nearest hospital or poison control centre.

IF YOU FORGET TO TAKE ULTRAFLOA® KID'S PROBIOTIC

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

POSSIBLE SIDE EFFECTS

ULTRAFLOA® KID'S PROBIOTIC may have side effects. Should your child has any of the following diagnosed conditions, consult with your healthcare professional before use: Weakened immune system, damaged heart valves, Atherosclerosis, Histoplasmosis, Hyperparathyroidism, Lymphoma, Kidney disease.

If your child is taking the following medication, please consult with your healthcare professional before taking: Antibiotic medicine (broad-spectrum), Diuretics, Liver medication. If any of the following happens, stop using **ULTRAFLOA® KID'S PROBIOTIC** and report 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 your child has them, they may have had a serious reaction to **ULTRAFLOA® KID'S PROBIOTIC**. Your child 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, bloating, flatulence.

Not all side effects and interactions reported for **ULTRAFLOA® KID'S PROBIOTIC** are included in this leaflet. Should your child's general health worsen or if they 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® KID'S PROBIOTIC**.

STORAGE AND DISPOSING OF ULTRAFLOA® KID'S 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® KID'S 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® KID'S PROBIOTIC

White 112 ml polypropylene container, with a white polypropylene screw cap.

The container has an inner desiccant sleeve and a tamper resistant seal.

Pack size: 30 or 60 chewable tablets.

IDENTIFICATION OF ULTRAFLOA® KID'S PROBIOTIC

Pink, round tablet with white and red dots and a raspberry 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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PASIENT INLIGTINGSBLAD

SKEDULERINGSSTATUS: [50]

Kategorie D: Komplementêre medisyne.

Disipline: Gesondheidsaanvulling

34.12 Meervoudige Bestandeel Formulasie

HANDELSNAAM EN DOSEERVORM,

ULTRAFLOA® KID'S PROBIOTIC,

30 & 60 koubare tablette

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

- **ULTRAFLOA® KID'S PROBIOTIC** is beskikbaar sonder doktersvoorskrif.
- U moet steeds **ULTRAFLOA® KID'S PROBIOTIC** versigtig gebruik om die beste resultate daaruit te kry.
- Hou hierdie inligtingsblad. Miskien moet u dit weer lees.
- Moenie **ULTRAFLOA® KID'S 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 **ULTRAFLOA® KID'S PROBIOTIC** is en waarvoor dit gebruik word.
- Wat jy moet weet voordat jy **ULTRAFLOA® KID'S PROBIOTIC** neem.
- Hoe om **ULTRAFLOA® KID'S PROBIOTIC** te neem.
- Moontlike nuwe-effekte.
- Hoe om **ULTRAFLOA® KID'S PROBIOTIC** te bêre.
- Inhoud van die pak en ander inligting

WAT ULTRAFLOA® KID'S PROBIOTIC BEVAT

Elke (1) tablet van **ULTRAFLOA® KID'S PROBIOTIC** bevat die volgende

aktiewe stowwe:

'n Probiotiese kombinasie van:	5 Biljoen KVE
<i>Lactobacillus acidophilus</i> NCFM®	2,5 Biljoen KVE
<i>Bifidobacterium lactis</i> Bi-07®	2,5 Biljoen KVE
Vitamiën D (as cholecalciferol)	1 µg (40 I.E.)

Onaktiewe bestanddele: Hidroksipropiellose, magnesiësuout van vetsure, appelsuur, mikrokristallyn-sellulose, polivinilpiperidoloon, framboosgeur, rooibetpoeiër (*Beta vulgaris* L.), (kleurstof), silikondoksied.

Bevat suiker (137,24 mg manitol, 125,22 mg fruktose en 67,18 mg xylitol per tablet)

Hierdie produk is glutenvry.

WAT IS ULTRAFLOA® KID'S PROBIOTIC EN WAARVOOR WORD DIT GEBRUIK
ULTRAFLOA® KID'S PROBIOTIC beskik oor 'n kombinasie van 5 biljoen organismes per tablet, wat daaglikse ondersteuning bied vir dermgesondheid en immuniteit.

VOORDAT JY ULTRAFLOA® KID'S PROBIOTIC NEEM

As jou kind enige chroniese medikasie neem, moenie hierdie produk gebruik sonder om jou gesondheidsorgpraktisyn te raadpleeg nie. Moenie

ULTRAFLOA® KID'S PROBIOTIC neem as u kind hipersensitief (allergies) is vir enige van die bestanddele nie. As jou kind allergeïe 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 **ULTRAFLOA® KID'S PROBIOTIC** neem.

SWANGERSKAP EN BORSVOEDING

Alhoewel hierdie produk spesifiek vir kinders geformuleer is, veiligheid tydens swangerskap en borsvoeding is nie vasgestel nie, raadpleeg u gesondheidsorgpraktisyn voor gebruik. As jy swanger is of borsvoed, dink jy kan swanger wees of beplan om 'n babu te hê, raadpleeg asseblief jou gesondheidsorgpraktisyn voordat jy hierdie medisyne neem.

BESTUUR EN GEbruik VAN MASIENE

Alhoewel hierdie produk 'n formulering vir kinders is, dit is nie altyd moontlik om te voorspel in watter mate **ULTRAFLOA® KID'S 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 vereiste van verstandelike waaksamheid, oordeel en/of gesonde koördinasie en visie nie, byvoorbeeld bestuur, ry, vlieg, seël, bedryfsmasjiene/toerusting, totdat hulle bewus is van die mate waartoe **ULTRAFLOA® KID'S PROBIOTIC** jou beïnvloed.

NEEM VAN ANDER MEDISYNE MET ULTRAFLOA® KID'S PROBIOTIC

Komplementêre medisyne produkte bevat bestanddele wat met sommige medisyne kan '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 **ULTRAFLOA® KID'S PROBIOTIC** kan die effekte van die medisyne verminder. Om hierdie interaksie te vermy, neem **ULTRAFLOA® KID'S PROBIOTIC** ten minste 2 ure voor of na antibiotika.

HOE OM ULTRAFLOA® KID'S PROBIOTIC TE NEEM

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

BELANGRIKE INLIGTING OOR DIE BESTANDELE VAN ULTRAFLOA® KID'S PROBIOTIC

ULTRAFLOA® KID'S PROBIOTIC bevat suiker wat 'n uitwerking kan hê op die beheer van jou kind se bloedsuiker as hulle diabetes mellitus het.

Aanwysings vir gebruik:

Kinders 3 tot 12 jaar: Kou een (1) tot twee (2) tablette per dag of soos voorgeskryf deur jou gesondheidspraktisyn. **Moenie meer as die aanbevole dosis neem nie.**

AS JY MEER ULTRAFLOA® KID'S PROBIOTIC NEEM AS WAT JY MOET

In die geval van oordosering, raadpleeg u dokter, apteker. Indien nie en hiervan beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.

AS JY VERGEET OM ULTRAFLOA® KID'S PROBIOTIC TE NEEM

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

MOONTLIKE NUWE-EFFEKTE

ULTRAFLOA® KID'S PROBIOTIC kan nuwe-effekte hê.

Indien jou kind enige van die volgende gediagnoseerde toestande het, raadpleeg jou gesondheidsorgpraktisyn voor gebruik: Verswakte immuunstelsel, beskadigde hartkleppe, aterosklerose, histoplasiose, hiperparatiroïedisme, limfoom, niersekte. As jou kind die volgende medisyne neem, raadpleeg asseblief jou gesondheidsorgpraktisyn voordat jy neem: Antibiotiese medisyne (breëspektrum), Diuretika, Lewermedisyne.

As enige van die volgende gebeur, hou op om **ULTRAFLOA® KID'S PROBIOTIC** te gebruik en vertel jou dokter of gaan na die ongevalleafdeling by jou naaste hospitaal:

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

Dit is alles baie ernstige gevolge. As jou kind dit het, het hulle dalk 'n ernstige reaksie op **ULTRAFLOA® KID'S PROBIOTIC** gehad. Jou kind 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, opgeblasenheid, minderigheid.

Nie alle nuwe-effekte en interaksies wat vir **ULTRAFLOA® KID'S PROBIOTIC** gerapporteer word, is by hierdie inligtingsblad ingesluit nie. Indien jou kind algemene gesondheid vererger of as hulle 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 aanlyn 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 **ULTRAFLOA® KID'S PROBIOTIC**.

HOE OM ULTRAFLOA® KID'S PROBIOTIC TE BEREË

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 **ULTRAFLOA® KID'S PROBIOTIC** gebruik as u sigbare tekens van agteruitgang opmerk nie.

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

AANBIEDING VAN ULTRAFLOA® KID'S PROBIOTIC

Wit 112 ml polipropileenhouer, met 'n wit polipropileen-skroefop.

Die houer het 'n binneste droogmiddelhuis en 'n peuterbestande seël.

Pak grootte: 30 of 60 koubare tablette.

IDENTIFIKASIE VAN ULTRAFLOA® KID'S PROBIOTIC

Pienk, ronde tablet met wit en rooi kolletjies en 'n framboosgeur.

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 REGISTRASIEHOUER

Versprei deur:

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