

## PATIENT INFORMATION LEAFLET

### SCHEDULING STATUS: S0

Category D: Complementary medicine.

Discipline: Health Supplement

34.12 Multiple substance formulation

PROPRIETARY NAME, STRENGTH, PHARMACEUTICAL FORM -

## ULTRAFLOA® IB PROBIOTIC, 30 Capsules

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

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

### WHAT ULTRAFLOA® IB PROBIOTIC CONTAINS

Each one (1) capsule of **ULTRAFLOA® IB PROBIOTIC** contains the following actives:

A Probiotic combination of:	60 Billion CFU
<i>Lactobacillus acidophilus</i> NCFM®	30 Billion CFU
<i>Bifidobacterium lactis</i> Bi-07®	30 Billion CFU
Vitamin D (as Cholecalciferol)	2,5 µg (100 I.U.)

**Inactive Ingredients:** Hydroxypropyl methylcellulose, magnesium salts of fatty acids, microcrystalline cellulose, silicon dioxide.

**This product is suitable for Vegetarians, is non-GMO and Gluten Free (Sugar Free)**

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

**ULTRAFLOA® IB PROBIOTIC** features a high-strength combination of 60 billion organisms per capsule, to improve the functioning of the gut by alleviating symptoms of bloating in patients with gastrointestinal disorders and supports immune health

### BEFORE YOU TAKE ULTRAFLOA® IB PROBIOTIC

If you are taking any chronic medication, do not use this product without consulting your healthcare professional. Do not take **ULTRAFLOA® IB PROBIOTIC** if you are hypersensitive (allergic) to any of the ingredients. If you have allergies, be sure to check with your healthcare professional before taking this supplement.

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

It is not always possible to predict to what extent **ULTRAFLOA® IB 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® IB PROBIOTIC** may affect you.

### TAKING OTHER MEDICINES WITH ULTRAFLOA® IB 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® IB PROBIOTIC** can reduce the effects of the medicine. To avoid this interaction, take **ULTRAFLOA® IB PROBIOTIC** at least 2 hours before or after antibiotics.

### HOW TO TAKE ULTRAFLOA® IB PROBIOTIC

- Do not share medicines prescribed for you with any other person.
- Always take **ULTRAFLOA® IB 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:

**Adult:** Take one (1) capsule per day or as directed by your healthcare professional.

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

### IF YOU TAKE MORE ULTRAFLOA® IB 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® IB PROBIOTIC

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

### POSSIBLE SIDE EFFECTS

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

Should you have 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 you are 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® IB 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® IB 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, diarrhea, bloating, flatulence.

Not all side effects and interactions reported for **ULTRAFLOA® IB 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® IB PROBIOTIC**.

### STORAGE AND DISPOSING OF ULTRAFLOA® IB 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® IB 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® IB 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 vegetable capsules.

### IDENTIFICATION OF ULTRAFLOA® IB PROBIOTIC

Size 0 transparent vegetable capsule containing an off-white to light yellow powder.

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

**ACCESS TO THE CORRESPONDING PROFESSIONAL INFORMATION**

Scan QR code.

**THIS LEAFLET WAS LAST REVISED ON**

05 November 2024

**NAME AND ADDRESS OF REGISTRATION HOLDER**

Distributed by:

Amipro Advanced Development Products (Pty) Ltd  
Unit 3, Eastgate Business Park, 1 South Road, Eastgate  
Extension,  
Sandton, 2146  
Tel: 011-802-8101



# PASIENT INLIGTINGSBLAD

SKEDULERINGSSTATUS: [S0](#)

Kategorie D: Komplementêre medisyne.

Disipline: Gesondheidsaanvulling

34.12 Meervoudige Bestaandeel Formulasie

## HANDELSNAAM EN DOSEERVORM,

### ULTRAFLOA® IB PROBIOTIC, 30 kapsules

LEES HIERDIE INLIGTINGSBLAD NOUKEURIG, WANT DIT BEVAT BELANGRIKE

#### INLIGTING VIR U

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

#### WAT ULTRAFLOA® IB PROBIOTIC BEVAT

Elke (1) kapsule van **ULTRAFLOA® IB PROBIOTIC** bevat die volgende

##### aktiewe stowwe:

• 'n Probiotiese kombinasie van:	60 biljoen KVE
• <i>Lactobacillus acidophilus</i> NCFM®	30 biljoen KVE
• <i>Bifidobacterium lactis</i> Bi-07®	30 biljoen KVE
• Vitamien D (as cholecalciferol)	2,5 µg (100 I.E.)

**Onaktiewe bestanddele:** Hidroksiopropielmetiellsellulose, magnesiumsoute van vetsure, mikrokristalyn-sellulose, silikondioksied.

#### Hierdie produk is geskik vir vegetariërs, is nie-GGO en glutenvry (suikervry)

#### WAT IS ULTRAFLOA® IB PROBIOTIC EN WAARVOOR WORD DIT GEBRUIK

**ULTRAFLOA® IB PROBIOTIC** beskik oor 'n hoë-sterkte kombinasie van 60 biljoen organismes per kapsule, om die funksionering van die ingewande te verbeter deur simptome van opgeblasenheid by pasiënte met gastro-intestinale afwykings te verlig en immuunsgesondheid te ondersteun.

#### VOORDAT JY ULTRAFLOA® IB PROBIOTIC NEEM

As jy enige chroniese medisyne neem, moenie hierdie produk gebruik sonder om jou gesondheidsorgpraktisyn te raadpleeg nie. Moenie **ULTRAFLOA® IB PROBIOTIC** neem as jy 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 medisyne neem.

#### SWANGERSKAP EN BORSVOEDING

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 baba te hê, raadpleeg asseblief jou gesondheidsorgpraktisyn voordat jy hierdie medisyne neem.

#### BESTUUR EN GEbruik VAN MASJINE

Dit is nie altyd moontlik om te voorspel in watter mate **ULTRAFLOA® IB 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 vererise van verstandelike waaksaamheid, oordeel en/of gesonde koördinasie en visie nie, byvoorbeeld bestuur, ry, vlieg, seil, bedryfsmasjine/toerusting, totdat hulle bewus is van die mate waartoe **ULTRAFLOA® IB PROBIOTIC** jou invloed.

#### NEEM VAN ANDER MEDISYNE SAAM MET ULTRAFLOA® IB 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® IB PROBIOTIC** kan die effekte van die medisyne verminder. Om hierdie interaksie te vermy, neem **ULTRAFLOA® IB PROBIOTIC** ten minste 2 ure voor of na antibiotika.

#### HOE OM ULTRAFLOA® IB PROBIOTIC TE NEEM

Moenie medisyne wat vir u voorgeskryf is, met enige ander persoon deel nie. Neem altyd **ULTRAFLOA® IB 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.

#### Aanwysings vir gebruik:

**Volwasse:** Neem een (1) kapsule per dag of soos aangedui deur jou gesondheidsorgpraktisyn.

**Moenie meer as die aanbevole dosis neem nie.**

#### AS JY MEER ULTRAFLOA® IB 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 ULTRAFLOA® IB PROBIOTIC TE NEEM

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

#### MOONTLIKE NUWE-EFFEKTE

**ULTRAFLOA® IB PROBIOTIC** kan nuwe-effekte hê.

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

As enige van die volgende gebeur, hou op om **ULTRAFLOA® IB 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 jy dit het, het jy dalk 'n ernstige reaksie op **ULTRAFLOA® IB 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 **ULTRAFLOA® IB 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.

#### VERSLAGDOENING VAN NUWE-EFFEKTE

As jy enige-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® IB PROBIOTIC

#### HOE OM ULTRAFLOA® IB PROBIOTIC TE BERE

Bère alle medisyne buite bereik van kinders.

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

Beskerme teen direkte sonlig en hitte.

Bère in die oorspronklike verpakking.

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

Moenie **ULTRAFLOA® IB PROBIOTIC** gebruik as u sigbare tekens van agteruitgang opmerk nie.

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

#### AANBIEDING VAN ULTRAFLOA® IB PROBIOTIC

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

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

**Pak grootte:** 30 groentekapsules.

#### IDENTIFIKASIE VAN ULTRAFLOA® IB PROBIOTIC

Grootte 0 deursigtige groentekapsule wat 'n spierwit tot liggeel poeier bevat.

**REGISTRASIE NOMMER** - Om deur SAHPRA toegeken 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:

Amipro Advanced Development Products (Pty) Ltd  
Unit 3, Eastgate Business Park, 1 South Road, Eastgate  
Extension,  
Sandton, 2146, Tel: 011-802-8101

