

PROFESSIONAL INFORMATION

SCHEDULING STATUS[50]

Category D: Complementary medicine.

Discipline: Health Supplement

34.12 Multiple substance formulation

PROPRIETARY NAME, STRENGTH, PHARMACEUTICAL FORM - ULTRAFLORA® BALANCE PROBIOTIC, 30 & 60 Capsules

COMPOSITION

Each one (1) capsule of ULTRAFLORA® BALANCE PROBIOTIC contains the following actives:

A Probiotic Blend of:	15 billion CFU)
Lactobacillus acidophilus NCFM®	7,5 billion CFU
Bifidobacterium lactis Bi-07®	7,5 billion CFU
Vitamin A (as Beta-carotene))	160 mcg
Vitamin D3 (Cholecalciferol)	2,5 mcg (100 I.U.)

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

This product is suitable for Vegetarians and Dairy free (Sugar Free)

PHARMACOLOGICAL CLASSIFICATION - Complementary Medicine

INDICATION & PHARMACOLOGICAL ACTION

ULTRAFLORA® BALANCE PROBIOTIC features a combination of 15 billion organisms per capsule, offering daily immune and digestive support, whilst helping to balance intestinal flora.

Ingredient	Benefit for inclusion
Lactobacillus acidophilus NCFM®	Acidophilus is considered a “good” bacterium. Your body needs good bacteria to support your immune system and digestive system.
Bifidobacterium lactis Bi-07®	Bifidobacteria are y-shaped bacteria found in your intestines, and they're incredibly important for your health. Bifidobacteria are healthy bacteria found in your intestines that help digest fibre, prevent infections and produce important healthy chemicals.
Vitamin A (as Beta-carotene)	In the body, beta-carotene converts into vitamin A (retinol). We need vitamin A for good vision and eye health, for a strong immune system, and for healthy skin and mucous membranes.
Vitamin D3 (Cholecalciferol)	Cholecalciferol is needed by the body for healthy bones, muscles, nerves, and to support the immune system. It works by helping the body to use more of the calcium found in foods or supplements.

- Keep this leaflet. You may need to read it again.
 - Do not share medication with any other person.
 - Ask your pharmacist if you need more information or advice.
 - You must consult a doctor should your condition worsen or does not improve.
- DO NOT USE THIS PRODUCT:**
- If you are hypersensitive (allergic) to any of the ingredients listed.
 - Do not accept this package if seals are broken.

INTERACTIONS

Always tell your healthcare professional if you are taking any other medicine. It is possible that exposure of certain supplement ingredients may interfere with certain medications. Taking antibiotics along with **ULTRAFLORA® BALANCE PROBIOTIC** can reduce the effects of the medicine. To avoid this interaction, take **ULTRAFLORA® BALANCE PROBIOTIC** at least 2 hours before or after antibiotics. (See **Warnings & Special precautions**)

DOSAGE AND DIRECTIONS FOR USE

Adult: Take one (1) capsules per day or as directed by your healthcare professional. **Do no take more than the recommended dose.**

SIDE EFFECTS

Should your general health worsen, or if you experience any untoward effects while being exposed to this product, please consult your doctor, pharmacist or other healthcare professional for advice.

KNOWN SYMPTOMS OF OVER DOSAGE AND PARTICULARS OF ITS TREATMENT

See side-effects.

Treatment: Discontinue use and consult your doctor, pharmacist or other healthcare professional for advice.



CONTRA INDICATIONS:

If you are taking any chronic medication, do not use this product without consulting your healthcare professional. Do not take **ULTRAFLORA® BALANCE 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.

WARNING AND SPECIAL PRECAUTIONS

Should you have any of the following diagnosed conditions, consult with your healthcare professional before use: Digestive tract disease, Weakened immune system, damaged heart valves, Iron deficiency, Liver disease, Malnutrition, Zinc deficiency, Atherosclerosis, Histoplasmosis, Hyperparathyroidism, Lymphoma, Kidney disease, Sarcoidosis. If you are taking the following medication, please consult with your healthcare professional before taking: Antibiotic medicine (broad-spectrum), Anticoagulants (Warfarin), Diuretics. If any of the following happens, stop using **ULTRAFLORA® BALANCE 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 **ULTRAFLORA® BALANCE 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.
- These are all very serious effects. If you have them, you may have had a serious reaction to **ULTRAFLORA® BALANCE PROBIOTIC**. You may need urgent medical attention or hospitalisation.
- Seek advice from a health care practitioner if you have any medical condition. Discontinue use immediately should any adverse reaction occur. Read this leaflet carefully because it contains important information for you. This product is available without a doctor's prescription.

IDENTIFICATION

Size 1 transparent vegetable capsule containing a white powder.

PRESENTATION

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 vegetable capsules.

STORAGE INSTRUCTION

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

Protect from direct sunlight and heat.

Store in the original bottle.

Keep the bottle tightly closed.

Replace the protective cap after each use.

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

Do not use **ULTRAFLORA® BALANCE PROBIOTIC** if you notice visible signs of deterioration.

REGISTRATION NUMBER

To be allocated by SAHPRA upon registration.

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

NAME AND BUSINESS ADDRESS OF APPLICANT

Distributed by:

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

DATE OF PUBLICATION

To be allocated by the regulatory authority.

PROFESIONELE INLIGTING

SKEDULERINGSSTATUS:SO

Kategorie D: Komplementêre medisyne.
Disipline: Gesondheidsaanvulling
33.7 Kombinasie Produk

HANDELSNAAM EN DOSEERVORM,
ULTRAFLOA® BALANCE PROBIOTIC ,
30 & 60 kapsules

SAMESTELING

Elke (1) kapsule van ULTRAFLOA® BALANCE PROBIOTIC bevat die volgende aktiewe stowwe:

’n Probiotiese mengsel van:	15 biljoenKVE
Lactobacillus acidophilus NCFM®	7,5 biljoen KVE
Bifidobacterium lactis Bi-07®	7,5 biljoen KVE
Vitamien A (as beta-karoteen))	160 mcg
Vitamien D3 (Cholecalciferol)	2,5 mcg (100 IE)

Onaktiewe bestanddele: hidroksipropylmetielcellulose, magnesiumsoute van vetsure, mikrokristallien cellulose, silikondioksied.

Hierdie produk is geskik vir vegetariërs en suiwelvry (suikervry)

FARMAKOLOGIESE KLASSIFIKASIE - Komplementêre medisyne

AANWYSLING EN FARMAKOLOGIESE WERKING

ULTRAFLOA® BALANCE PROBIOTIC beskik oor ’n kombinasie van 15 biljoen organismes per kapsule, wat daaglikke immuun- en spysverteringsondersteuning bied, terwyl dit help om die dermiflora te balanseer.

Bestanddeel	Voordeel vir insluiting
Lactobacillus acidophilus NCFM®	Acidophilus word beskou as ’n "goeie" bakterie. Jou liggaam het goeie bakterieë nodig om jou immuunstelsel en spysverteringstelsel te ondersteun. Bifidobakterieë is y-vormige bakterieë wat in jou ingewande voorkom, en hulle is ongelooflik belangrik vir jou gesondheid. Bifidobakterieë is gesonde bakterieë wat voorkom in jou ingewande wat help om vesel te verteer, infeksies te voorkom en te produseer belangrike gesonde chemikalieë. In die liggaam word beta-karoteen omgeskakel in vitamien A (retinol). Ons benodig vitamien A vir goeie visie en ooggesondheid, vir ’n sterk immuunstelsel en vir gesonde vel en slymvliese. Cholecalciferol word deur die liggaam benodig vir gesonde bene, spiere, senuwees en om die immuunstelsel te ondersteun. Dit werk deur die liggaam te help om meer van die kalsium wat in voedsel of aanvullings voorkom, te gebruik.
Bifidobacterium lactis Bi-07®	
Vitamien A (as beta-karoteen)	
Vitamien D3 (Cholecalciferol)	

Raadpleeg ’n gesondheidsorgpraktisyn as u enige mediese toestand het. Staak gebruik onmiddellik indien enige nadelige reaksie plaasvind. Lees hierdie voubljiet aandagtig deur, want dit bevat belangrike inligting vir u. Hierdie produk is beskikbaar sonder doktersvoorskrif.

- Hou hierdie voubljiet. Miskien moet u dit weer lees.
- Moenie medisyne met enige ander persoon deel nie.
- Vra jou apteker of jy meer inligting of advies benodig.
- Jy moet ’n dokter raadpleeg indien jou toestand vererger of nie verbeter nie.

MOENIE HIERDIE PRODUK GEBRUIK NIE:

- As jy hipersensitief (allergies) is vir enige van die bestanddele wat gelys word.
- Jy moet nie hierdie produk aanvaar as seëls gebreek word nie.

INTERAKSIES

Vertel altyd jou gesondheidsorgpraktisyn as jy enige ander medisyne gebruik. Dit is moontlik dat blootstelling van sekere aanvullingsbestanddele met sekere medisyne kan inmeng. (Sien **Waarskuwings en Spesiale voorsorgmaatreëls**)

DOSIS EN AANWYSINGS VIR GEBRUIK

Volwassene: Neem een (1) kapsules per dag of soos voorgeskryf deur jou gesondheidsorgpraktisyn.

Moenie meer as die aanbevole dosis neem nie.

NEWE-EFFEKTE

Indien jou algemene gesondheid vererger, of as jy enige nadelige effekte ervaar terwyl jy aan hierdie produk blootgestel word, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgpraktisyn vir raad.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE

BEHANDELING DAARVAN

Sien newe-effekte.

Behandeling:

Staak gebruik en raadpleeg jou dokter, apteker of ander gesondheidsorgpraktisyn vir advies.

KONTRA-INDIKASIES:

As jy enige chroniese medisyne neem, moenie hierdie produk gebruik sonder om jou gesondheidsorgpraktisyn te raadpleeg nie. Moenie **ULTRAFLOA® BALANCE 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 voordat jy hierdie medisyne neem. Die neem van antibiotika saam met **ULTRAFLOA® BALANCE PROBIOTIC** kan die effekte van die medisyne verminder. Om hierdie interaksie te vermy, neem **ULTRAFLOA® BALANCE PROBIOTIC** ten minste 2 uur voor of na antibiotika.

WAARSKUWING EN SPESIALE VOORSORGMAATREËLS

As jy enige van die volgende gediagnoseerde toestande het, raadpleeg jou gesondheidsorgpraktisyn voor gebruik: Spysverteringskanaalsiekte, Verswakte immuunstelsel, beskadigde hartkleppe, Ystertekort, Leversiekte, Wanvoeding, Sinktekort, Aterosklerose, Histoplasmose, Hyperparatiroedisme, Limfoom, Niersiekte, Sarkoidose. As jy die volgende medisyne neem, raadpleeg asseblief jou gesondheidswerker voordat jy neem: Antibiotiese medisyne (breëspektrum), Antikoagulanste (Warfarin), Diuretika. As enige van die volgende gebeur, hou op om **ULTRAFLOA® BALANCE PROBIOTIC** te gebruik en vertel jou dokter of gaan na die ongevalle-afdeling 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® BALANCE 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, opgeblaseheid, windigheid.

Dit is alles baie ernstige gevolge. As u dit het, het u moontlik ’n ernstige reaksie op **ULTRAFLOA® BALANCE PROBIOTIC** gehad. Miskien het u dringende mediese hulp of hospitalisasie nodig.

IDENTIFIKASIE

Grootte 1 deursigtig groentekapsule wat ’n wit poeier bevat.

AANBIEDING

Wit 112 ml polipropileenhouer, met ’n wit polipropileen-skroefdop.

Die houer het ’n binneste droogmiddelhuls en ’n peuterbestande seël.

Pak grootte: 30 of 60 groentekapsules.

BERGING INSTRUKSIE

Hou in ’n koel, donker plek, onder 25 °C.

Beskerm teen direkte sonlig en hitte.

Stoor in die oorspronklike bottel.

Hou die bottel styf toe.

Vervang die beskermende dop na elke gebruik.

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

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

REGISTRASIE NOMMER

Om by registrasie deur SAHPRA toegeken te word.

Hierdie medisyne is nie deur SAHPRA gevalueer vir kwaliteit, veiligheid of beoogde gebruik nie.

NAAM EN BESIGHEIDSADRES VAN AANSOEKER

Versprei deur:

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

DATUM VAN PUBLIKASIE

Om deur die regulerende owerheid toegeken te word.