

PROFESSIONAL INFORMATION

SCHEDULING STATUS: [S0](#)

Category D: Complementary medicine.
Discipline: Discipline specific
33.7 Combination Product



PROPRIETARY NAME, STRENGTH, PHARMACEUTICAL FORM - ULTRAFLO[®] ACUTE CARE PROBIOTIC,

10 & 30 Capsules

COMPOSITION

Each one (1) capsule of ULTRAFLO[®] ACUTE CARE PROBIOTIC contains the following actives:

Per capsule:	
Saccharomyces boulardii	6 billion CFU
A Proprietary Probiotic Blend of: <i>Bifidobacterium lactis</i> Bi-07 [™] <i>Bifidobacterium lactis</i> Bi-04 [™] <i>Lactocaseibacillus paracasei</i> Lpc-37 [™] <i>Lactobacillus acidophilus</i> NCF [®]	8, 5 billion CFU
Blackberry fruit and leaf extract (<i>Rubus fruticosus</i> L.)	50 mg
Vitamin D (as Cholecalciferol)	1,25 µg

Inactive Ingredients: Hydroxypropyl methylcellulose, magnesium salts of fatty acid, microcrystalline cellulose, silicon dioxide

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

PHARMACOLOGICAL CLASSIFICATION - Complementary Medicine

INDICATION & PHARMACOLOGICAL ACTION

ULTRAFLO[®] ACUTE CARE PROBIOTIC provides 14,5 billion organisms per capsule, reducing the risk of antibiotic-associated diarrhoea, promoting normal bowel movements and supporting immune function.

Ingredient	Benefit for inclusion
Saccharomyces boulardii	The probiotic activity of <i>S. boulardii</i> ranges from improving gut barrier function, eradicating pathogens, producing antimicrobial peptides, stimulating the immune system, and inhibiting inflammation. Specifically, <i>S. boulardii</i> is used for the prevention and treatment of gastrointestinal tract disorders, including diarrhoea symptoms.
Bifidobacterium lactis	<i>B. lactis</i> has several gut health benefits, such as improving intestinal mobility and relieving constipation, providing defence against intestinal pathogens, and improving macronutrient absorption.
Lactocaseibacillus paracasei	Supports the growth of beneficial microbes, protecting the gut lining and reducing the adhesion of pathogens
Lactobacillus acidophilus	Acidophilus may be used as a probiotic to promote the growth of good bacteria in your body.
Blackberry fruit (<i>Rubus fruticosus</i> L.)	On the basis of the chemical constituents, the plant is very useful anti-diarrheal and soothes inflamed mucosa.
Vitamin D (as Cholecalciferol)	This vitamin is also pivotal for boosting the immune system, enhancing mood and muscle function, and supporting heart health.

- 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 practitioner 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 ULTRAFLO[®] ACUTE CARE PROBIOTIC can reduce the effects of the medicine. To avoid this interaction, take ULTRAFLO[®] ACUTE CARE PROBIOTIC at least 2 hours before or after antibiotics. (See **Warnings & Special precautions**)

DOSE AND DIRECTIONS FOR USE

Adult: Acute: Take two (2) capsules per day or as directed by your healthcare practitioner.

Maintenance: Take one (1) capsule per day or as directed by your healthcare practitioner.

Do not 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 practitioner 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 practitioner for advice.

CONTRA INDICATIONS:

If you are taking any chronic medication, do not use this product without consulting your healthcare practitioner. Do not take ULTRAFLO[®] ACUTE CARE PROBIOTIC if you are hypersensitive (allergic) to any of the ingredients. If you have allergies, be sure to check with your healthcare practitioner before taking this supplement.

WARNING AND SPECIAL PRECAUTIONS

Should you have any of the following diagnosed conditions, consult with your healthcare practitioner before use: Digestive tract disease, Weakened immune system, Yeast allergy, damaged heart valves. If you are taking the following medication, please consult with your healthcare practitioner before taking: Antibiotic medicine (broad-spectrum), Antifungal medicine (used to treat fungus infections), Calcipotriene (used to treat psoriasis), Calcium channel blockers and thiazide diuretics (used to treat high blood pressure), Digoxin (used to treat arrhythmias). If any of the following happens, stop using ULTRAFLO[®] ACUTE CARE 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, changes in mood, decreased appetite.

These are all very serious effects. If you have them, you may have had a serious reaction to ULTRAFLO[®] ACUTE CARE PROBIOTIC. You may need urgent medical attention or hospitalisation.

Side effects that usually do not require medical attention (report to your healthcare practitioner 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 ULTRAFLO[®] ACUTE CARE 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 0 transparent vegetable capsule containing a light brown powder.

PRESENTATION

10 Capsules: Packed in a white 54 ml HDPE container, with a white polypropylene screw cap. The container has an inner desiccant sleeve and a tamper resistant seal.

30 Capsules: Packed in a 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: 10 or 30 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 ULTRAFLO[®] ACUTE CARE 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.

PROFESSIONELE INLIGTING

SKEDULERINGSSTATUS: 50

Kategorie D: Komplementêre medisyne.

Dissipline: Dissipline spesifiek

33.7 Kombinasie Produk

HANDELSNAAM EN DOSEERVORM,

ULTRAFLOORA® ACUTE CARE PROBIOTIC,

10 & 30 kapsules

SAMESTELING

Elke (1) kapsule ULTRAFLOORA® ACUTE CARE PROBIOTIC bevat die volgende aktiewe

stowwe:

Saccharomyces boulardii	6 biljoen KVE
'n Probiotiese mengsel van: Bifidobacterium lactis Bi-07® Bifidobacterium lactis Bi-04™ Lactocaseibacillus paracasei Lpc-37™ Lactobacillus acidophilus NCF®	8, 5 biljoen KVE
Braambessie vrugte en blaar ekstrak (Rubus fruticosus L.)	50 mg
Vitamiën D (as Cholekalsiferol)	1,25 µg

Onaktiewe bestanddele: Hidroksipropylmetielcellulose, Magnesiumsoute van vetsuur, Mikrokristallyne sellulose, Silikondioksied.

Hierdie produk is geskik vir vegetariërs en glutenvry (suikervry)

FARMAKOLOGIESE KLASSIFIKASIE - Komplementêre medisyne

AANDUIDING EN FARMAKOLOGIESE WERKINGE

ULTRAFLOORA® ACUTE CARE PROBIOTIC beskik oor 'n kombinasie van 14.5 biljoen organismes per kapsule, wat die risiko van antibiotika-geassosieerde diarree verminder, normale dermbewegings bevorder en immuunfunksie ondersteun

Bestanddeel	Voordeel vir insluiting
Saccharomyces boulardii	Die probiotiese aktiwiteit van <i>S. boulardii</i> wissel van die verbetering van dermversperringsfunksie, die uitwissing van patogene, die vervaardiging van antimikrobiëse peptiede, die stimulering van die immuunstelsel en die inhibering van inflammasie. Spesifiek, <i>S. boulardii</i> word gebruik vir die voorkoming en behandeling van spysverteringskanaalafwykings, insluitend diarree simptome.
Bifidobacterium lactis	<i>B. lactis</i> het verskeie voordele vir die gesondheid van die ingewande, soos die verbetering van dermmobilititeit en die verligting van hardlywigheid, die verskaffing van verdediging teen dermatogene en die verbetering van makronutriëntabsorpsie.
Lactocaseibacillus paracasei	Ondersteun die groei van voordelige mikrobes, beskerm die dermoëring en verminder die adhesie van patogene
Lactobacillus acidophilus	Acidophilus kan gebruik word as 'n probiotika om die groei van goeie bakterieë in jou liggaam te bevorder.
Braambessie vrugte en blaar ekstrak (Rubus fruticosus L.)	Die plant is baie nuttig anti-diarree en streeklontsteekte slymvlies.
Vitamiën D (as Cholekalsiferol)	Hierdie vitamien is ook deurslaggewend vir die bevordering van die immuunstelsel, die verbetering van bui en spierfunksie, en die ondersteuning van hartgesondheid.

KONTRA-INDIKASIE:

As jy enige chroniese medisyne neem, moenie hierdie produk gebruik sonder om jou gesondheidsorgpraktisyn te raadpleeg nie. Moenie ULTRAFLOORA® ACUTE CARE 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 aanvulling neem. Die neem van antibiotika saam met ULTRAFLOORA® ACUTE CARE PROBIOTIC kan die effek van die medisyne verminder. Om hierdie interaksie te vermy, neem ULTRAFLOORA® ACUTE CARE PROBIOTIC ten minste 2 ure voor of na antibiotika.

WAARSKUWING EN SPESIALE VOORSORGMATREËLS

As jy enige van die volgende gediagnoseerde toestande het, raadpleeg jou gesondheidsorgpraktisyn voor gebruik: Spysverteringskanaalsiekte, verswakte immuunstelsel, gisallergie, beskadigde hartkleppe. As jy die volgende medikasie neem, raadpleeg asseblief jou gesondheidswerker voordat jy neem: Antibiotiese medisyne (breëspektrum), Antifungale medisyne (gebruik om swaminfeksies te behandel), Calcipotriene (gebruik om psoriase te behandel), Kalsiumkanaalblokkers en tiasieddiuretika (gebruik om hoë bloeddruk te behandel), Digoxin (gebruik om aritmieë te behandel). As enige van die volgende gebeur, hou op om ULTRAFLOORA® ACUTE CARE 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, veranderinge in bui, verminderde eetlus.

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

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

- Maagongemak, diarree, opgeblasenheid, winderigheid.

Dit is alles baie ernstige gevolge. As u dit het, het u moontlik 'n ernstige reaksie op ULTRAFLOORA® ACUTE CARE PROBIOTIC gehad. Miskien het u dringende mediese hulp of hospitalisasie nodig.

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

- Hou hierdie inligtingsblad. 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 int erfere. (Sien **Waarskuwings en Spesiale voorsorgmaatreëls**)

DOSIS EN AANWYSINGS VIR GEBRUIK

Volwasse: Akuut: Neem twee (2) kapsules per dag of soos voorgeskryf deur jou gesondheidsorgpraktisyn.

Onderhoud: Neem een (1) kapsule 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 nuwe-effekte.

Behandeling:

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

IDENTIFIKASIE

Grootte 0 deursigtige groentekapsule wat 'n ligbruin poeier bevat.

AANBIEDING

10 kapsules: Verpak in 'n wit 54 ml HDPE-houer, met 'n wit polipropileen-skroefdop. Die houër het 'n binneste droogmiddelhuël en 'n peuteerbestande seël.

30 kapsules: Verpak in 'n wit 112 ml polipropileenhouer, met 'n wit polipropileen-skroefdop. Die houër het 'n binneste droogmiddelhuël en 'n peuteerbestande seël.

Pak grootte: 10 of 30 groentekapsules.

BERGING INSTRUKSIE

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

Beskerm teen direkte sonlig en hitte.

Bêre 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® ACUTE CARE 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 geëvalueer 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.