

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S6

Category D: Complementary medicine.

Discipline: Discipline specific

33.7 Combination Product

PROPRIETARY NAME, STRENGTH, PHARMACEUTICAL FORM -

ULTRAFLOA® ACUTE CARE PROBIOTIC,

10 & 30 Capsules

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

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

WHAT ULTRAFLOA® ACUTE CARE PROBIOTIC CONTAINS

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

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

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

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

WHAT ULTRAFLOA® ACUTE CARE PROBIOTIC IS AND WHAT IT IS USED FOR

ULTRAFLOA® 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.

BEFORE YOU TAKE ULTRAFLOA® ACUTE CARE PROBIOTIC

If you are taking any chronic medication, do not use this product without consulting your healthcare professional. Do not take **ULTRAFLOA® ACUTE CARE 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® ACUTE CARE 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® ACUTE CARE PROBIOTIC** may affect you.

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

HOW TO TAKE ULTRAFLOA® ACUTE CARE PROBIOTIC

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



Directions for use:

Adult:

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

Maintenance: 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® ACUTE CARE 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® ACUTE CARE PROBIOTIC

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

POSSIBLE SIDE EFFECTS

ULTRAFLOA® ACUTE CARE PROBIOTIC may have side effects.

Should you have any of the following diagnosed conditions, consult with your healthcare professional 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 professional 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 **ULTRAFLOA® 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 **ULTRAFLOA® ACUTE CARE 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® ACUTE CARE 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® ACUTE CARE PROBIOTIC**.

STORAGE AND DISPOSING OF ULTRAFLOA® ACUTE CARE 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® ACUTE CARE 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® ACUTE CARE PROBIOTIC

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.

IDENTIFICATION OF ULTRAFLOA® ACUTE CARE PROBIOTIC

Size 0 transparent vegetable capsule containing a light brown 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

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NAME AND ADDRESS OF REGISTRATION HOLDER

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PASIENT INLIGTINGSBLAD

SKEDULERINGSSTATUS: **S0**

Kategorie D: Komplementêre medisyne.

Dissipline: Dissipline spesifiek

33.7 Kombinasie Produk

HANDELSNAAM EN DOSEERVORM,

ULTRAFLOA® ACUTE CARE PROBIOTIC, 10 & 30

kapsules

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

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

WAT ULTRAFLOA® ACUTE CARE PROBIOTIC BEVAT

Eke een (1) kapsules **ULTRAFLOA® ACUTE CARE PROBIOTIC** bevat die volgende aktiewe:

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

Onaktiewe bestanddele: Hidroksiopropielmetiellsellulose, magnesiumsoutte van vetsuur, mikrokristallyn-sellulose, silikondioksied.

Hierdie produk is geskik vir vegetêriërs en glutenvry (suikervry)

WAT IS ULTRAFLOA® ACUTE CARE PROBIOTIC EN WAARVOOR WORD DIT GEBRUIK

ULTRAFLOA® ACUTE CARE PROBIOTIC bevat 'n kombinasie van 14,5 biljoen organismes per kapsule, wat die risiko van antibiotika-geassosieerde diarree vermindert, normale stoelgang bevorder en immuunfunksie ondersteun.

VOORDAT JY ULTRAFLOA® ACUTE CARE PROBIOTIC NEEM

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

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

SWANGERSKAP EN BORSVOEDING

Veiligheid tydens 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 babu te hê, raadpleeg asseblief jou gesondheidsorgpraktisyn voordat jy hierdie aanvulling neem.

BESTUUR EN GEBRUIK VAN MASIENE

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

NEEM VAN ANDER MEDISYNE SAAM MET ULTRAFLOA® ACUTE CARE 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 gesondheidsorgpraktisyn te raadpleeg nie. Die neem van antibiotika saam met **ULTRAFLOA® ACUTE CARE PROBIOTIC** kan die effekte van die medisyne verminder. Om hierdie interaksie te vermy, neem **ULTRAFLOA® ACUTE CARE PROBIOTIC** ten minste 2 ure voor of na antibiotika.

HOE OM ULTRAFLOA® ACUTE CARE PROBIOTIC TE NEEM

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

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.

AS JY MEER ULTRAFLOA® ACUTE CARE 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® ACUTE CARE PROBIOTIC TE NEEM

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

MOONTLIKE NEWE-EFFEKTE

ULTRAFLOA® ACUTE CARE PROBIOTIC kan newe-effekte hê.

Indien jy enige van die volgende gediagnoseerde toestande het, raadpleeg jou gesondheidsorgpraktisyn vir gebruik: Spysverteringskanaalsiekte, verswakte immuunstelsel, gisallergie, beskadigde hartkleppe. As jy die volgende medikasie neem, raadpleeg asseblief jou gesondheidsorgpraktisyn voordat jy neem: Antibiotiese medisyne (breëspektrum), Antiswam medisyne (gebruik om swaminfeksies te behandel), Kalsipotriene (gebruik om psoriasis te behandel), Kalsiumkanaalblokkers en tiasiedilatorika (gebruik om hoë bloeddruk te behandel), Digoksien (gebruik om aritmieë te behandel).

As enige van die volgende gebrue, hou op om **ULTRAFLOA® ACUTE CARE PROBIOTIC** te gebruik en vertel jou dokter of gaan na die ongevalledeffing by jou naaste hospitaal:

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

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

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

- Maagongemak, diarree, opgeblasenheid, winderigheid.

Nie alle newe-effekte en interaksies wat vir **ULTRAFLOA® ACUTE CARE PROBIOTIC** gerapporteer word, is by hierdie inligtingsblad ingesluit nie.

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

AANMELDING VAN NEWE-EFFEKTE

As jy newe-effekte ervaar, praat met jou dokter, apteker of ander gesondheidsorgpraktisyn. U kan ook newe-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 newe-effekte aan te meld, kan u help om meer inligting te verskaf oor die veiligheid van **ULTRAFLOA® ACUTE CARE PROBIOTIC**.

HOE OM ULTRAFLOA® ACUTE CARE PROBIOTIC TE BÊRÊ

Bêre alle medisyne buite bereik van kinders.

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

Beskermer 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® ACUTE CARE PROBIOTIC** gebruik as u sigbare tekens van agteruitgang opmerk nie.

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

AANBIEDING VAN ULTRAFLOA® ACUTE CARE PROBIOTIC

10 kapsules: Verpak in 'n wit 54 ml HDPE-houer, met 'n wit polipropileen-skoefdoop. Die houer het 'n binneste droogmiddelhuus en 'n peuterbestande seël.

30 kapsules: Verpak in 'n wit 112 ml polipropileenhouer, met 'n wit polipropileen-skoefdoop. Die houer het 'n binneste droogmiddelhuus en 'n peuterbestande seël.

Pak grootte: 10 of 30 groentekapsules.

IDENTIFIKASIE VAN ULTRAFLOA® ACUTE CARE PROBIOTIC

Grootte 0 deursigtige groentekapsule wat 'n ligbruin 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:

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