

PROFESSIONAL INFORMATION

Releaf Probiotic 12-Strain



SCHEDULING STATUS: **S0**

PROPRIETARY NAME AND DOSAGE FORM:

Releaf Probiotic 12-Strain (capsules).

COMPOSITION:

Each capsule contains:
2 billion CFU (colony forming units) HOWARU® probiotics consisting of a blend of:
Bifidobacterium lactis; BI-04®
Bifidobacterium lactis; HN019®
Lactobacillus acidophilus; La-14®
Lactobacillus infantis; Bi-07®
Lactobacillus gasseri; Lg-36™
Lactobacillus brevis; Lbr-35™
Lactobacillus casei; Lc-11®
Lactobacillus paracasei; Lpc-37®
Lactobacillus plantarum; Lp-115®
Lactobacillus rhamnosus; Lr-32®
Lactobacillus salivarius; Ls-33®
Lactococcus lactis; Ll-23™
Inactive ingredients: Magnesium stearate and microcrystalline cellulose.
Sugar free.

CATEGORY AND CLASS:

Category of medicine: D
Class: D 34.9 Probiotics.
Complementary Medicine: Health Supplement.

PHARMACOLOGICAL ACTION:

Pharmacodynamic properties:
Releaf Probiotic 12-Strain contains a combination of 12 probiotic strains, which assist in improving or normalizing the microbial balance in the human intestines and thereby improving the functioning of the digestive tract/gut.

Bifidobacterium lactis; BI-04®
Bifidobacterium lactis; HN019®
Lactobacillus acidophilus; La-14®
Lactobacillus infantis; Bi-07®
Lactobacillus gasseri; Lg-36™
Lactobacillus brevis; Lbr-35™
Lactobacillus casei; Lc-11®
Lactobacillus paracasei; Lpc-37®
Lactobacillus plantarum; Lp-115®
Lactobacillus rhamnosus; Lr-32®
Lactobacillus salivarius; Ls-33®
Lactococcus lactis; Ll-23™

Pharmacokinetic properties:

The active ingredients in this formulation are well known. Pharmacokinetic studies have not been conducted **Releaf Probiotic 12-Strain**.

INDICATIONS:

Releaf Probiotic 12-Strain contains a combination of 12 probiotic strains, which assist in improving or normalizing the microbial balance in the human intestines and thereby improving the functioning of the digestive tract/gut.

CONTRAINDICATIONS:

Hypersensitivity to any of the ingredients.
Not recommended during pregnancy and/or lactation.

WARNINGS and SPECIAL PRECAUTIONS:

Might cause gastrointestinal reactions.

Effects on the ability to drive and use machinery:

No studies on the effect of **Releaf Probiotic 12-Strain** on the ability to drive or operate machinery were performed. It is unlikely that **Releaf Probiotic 12-Strain** would affect the ability to drive or operate machinery.

INTERACTIONS:

Adverse effects have not become known with the simultaneous ingestion of **Releaf Probiotic 12-Strain** with food and drink.

Antibiotics might decrease the effects of probiotics (bifidobacterial and lactobacillus species). Advise patients to take antibiotics and this product at least 2 hours apart. Avoid taking probiotics (bifidobacterial and lactobacillus species) during digestive tract surgery, as it might contribute to infection.

Lactobacillus could cause infection in patients with short bowel syndrome, who are immunocompromised or who are taking immunosuppressants such as cyclosporine, tacrolimus, azathioprine and cancer chemotherapeutic agents like cyclophosphamide and cisplatin.

HUMAN REPRODUCTION:

Pregnancy and lactation:

Not recommended for use in pregnancy and lactation.
Consult a healthcare professional for further information.

DOSAGE AND DIRECTIONS FOR USE:

Adults and children above 12 years of age: Take 1 capsule daily.

It is advisable to stagger the administration of the antibiotic and probiotic such that the probiotic is administered at least two hours after the antibiotic dose, otherwise the antibiotic may reduce the efficacy of the probiotic microorganisms. Probiotics must be administered for at least one week following the completion of the antibiotic course.

If the symptoms worsen or persist, please consult your healthcare practitioner.

SIDE EFFECTS:

Gastrointestinal disorders:

Less frequent: Diarrhoea.
Less frequent: Bloating and flatulence.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

No known symptoms of overdosage.

Treatment of overdosage is symptomatic and supportive.

IDENTIFICATION:

A size 0 opaque white and purple gelatin capsule, with "RELEAF P/12 STRAIN" printed on the white capsule body.

PRESENTATION:

10's: The capsules are available in PVC/aluminium blister strips, with each blister strip containing 10 capsules. Each carton contains 1 blister strip.
30's: The capsules are available in PVC/aluminium blister strips, with each blister strip containing 10 capsules. Each carton contains 3 blister strips.

STORAGE INSTRUCTIONS:

Store in a cool, dry place at or below 25 °C.
Protect from light.
KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

To be allocated.

Releaf Probiotic 12-Strain has not been evaluated by the SAHPRA for its quality, safety or intended use. **Releaf Probiotic 12-Strain** does not intend to prevent or cure any form of illness or disease, and should not replace any medication. If you suffer from a chronic medical condition, consult your healthcare practitioner before using this product. Keep away from children. Do not exceed the recommended dose.

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

RELEAF PHARMACEUTICALS (PTY) LTD
14 De Vreugde Crescent
Dal Josaphat
Paarl
7646
Tel: +27 (21)001 9748
Email: Info@releafpharmaceuticals.co.za



DATE OF PUBLICATION:

February 2018. RP0147/17A

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PATIENT INFORMATION LEAFLET
This leaflet tells you about **Releaf Probiotic 12-Strain**.

Health Supplement

SCHEDULING STATUS: **S0**

PROPRIETARY NAME AND DOSAGE FORM:

Releaf Probiotic 12-Strain (capsules).

Read all of this leaflet carefully because it contains important information for you. **Releaf Probiotic 12-Strain** is available without a doctor's prescription. Nevertheless, you still need to use **Releaf Probiotic 12-Strain** carefully to get the best results from it.

Keep this leaflet. You may need to read it again.
Do not share **Releaf Probiotic 12-Strain** with any other person.
Ask your pharmacist if you need more information or advice.
You must see a doctor if your symptoms worsen or do not improve.

WHAT Releaf Probiotic 12-Strain CONTAINS:

Each capsule contains:
Active ingredients are:
2 billion CFU (colony forming units) HOWARU® probiotics consisting of a blend of:
Bifidobacterium lactis; BI-04®
Bifidobacterium lactis; HN019®
Lactobacillus acidophilus; La-14®
Lactobacillus infantis; Bi-07®
Lactobacillus gasseri; Lg-36™
Lactobacillus brevis; Lbr-35™
Lactobacillus casei; Lc-11®
Lactobacillus paracasei; Lpc-37®
Lactobacillus plantarum; Lp-115®
Lactobacillus rhamnosus; Lr-32®
Lactobacillus salivarius; Ls-33®
Lactococcus lactis; Ll-23™
Inactive ingredients are: Magnesium stearate and microcrystalline cellulose.
Sugar free.

WHAT Releaf Probiotic 12-Strain IS USED FOR:

Releaf Probiotic 12-Strain contains a combination of 12 probiotic strains, which assist in improving or normalizing the microbial balance in the human intestines and thereby improve the functioning of the digestive tract/gut.

BEFORE YOU TAKE Releaf Probiotic 12-Strain:

Do NOT take Releaf Probiotic 12-Strain:

- If you are allergic to any of the ingredients.
- If you are pregnant or breastfeeding your baby (see "Pregnancy and breastfeeding") (see "HOW TO TAKE Releaf Probiotic 12-Strain").

Take special care with Releaf Probiotic 12-Strain:

Might cause gastrointestinal reactions.

Releaf Probiotic 12-Strain does not intend to prevent or cure any form of illness or disease, and should not replace any medication. If you suffer from a chronic medical condition, consult your healthcare practitioner before using this product. Keep away from children. Do not exceed the recommended dose.

Please consult your doctor or pharmacist prior to use if you:

- are having digestive tract surgery.
- have short bowel syndrome.
- are immunocompromised.

Taking Releaf Probiotic 12-Strain with food and drink:

There are no known side effects to taking **Releaf Probiotic 12-Strain** with food and drink.

Pregnancy and breastfeeding:

Do not use **Releaf Probiotic 12-Strain** during pregnancy or while you are breastfeeding your baby, as safety and efficacy have not been established.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

Driving and using machinery:

No studies on the effect on the ability to drive or use machinery have been performed. It is unlikely **Releaf Probiotic 12-Strain** would affect your ability to drive or use machinery. However, please exercise care until you are certain that your ability to perform such activities is not affected.

Taking other medicines with Releaf Probiotic 12-Strain:

Always tell your healthcare professional if you are taking other medicines on a regular basis, including complementary or traditional medicines. The use of **Releaf Probiotic 12-Strain** with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

- Do not take **Releaf Probiotic 12-Strain** in combination with medicines such as:
- Antibiotics (unless the probiotic is administered at least two hours after the antibiotic dose).
- Immunosuppressants such as cyclosporine, tacrolimus, azathioprine and cancer chemotherapeutic agents like cyclophosphamide and cisplatin.

HOW TO TAKE Releaf Probiotic 12-Strain:

The usual dose is:

Adults and children above 12 years of age: Take 1 capsule daily.

It is advisable to stagger the administration of the antibiotic and probiotic such that the probiotic is administered at least two hours after the antibiotic dose, otherwise the antibiotic may reduce the efficacy of the probiotic microorganisms. Probiotics must be administered for at least one week following the completion of the antibiotic course.

If the symptoms worsen or persist, please consult your healthcare practitioner.

If you take more Releaf Probiotic 12-Strain than you should:

No known information on overdosage.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, immediately seek help at the nearest hospital or poison control center.

If you forget to take Releaf Probiotic 12-Strain:

Always take **Releaf Probiotic 12-Strain** as prescribed. If you miss a dose, take it as soon as you remember. If you do not remember the missed dose until the next dose is due, skip the missed dose and go back to your regular dosing schedule (see "HOW TO TAKE **Releaf Probiotic 12-Strain**"). Do not take a double dose to make up for forgotten individual doses.

POSSIBLE SIDE EFFECTS:

Releaf Probiotic 12-Strain can have side effects.

Not all side effects reported for **Releaf Probiotic 12-Strain** are included in this leaflet. Should your general health worsen while receiving **Releaf Probiotic 12-Strain**, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking Releaf Probiotic 12-Strain and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Diarrhoea (*less frequent*).
- Bloating and flatulence (*less frequent*).

Please report/ inform your doctor or pharmacist if you notice any side effects not mentioned in this leaflet.

STORAGE AND DISPOSING OF Releaf Probiotic 12-Strain:

Store in a cool, dry place at or below 25 °C. Do not remove the blisters from the original packing until required for use.

Protect from light.

STORE ALL MEDICINE OUT OF REACH OF CHILDREN.

Do not use after the expiry date stated on the label. Return all unused **Releaf Probiotic 12-Strain** to your pharmacist.

Do not dispose of unused **Releaf Probiotic 12-Strain** in drains or sewerage systems (e.g. toilets).

PRESENTATION OF Releaf Probiotic 12-Strain:

Releaf Probiotic 12-Strain are available in PVC/aluminium blister strips, with each blister strip containing 10 capsules. Each carton of 10 capsules contains 1 blister strip, and each carton of 30 capsules contains 3 blister strips.

IDENTIFICATION OF Releaf Probiotic 12-Strain:

A size 0 opaque white and purple gelatin capsule, with "RELEAF P/12 Strain" printed on the white capsule body.

REGISTRATION NUMBER:

To be allocated.

Releaf Probiotic 12-Strain has not been evaluated by the SAHPRA for its quality, safety or intended use.

NAME AND ADDRESS OF THE REGISTRATION HOLDER:

RELEAF PHARMACEUTICALS (PTY) LTD
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DATE OF PUBLICATION:

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PASIËNTINLIGTINGSBLAD

Inligting oor **Releaf Probiotic 12-Strain**.

Gesondheidsaanvulling

SKEDULERINGSSTATUS: **S0**

EIENDOMSNAAM EN DOSEERVORM:

Releaf Probiotic 12-Strain (kapsules).

Lees die hele inligtingsblad deeglik, want dit bevat belangrike inligting. **Releaf Probiotic 12-Strain** is beskikbaar sonder 'n dokter se voorskrif. U moet egter steeds **Releaf Probiotic 12-Strain** versigtig gebruik om die beste resultate daarmee te verkry.

Hou hierdie inligtingsblad. Dit kan nodig wees dat u dit weer lees. Moenie **Releaf Probiotic 12-Strain** met enige ander persoon deel nie.

Indien u verdere inligting of advies verlang, vra asseblief u apteker.

U moet 'n dokter raadpleeg indien u simptome vererger.

WAT Releaf Probiotic 12-Strain BEVAT:

Elke kapsule bevat:

Aktiewe bestanddele is:

2 biljoen KVE (kolonievormende eenhede) HOWARU® probiotika bestaan uit 'n mengsel van:

Bifidobacterium lactis; BI-04®

Bifidobacterium lactis; HN019®

Lactobacillus acidophilus; La-14®

Lactobacillus infantis; Bi-07®

Lactobacillus gasseri; Lg-36™

Lactobacillus brevis; Lbr-35™

Lactobacillus casei; Lc-11®

Lactobacillus paracasei; Lpc-37®

Lactobacillus plantarum; Lp-115®

Lactobacillus rhamnosus; Lr-32®

Lactobacillus salivarius; Ls-33®

Lactococcus lactis; Ll-23™

Die ander bestanddele is magnesiumstearaat en mikrokristallyne sellulose.

Suikervry.

WAARVOOR Releaf Probiotic 12-Strain GEBRUIK WORD:

Releaf Probiotic 12-Strain is 'n kombinasie van 12 probiotiese stamme wat help met die verbetering van normalisering van die mikrobiiese balans in die menslike dermkanaal en sodoende die funksionering van die spysverteringskanaal verbeter.

VOOR U Releaf Probiotic 12-Strain NEEM:

Moet NIE **Releaf Probiotic 12-Strain** neem NIE:

- Indien u allergies is vir enige van die bestanddele.
- Indien u swanger is of u baba borsvoed (see "Swangerskap en borsvoeding") (sien "HOE OM **Releaf Probiotic 12-Strain** TE GEBRUIK").

Neem spesiale sorg met Releaf Probiotic 12-Strain:

Kan gastro-intestinale reaksies veroorsaak.

Releaf Probiotic 12-Strain beoog nie om enige ongesteldheid of siektetoestand te genees nie en moet nie enige medikasie vervang nie. Mense wat aan 'n chroniese mediese toestand ly moet hulle gesondheidspraktisyn raadpleeg voor hulle hierdie produk gebruik. Hou buite bereik van kinders. Moenie die voorgeskrewe dosis oorskry nie.

Raadpleeg asseblief u dokter of apteker voor gebruik indien u:

- chirurgie aan die dermkanaal ondergaan het.
- kort-derm sindroom het.
- immuunonderdruk is.

Releaf Probiotic 12-Strain met kos en drinkgoed:

Daar is geen bekende nuwe-effekte om **Releaf Probiotic 12-Strain** saam met kos en drinkgoed te neem nie.

Swangerskap en borsvoeding:

Moenie **Releaf Probiotic 12-Strain** neem terwyl u swanger is of u baba borsvoed nie, aangesien die veiligheid hiervan nie bepaal is nie.

Indien u swanger is of u baba borsvoed, raadpleeg asseblief u dokter, apteker of ander professionele gesondheidsorgwerker voor u hierdie medisyne neem.

Bestuur en die gebruik van masjinerie:

Geen navorsingstudies is uitgevoer oor die effek op die vermoë om te bestuur of masjinerie te hanteer nie. Dit is onwaarskynlik dat **Releaf Probiotic 12-Strain** die vermoë om te bestuur of masjinerie te gebruik sal beïnvloed. Wees egter versigtig tot u seker is u vermoë om hierdie aktiwiteite uit te voer word nie beïnvloed nie.

Die neem van ander medisyne saam met Releaf Probiotic 12-Strain:

Lig altyd u gesondheidspraktisyn in wanneer u medisyne op 'n gereelde grondslag neem, insluitend komplementêre of tradisionele medisyne. Die gebruik van **Releaf Probiotic 12-Strain** saam met hierdie medisyne mag ongewenste wisselwerkings veroorsaak. Raadpleeg asseblief u dokter, apteker of ander professionele gesondheidsorgwerker.

Moenie **Releaf Probiotic 12-Strain** in kombinasie met medisyne soos die volgende gebruik nie:

- Antibiotika (Tensy die probiotika vir ten minste twee ure na die antibiotika geneem word).
- Immuno-ondridders soos siklosporien, takrolimus, asatioprien en kanker chemoterapeutiese middels soos siklofosfamied en sispatrien.

HOE OM Releaf Probiotic 12-Strain TE GEBRUIK:

Die gewone dosis is:

Volwassenes en kinders bo 12 jaar oud: Neem 1 kapsule daaglik.

Dit word aanbeveel om die toediening van die antibiotika en probiotika te versprei sodat die probiotika ten minste twee ure na die antibiotika geneem word, anders mag die antibiotika die effektiwiteit van die probiotiese mikroorganismes verminder. Probiotika moet vir ten minste een week na die voltooiing van die antibiotiese kursus geneem word.

As die simptome vererger of voortduur, raadpleeg 'n gesondheidsorgpraktisyn.

Indien u meer Releaf Probiotic 12-Strain geneem het as wat u moes:

Geen inligting bekend oor oordosering nie.

In die geval van 'n oordosis, raadpleeg u dokter of apteker. Indien nie een van hulle beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.

Indien u vergeet om Releaf Probiotic 12-Strain te neem:

Neem **Releaf Probiotic 12-Strain** altyd soos voorgeskryf. Indien u 'n dosis vergeet het, neem dit sou gou as wat u onthou. Indien u egter nie van die vergete dosis onthou voordat dit tyd is vir die volgende dosis is nie, slaan die vergete dosis oor en keer terug na u gewone doseringskedule (sien "HOE OM **Releaf Probiotic 12-Strain** TE GEBRUIK"). Moenie 'n dubbele dosis neem om te vergoed vir die oorgeslane individuele dosis nie.

MOONTLIKE NUWE-EFFEKTE:

Releaf Probiotic 12-Strain kan nuwe-effekte hê.

Nie alle nuwe-effekte wat vir **Releaf Probiotic 12-Strain** gemeld is, is in hierdie inligtingstuk vervat nie. Indien u algemene gesondheid agteruitgaan terwyl u **Releaf Probiotic 12-Strain** gebruik, raadpleeg asseblief u dokter, apteker of ander professionele gesondheidsorgwerker vir advies.

Indien en enige van die volgende gebeur, moet u die gebruik van Releaf Probiotic 12-Strain staak en u dokter dadelik in kennis stel of na die naaste ongevalle afdeling van die naaste hospitaal gaan:

- Diarree (*minder herhaaladelik*).
- Opgeblaseheid en windigheid (*minder herhaaladelik*).

Lig asseblief u dokter of apteker in indien u enige nuwe-effekte opmerk wat nie in hierdie inligtingstuk genoem word nie.

BERGING EN WEGDOEN VAN Releaf Probiotic 12-Strain:

Bewaar in 'n koel, droë plek by of onder 25 °C. Moenie die bergingverpakking uit die oorspronklike verpakking verwyder totdat dit nodig is vir gebruik nie.

Beskerm teen lig.

HOU ALLE MEDIOSYNE BUITE BEREIK VAN KINDERS.

Moenie gebruik na die vervaldatum op die etiket nie. Neem alle ongebruikte **Releaf Probiotic 12-Strain** na u apteker terug.

Moenie ongebruikte **Releaf Probiotic 12-Strain** in afvoertype of rioolsisteme (byvoorbeeld toilette) weggooi nie.

AANBIEDING VAN Releaf Probiotic 12-Strain:

Releaf Probiotic 12-Strain is beskikbaar in PVC/aluminium stolpverpakking, met elke stolpverpakking wat 10 kapsules bevat. Elke dosie van 10 kapsules bevat 1 stolpverpakking en elke dosie van 30 kapsules bevat 3 stolpverpakkinge.

IDENTIFIKASIE VAN Releaf Probiotic 12-Strain:

'n Ondersigtige grootte 0 wit en pers gelatin kapsule, met "RELEAF P/12 STRAIN" gedruk op die wit kapsulliggaam.

REGISTRASIENOMMER:

Sal toegeken word.

Releaf Probiotic 12-Strain is nie deur die Saphra geëvalueer vir gehalte, veiligheid of beoogde gebruik nie.

NAAM EN SAKEADRES VAN DIE HOUER VAN DIE REGISTRASIE:

RELEAF PHARMACEUTICALS (EDMS) BPK
De Vreugde Singel 14

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