

PROFESSIONAL INFORMATION

Releaf Probiotic Active 12-Strain



SCHEDULING STATUS: [S0]

PROPRIETARY NAME AND DOSAGE FORM:
Releaf Probiotic Active 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; LI-23[™]

Zinc picolinate 25 mg
Vitamin A (retinol) 4994,6 I.U. (1 500 mcg RE)
Vitamin D₃ (cholecalciferol) 40 I.U. (1.0 mcg)

Inactive ingredients: Magnesium stearate and microcrystalline cellulose.
Sugar free.

CATEGORY AND CLASS:
Category of medicine: D
Class: D 34.12 Multiple Substance Formulation.
Complementary Medicine: Health Supplement.

PHARMACOLOGICAL ACTION:
Pharmacodynamic properties:
Releaf Probiotic Active 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[®]
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Lactobacillus rhamnosus; Lr-32[®]
Lactobacillus salivarius; Ls-33[®]
Lactococcus lactis; LI-23[™]

Releaf Probiotic Active 12-Strain also contains vitamins A, D₃ and zinc picolinate.

Zinc picolinate: A mineral that contributes to the maintenance of good health. It helps in connective tissue formation, to maintain healthy skin, to maintain immune function and assists the body to metabolise carbohydrates, fats and proteins.

Vitamin A (retinol): A vitamin that contributes to the maintenance of good health. It contributes to the maintenance of good eyesight, skin, membranes, immune function and the development and maintenance of strong bones and teeth.

Vitamin D₃ (cholecalciferol): A vitamin that assists in the uptake and distribution of calcium and phosphorus within the body.

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

INDICATIONS:
Releaf Probiotic Active 12-Strain contains a combination of 12 probiotic strains, with Vitamin A, D₃ and Zinc, for the active person. Supports the immune system and connective tissue formation. Promotes good health while training.

CONTRAINDICATIONS:
Hypersensitivity to any of the ingredients.
Not recommended during pregnancy and/or lactation.
Not recommended for patients with hypercalcaemia, renal impairment or calculi and with heart diseases.
Not recommended for patients who might be at increased risk of organ damage if hypercalcaemia occurred.

WARNINGS and SPECIAL PRECAUTIONS:
Probiotics might cause gastrointestinal reactions. Vitamin D₃ might cause constipation and flatulence. Vitamin A might cause hypervitaminosis.

Effects on the ability to drive and use machinery:
No studies on the effect of **Releaf Probiotic Active 12-Strain** on the ability to drive or operate machinery were performed. It is unlikely that **Releaf Probiotic Active 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 Active 12-Strain** and food and drink.

Probiotics:
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.

Zinc picolinate:
Iron supplements, penicillamine, phosphorus-containing preparations and tetracyclines may reduce the adsorption of zinc. However, zinc supplements can reduce the adsorption of copper, fluoroquinolones, iron, penicillamine and tetracyclines.

Vitamin A:
An increased risk of hypervitaminosis A is associated with administering vitamin A in combination with synthetic retinoids such as acitretin, isotretinoin and tretinoin. Vitamin A might affect the effectiveness of the measles vaccine. Advise patients not to use this product when receiving the vaccine.

Neomycin, colestyramine or liquid paraffin may reduce the adsorption of vitamin A. Absorption may also be impaired in cholestatic jaundice and fat-malabsorption conditions.

Vitamin D₃:
An increased risk of hypercalcaemia exists if vitamin D₃ is given with thiazide diuretics, calcium, or phosphate. Thiazide diuretics reduces the urinary excretion of calcium. Vitamin D₃ should not be given to patients with hypercalcaemia and patients with renal impairment or calculi, heart disease, and who might be at increased risk of organ damage if hypercalcaemia occurred. Plasma phosphate and calcium concentrations should be monitored during treatment with Vitamin D₃ at regular intervals.

Some antiepileptics (such as carbamazepine, phenobarbital, phenytoin and primidone), rifampicin, isoniazid and corticosteroids may reduce the effectiveness of vitamin D₃.

HUMAN REPRODUCTION:
Pregnancy and lactation:
Not recommended for use during pregnancy and lactation.
Consult a healthcare professional for further information.

DOSAGE AND DIRECTIONS FOR USE:
Adults: 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.
Do not use after the expiry date.
Do not exceed the recommended daily dose.

SIDE EFFECTS:
Probiotics:
Gastrointestinal disorders:
Less frequent: Diarrhoea.
Less frequent: Bloating and flatulence.

Zinc picolinate:
Gastrointestinal disorders:
Frequent: Abdominal pain, dyspepsia, nausea, vomiting, diarrhoea, gastric irritation and gastritis.

Vitamin A:
General disorders and administrative site conditions:
Frequent: Excessive or long-term use might cause hypervitaminosis, which is associated with fatigue, irritability, anorexia and loss of weight, vomiting and other gastrointestinal disturbances, low-grade fever, hepatomegaly, skin changes (yellowing, dryness, sensitivity to sunlight), pruritus, alopecia, dry hair, cracking and bleeding lips, anemia, headache, hypercalcaemia, subcutaneous swelling, nocturia, pains in bones and joints, as well as raised intracranial pressure and papilloedema mimicking brain tumors, and visual disturbances which may be severe.

Children and patients with liver disease might be more susceptible to these side-effects.

Vitamin D₃:
Gastrointestinal disorders:
Frequent: Constipation and flatulence.
Less frequent: Nausea, abdominal pain and diarrhoea.

Skin and subcutaneous tissue disorders:
Less frequent: Skin rashes and urticaria.
Renal and urinary disorders:
Less frequent: The formation of kidney stones.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
In acute overdosage zinc salts are corrosive and zinc toxicity may occur. High doses of zinc may lead to copper deficiency and associated sideroblastic anemia and neutropenia. Blood counts and serum cholesterol should be monitored in order to detect early signs of copper deficiency.

Acute vitamin A intoxication is characterised by sedation, dizziness, confusion, diarrhoea and vomiting, sore mouth, bleeding gums, desquamation, and increased intracranial pressure (resulting in bulging fontanelle in infants or severe headache in adults). Hepatomegaly, visual disturbances and severe irritability may occur.

Symptoms of vitamin D₃ overdosage may lead to the development of hyperphosphataemia or hypercalcaemia, of which the symptoms may include anorexia, lassitude, nausea and vomiting, constipation or diarrhoea, polyuria, nocturia, sweating, headache, thirst, dryness and vertigo. Excessive intake of vitamin D₃ may cause gastrointestinal irritation, gastric hypersecretion, hypercalcaemia, renal and cardiovascular damage. Hypersensitivity reactions, skin irritation and contact dermatitis has been reported.

Treatment of overdosage is symptomatic and supportive.

IDENTIFICATION:
A size 0 opaque white and pink gelatin capsule, with "RELEAF P/Active" 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 Active 12-Strain has not been evaluated by the SAHPRA for its quality, safety or intended use. **Releaf Probiotic Active 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



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PATIENT INFORMATION LEAFLET

This leaflet tells you about **Releaf Probiotic Active 12-Strain**.

Health Supplement

SCHEDULING STATUS: [S0]

PROPRIETARY NAME AND DOSAGE FORM:
Releaf Probiotic Active 12-Strain (capsules).

Read all of this leaflet carefully because it contains important information for you. **Releaf Probiotic Active 12-Strain** is available without a doctor's prescription. Nevertheless, you still need to use **Releaf Probiotic Active 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 Active 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 Active 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[®]
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Inactive ingredients are: Magnesium stearate and microcrystalline cellulose.
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WHAT Releaf Probiotic Active 12-Strain IS USED FOR:
Releaf Probiotic Active 12-Strain contains a combination of 12 probiotic strains, with Vitamin A, D₃ and Zinc, for the active person. Supports the immune system and connective tissue formation. Promotes good health while training.

Zinc picolinate: A mineral that contributes to the maintenance of good health. It helps in connective tissue formation, to maintain healthy skin, to maintain immune function and assists the body to metabolise carbohydrates, fats and proteins.

Vitamin A (retinol): A vitamin that contributes to the maintenance of good health. It contributes to the maintenance of good eyesight, skin, membranes, immune function and the development and maintenance of strong bones and teeth.

Vitamin D₃ (cholecalciferol): A vitamin that assists in the uptake and distribution of calcium and phosphorus within the body.

BEFORE YOU TAKE Releaf Probiotic Active 12-Strain:
Do NOT take Releaf Probiotic Active 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 Active 12-Strain**").
- If you have an abnormally high level of calcium in the blood (hypercalcaemia).
- If you are suffering from kidney failure.
- If you are suffering from kidney stones or have calcium deposits in your kidneys.
- If you have a heart disease.
- If you might be at increased risk of organ damage if hypercalcaemia occurred.
- If you are suffering from an excessive supply of vitamin D₃.

Take special care with Probiotic Active 12-Strain:
Probiotics might cause gastrointestinal reactions.
If you are on long term treatment with vitamin D₃, the quantity of calcium and phosphates in the blood must be regularly monitored, especially in the elderly and where treatment is being taken at the same time as cardiac glycosides or diuretics (water tablets).

Releaf Probiotic Active 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.
- If you are receiving or have recently received the measles vaccine.
- Are immunocompromised.
- Have had kidney stones.
- If you have cholestatic jaundice and fat-malabsorption conditions, as these might impair the absorption of vitamin A, making **Releaf Probiotic Active 12-Strain** less effective.

Taking Releaf Probiotic Active 12-Strain with food and drink:
There are no known side effects to taking **Releaf Probiotic Active 12-Strain** with food and drink. Zinc picolinate is best taken with meals to prevent side-effects.

Pregnancy and breastfeeding:
Do not use **Releaf Probiotic Active 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 that **Releaf Probiotic Active 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.

