

ATOGLA PROBIO

(Lactobacillus rhamnosus GG ATCC 53103)

Reference Safety Information for ATOGLA PROBIO (Capsules and Sachets)

COMPOSITION: Lactobacillus rhamnosus GG

STRENGTH:

- Capsule: 10 billion CFU
- Sachet: 6 billion CFU

MECHANISM OF ACTION:

Lactobacillus rhamnosus GG decreases IL-10 production, provides protection against pathogenic macromolecules in the gut and accelerated immunological maturation, regulation of the immune response, stimulation of peripheral blood cells to secrete IL-10 and transforming growth factor β .^[1]

DOSAGE AND ADMINISTRATION: [6, 7]

- Lactobacillus rhamnosus GG should be taken after food. It can be mixed with water or milk.
- In children: 5 to 10 billion CFU per day
- In adults: 10 to 20 billion CFU per day

CLINICAL USE: [1, 10, 11]

- As supplementary agent/add-on strategy in clinical cases of dry skin including atopic dermatitis and eczema.

CONTRAINDICATIONS: [2, 3, 4]

Use of Lactobacillus rhamnosus GG in severe acute pancreatitis, in patients with allergy to any of the components, immunocompromised patients is contraindicated. Use is also not advised in patients at risk of opportunistic infections and in those with badly damaged GI tracts.

DRUG INTERACTIONS: [5]

Lactobacillus rhamnosus GG should be used cautiously in patients taking immunosuppressant, such as cyclosporine, tacrolimus, azathioprine, and chemotherapeutic agents, since probiotics could cause an infection or pathogenic colonization in immunocompromised patients.

USE IN SPECIAL POPULATIONS:

- **Paediatric:** Highly efficacious and safe.^[3, 8, 10]

- **Pregnancy:** Trials investigating lactobacillus rhamnosus GG use in pregnant women shows it is safe.^[2, 9, 10]
- **Liver impairment:** No data available ^[2]
- **Renal failure:** No data available ^[2]

SIDE EFFECTS: ^[2, 5, 12]

Lactobacillus rhamnosus is generally considered safe and well tolerated. Side effects includes abdominal cramping, fever, chills, soft stools, flatulence, taste disturbances, bloating, dizziness, trouble breathing

Reporting of adverse reactions

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via any point of contact of Torrent Pharma available at: https://www.torrentpharma.com/index.php/site/info/adverse_event_reporting by reporting side effects, you can help provide more information on the safety of this medicine.

Manufactured by:

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Abbreviations:

IL-10: interleukin 10; TGF- β : transforming growth factor beta

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