

VIZYLAC GG DROPS

For the use of a Registered Medical Practitioner or Hospital or a Laboratory only.

Abbreviated Prescribing information for VIZYLAC GG DROPS (*Lactobacillus rhamnosus* GG (ATCC 53103))

[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

Mechanism of action: The underlying mechanisms of probiotic action are unclear but may include strengthening of the non-immunological gut barrier, pathogen growth inhibition and interference with adhesion, and enhancement of mucosal immune systems, as well as the systemic immune response. Probiotics appear effective in preventing and reducing the severity of a number of conditions, but there is insufficient evidence with respect to any suggested benefits from probiotics in prevention or therapy of ischaemic heart diseases, autoimmune disease or cancer.

DOSAGE AND ADMINISTRATION: Shake the bottle well until the suspended materials are dispersed. Remove the cap. Tilt the bottle at about 45° angle to release 7 drops in a spoon. Do not administer directly from the bottle into the mouth or add hot milk or food. To be given only under medical advice by physician/ certified dietician/ nutritionist for children below 5 years. 7 drops per day before or after the first meal or as directed by healthcare professionals. Use within 14 days from the date of opening under recommended storage condition, discard the unused material after 16 days. Keep the bottle closed.

CONTRAINDICATION: There are no absolute contraindications to probiotics comprised of *Lactobacillus* sp. But some may have an Allergies to *Lactobacillus rhamnosus*. There are typically few or no adverse effects; flatulence or mild abdominal discomfort, usually selflimited, are reported occasionally. There have been reports of pathologic infection, including bacteremia with probiotic species following oral administration. These are rare, occurring in severely ill or immunocompromised hosts, or in children with short-gut syndrome. It is prudent to avoid probiotics in these patients, or to be aware of the risk of sepsis. A recent systematic review examined the safety of *L. rhamnosus* GG and *Bifidobacterium* sp. and concluded that the risk of sepsis is low, with no cases reported in any prospective clinical trial. There are no reports of sepsis or other pathologic colonization in healthy patients. There are also no known interactions with medications or other supplements.

WARNINGS & PRECAUTIONS: Before using this product, tell the doctor or pharmacist if you are allergic to it; or if you have any other allergies. This product may contain inactive ingredients, which can cause allergic reactions or other problems. Talk to pharmacist for more details. If you have any of the following health problems, consult the doctor or pharmacist before using this product: diarrhoea lasting more than 2 days (especially if you also have a high fever), weakened immune system (such as due to chemotherapy, HIV infection), recurring vaginal infections, recurring urinary tract infections. Liquid products, foods, powders, or chewable tablets may contain sugar and/or aspartame. Caution is advised if you have diabetes, phenylketonuria (PKU), or any other condition Page 6 of 14 that requires you to limit/avoid these substances in your diet. Ask your doctor or pharmacist about using this product safely.

DRUG INTERACTION: Antibiotic drugs interact with lactobacillus: Taking antibiotics along with lactobacillus can reduce the effectiveness of lactobacillus. To avoid this interaction, take lactobacillus products at least 2 hours before or after antibiotics. **Medications that decrease the immune system (Immunosuppressants) interacts with lactobacillus:**

Lactobacillus contains live bacteria and yeast. Taking lactobacillus along with medications that decrease the immune system might increase the chances of getting sick. Some medications that

decrease the immune system include azathioprine, basiliximab, cyclosporine, daclizumab, muromonab-CD3, mycophenolate, tacrolimus, sirolimus, prednisone, corticosteroids (glucocorticoids).

ADVERSE REACTIONS: Probiotics are generally regarded as safe, and side effects in ambulatory care have rarely been reported. Bacterial translocation, sepsis, and the risk of carrying antibiotic resistance plasmids that may spread resistance to antibiotics have been reported. The latter has been reported for some probiotics, such as *L. reuteri* ATCC 55730 and *Enterococcus faecium* but not for LGG.

Manufactured by:

Sunberg Lifesciences Pvt. Ltd.

No. C-75, 76, 77, 15th Cross, PIPDIC Industrial Estate,
Mettupalayam, Puducherry-605009, India.

IN/ VIZYLAC GG DROPS- 1.0 Billion CFU /JUL-21/01/ABPI

(Additional information is available on request)