LACTOBACILLUS

M. SOLDUZIAN

PHARM. D BCPS

ASSISTANT PROFESSOR OF PHARMACOTHERAPY

TABRIZ UNIVERSITY OF MEDICAL SCIENCES

GENERAL INFORMATION

ADMINISTRATION

- Lactobacillus containing Infant drops should be Shaken well before use.
- Drops can be placed directly in infant's mouth, administered while on the breast, or mixed with breast milk or formula.

USE

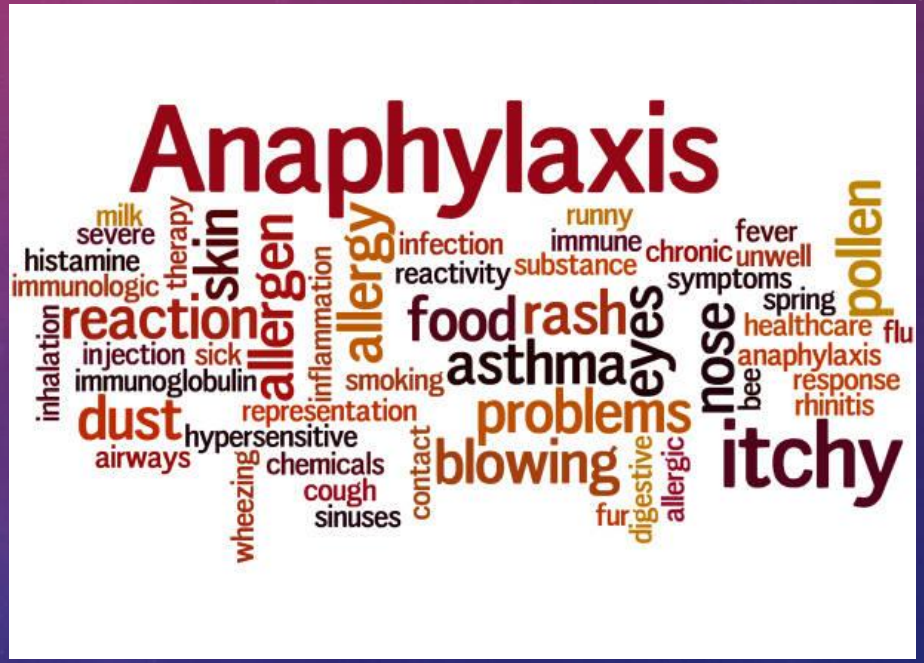
- Promote normal physiologic and bacterial flora of the intestinal tract (dietary supplement)

ADVERSE REACTIONS

- Gastrointestinal:
  - Bloating (intestinal), flatulence
- Allergic reactions could occur, it is rare but could be serious

CONTRAINDICATIONS

- **Allergy to product**



WARNINGS/PRECAUTIONS

- **Disease-related:**
  - Immunocompromised patients: Use dietary supplements containing live bacteria or yeast with caution in immunocompromised patients. A fatal case of GI mucormycosis caused by the mold Rhizopus oryzae has been previously reported in a premature infant administered a dietary supplement containing 3 species of live bacteria.

WARNINGS/PRECAUTIONS (CONT.)

- **Dosage form specific issues:**
  - Interchangeability: Significant differences may exist from one preparation compared to another with respect to biologic activity and composition.
  - Lactose: Some products may contain lactose; use with caution in patients with lactose intolerance.

WARNINGS/PRECAUTIONS (CONT.)

- **Other warnings/precautions:**
  - Dietary supplement: Probiotics are classified as dietary supplements; therefore, there are no safety reviews or approved therapeutic indications by the FDA. There is no conclusive evidence to support widespread use in the treatment of diarrhea.

WARNINGS/PRECAUTIONS (CONT.)

- **Warnings: Additional Pediatric Considerations**
  - Dietary supplements containing live bacteria or yeast may be associated with a risk of invasive fungal disease in the immunocompromised. A premature neonate developed a fatal case of GI mucormycosis caused by Rhizopus oryzae; this mold was found in an unopened bottle of ABC Dophilus powder that was used to treat the infant
  - Case reports of Lactobacillus sepsis have also been reported in at least 5 pediatric patients (ages 18 days to 17 years) treated with Lactobacillus Rhamnosus GG

WARNINGS/PRECAUTIONS (CONT.)

- **Warnings: Additional Pediatric Considerations**
  - The AAP recommends avoiding use of probiotics in pediatric patients who are seriously or chronically ill, including ill preterm neonates and patients with indwelling medical devices or IV catheters.
  - Other trials evaluating the addition of probiotic formulations (various live bacteria/yeast have been reported) to infant formula have reported no adverse effects when used in healthy infants. Use with caution; Lactobacillus-containing products are considered a dietary supplement and therefore less regulated by the FDA in terms of production, safety and efficacy, and definitive data reporting in these areas are lacking

INTERACTIONS

- Theoretically antibiotics could affect the probiotics effects, specially clindamycin and beta lactams
- It is better if this complements are avoided in patients using immunosuppressant drugs such as corticosteroids

OVERALL SUPPORTED PLACES IN THERAPY FOR LACTOBACILLUS PROBIOTICS

- In Pouchitis
  - Studies have demonstrated a benefit from other probiotics including Lactobacillus rhamnosus GG
- Ulcerative colitis
  - Lactobacillus GG appeared to be more effective than standard treatment involving mesalazine in prolonging relapse-free time, but did not influence relapse rates in patients with quiescent ulcerative colitis
  - Another small, double-blind, placebo-controlled study reported significantly lower clinical and endoscopic disease activity in pediatric patients with ulcerative colitis treated with Lactobacillus reuteri ATCC 55730
- In diarrheal illnesses
  - A 2010 meta-analysis that included 63 randomized controlled trials (using several different probiotic preparations) in adults and children found that probiotics reduced the overall risk of diarrhea lasting four or more days by 59 percent (relative risk 0.41, 95% CI 0.32-0.53) and the mean duration of diarrhea by 25 hours (95% CI 16-34 hours) . The two most commonly studied probiotics were Lactobacillus GG and S. boulardii.

OVERALL SUPPORTED PLACES IN THERAPY FOR LACTOBACILLUS PROBIOTICS (CONT.)

- In allergic disease
  - the World Allergy Organization (WAO) suggests using prebiotics only in infants who are not exclusively breastfed and probiotics in pregnant and lactating women and in infants when there is high risk of allergy in the children (defined as presence of a biologic parent or sibling with asthma, allergic rhinitis, eczema, or food allergy). The probiotic recommendation was based upon their analysis of the data that found a net benefit of prevention of eczema, but not any other allergic outcome, with probiotic treatment. In addition, the risk of possible adverse events was felt to be low.
  - The timing, duration, and choice of probiotic (strain and dose) are not specified in the WAO guidelines. Probiotics were given in the last four to six weeks of pregnancy in most of the studies reviewed, but there was much greater variability in timing and duration of postnatal therapy in the infant and/or breastfeeding mother. In addition, the only probiotic strain with reproducible data is Lactobacillus rhamnosus GG (LGG).

GOOD LUCK