

1. PROBIOTICS

Granular Theralac® is a medical strength, multi-strain, probiotic dietary supplement containing naturally occurring, beneficial bacteria guaranteed at 25 billion colony forming units (CFU)/serving through expiration, if kept refrigerated. The probiotic composition is presented in Table 1. Strains LA-1 and BL-04 have been used for many years in probiotic supplements, strains LR-32, LPC-37 and Bi-07 are new generation probiotics selected for effectiveness and compatibility.

2. PREBIOTICS

Granular Theralac® contains two prebiotics that enhance its probiotic activity: **LactoStim®** (Sunflower Lecithin + Oleic Acid) and Sodium Alginate. LactoStim® is a nutrient utilized by probiotic bacteria for fast growth and reproduction (Protected by 5 U.S. Patents).

3. ACID-PROOF ENTERIC PROTECTION

The probiotics in **Granular Theralac®** are protected from stomach acid by a gel matrix composed of food grade sodium alginate. The gel matrix forms in the stomach at low pH and dissolves in the small intestine at high pH allowing acid sensitive probiotics to reach the intestinal tract alive at high strength and activity. Studies show that greater than 99% of unprotected probiotics are killed by stomach acid. **Granular Theralac®** is protected by U.S. Patents 7,122,370 and 7,229,818.

4. STRUCTURAL ACTIONS

The probiotic strains in **Granular Theralac®** are backed by scientific and clinical studies; their principal action is to increase the population of beneficial bacteria in the intestinal tract and correct any probiotic deficiency that may exist. **Granular Theralac®**'s probiotic strains adhere to the soft lining (wall) of the intestinal tract and promote a healthy surface. A healthy intestinal surface encourages optimum absorption of nutrients, including vitamins and

TABLE 1: PROBIOTIC COMPOSITION OF GRANULAR THERALAC®

| PROBIOTIC SPECIES | STRAIN | CFU/SERVING | SCIENTIFIC STUDIES* |
|----------------------------------|-------------|-------------|---------------------|
| <i>Lactobacillus acidophilus</i> | LA-1 (NCFM) | 10 Billion | 15 |
| <i>Lactobacillus rhamnosus</i> | LR-32 | 1 Billion | 3 |
| <i>Lactobacillus paracasei</i> | LPC-37 | 1 Billion | 3 |
| <i>Bifidobacterium lactis</i> | BL-04 | 10 Billion | 6 |
| <i>Bifidobacterium lactis</i> | Bi-07 | 3 Billion | 5 |

minerals, and supports overall health and wellness. When probiotics actively colonize intestinal surfaces it becomes difficult for undesirable bacteria to occupy the same space. This is referred to as competitive exclusion.

5. FUNCTIONAL ACTIONS

High potency probiotics such as **Granular Theralac®** are indicated for a number of functional conditions that may result from or cause a deficiency of probiotic bacteria in the intestinal tract. These may include the following:

- ✓ Occasional diarrhea
- ✓ Occasional constipation
- ✓ Repopulation following antibiotic use
- ✓ Certain food allergies
- ✓ Weak immune response
- ✓ Poor nutrient absorption
- ✓ Various dysbiosis conditions

The most common response to taking **Granular Theralac®** is normalized elimination, firmer more predictable bowel movements. This is usually followed by increased energy and intestinal comfort.



6. PREPARATION AND USE

Granular Theralac® is prepared by gently FOLDING or stirring one serving (¼ level teaspoon) into soft food (applesauce or mashed banana are good examples) and waiting about one (1) minute before serving. For best results preparation should be done immediately prior to serving. There are three recommended dosage programs shown in Table 2. The STANDARD program is the best choice for most children ages 6 months and up and is stated on the product's label under SUGGESTED USE: As a dietary supplement FOLD or gently stir, do not mix, into soft food. Wait 1 minute, then serve. The INTENSIVE program is recommended for children experiencing intestinal dysbiosis such as periods of occasional constipation or diarrhea. The HEALTH MAINTENANCE program is recommended as follow up to the STANDARD or INTENSIVE programs. NOTE: Medical professionals often recommend higher doses for certain conditions, such as 2-4 servings daily in divided doses (check with your doctor before using higher doses).

TABLE 2: DOSAGE PROGRAMS FOR GRANULAR THERALAC® – 40 SERVINGS/BOTTLE

| PROGRAM | SERVINGS/DAY | SERVINGS/WEEK* | DURATION** |
|-----------|---------------------|-------------------------------|------------|
| STANDARD | One/day for 2 weeks | Followed by 2/wk for 13 weeks | 15 weeks |
| INTENSIVE | One/day for 40 days | ----- | 40 days |

* Give servings approximately 3.5 days apart; for example, one Monday AM and one Thursday PM. ** Any program can be repeated, all programs supply 1,000 billion CFU over stated period.

7. FOR ADULTS THAT CANNOT SWALLOW CAPSULES:

Granular Theralac® can be taken by any adult that has trouble swallowing capsules.

8. ADVERSE REACTIONS

1) HERXHEIMER REACTION

Probiotic bacteria in the Lactobacillus and Bifidobacterium genera are generally recognized as safe (G.R.A.S.) by the United States FDA. Studies show that dosages of one trillion CFU/day or higher are safe. When the intestinal microflora is severely out of balance, high potency probiotics may cause mild to moderate discomfort, (bloating, gas, loose stools) for a short time as harmful microorganisms die off and release toxic byproducts faster than the body can eliminate them. This is called the Herxheimer Reaction and is a positive sign the probiotic is working (dosage can be reduced to moderate symptoms). Have the child drink plenty of water, omit sugar and eat light if a Herxheimer Reaction occurs. If symptoms persist see your doctor.

9. ALLERGIC REACTIONS

Granular Theralac® does not contain: Eggs, Soy, Gluten, Wheat, Casein, Whey Proteins, Tree Nuts, Peanuts, Shellfish or Beef Products. Microcrystalline cellulose and silica are inert ingredients. Sodium phosphate is used as a buffer. Consult with your doctor before taking any **Granular Theralac®** product if specific food allergies exist.

10. HOW SUPPLIED

Granular Theralac® is supplied in powdered form in 30 gram net weight amber glass bottles. One (1) serving is one level ¼ teaspoon that provides 750 mg containing 25 billion CFU. The powder is white and has no taste. Totally Inert Packaging (TIP) technology is utilized to provide maximum stability and shelf life: The powder is packaged in hermetically sealed amber glass bottles. Keep bottles tightly closed. Refrigerate to assure potency through expiration date, can be kept at room temperature (65-75F) for up to two weeks while traveling.