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# Tears Again® HYDRATE™

**Specially formulated for the Dietary Management of Dry Eye Syndrome, Blepharitis, and Meibomian Gland Dysfunction.**

**DESCRIPTION:**

Tears Again® HYDRATE™ is a Medical Food specially formulated for the Dietary Management of Dry Eye Syndrome, Blepharitis, and Meibomian Gland Dysfunction. Tears Again® HYDRATE™ is intended to be used under the supervision of a physician. Tears Again® HYDRATE™ is formulated to contain the omega-3 fatty acid, Flaxseed Oil, but has also included Evening Primrose Oil (EPO), a substance having exceptionally high content of the even rarer essential fatty acid, gamma linolenic acid (Omega-6) as well as Bilberry Extract (BBE). The clinically supported tear specific ingredients in Tears Again® HYDRATE™ are microencapsulated through a unique proprietary liposome process to enhance absorption. This delivery system, termed Hypersorb®, eliminates digestive problems commonly associated with EFAs and is especially suited for the oral delivery of ingredients with poor bioavailability.

**CONTAINS:**

Flaxseed Oil	1000 mg
Evening Primrose Oil	500 mg
Bilberry Extract	40 mg

**Flaxseed Oil** is derived from the seeds of the flax plant and is one of the richest sources of the Omega-3 fatty acid, Alpha-Linolenic Acid (ALA). Recent reports have linked dietary Flaxseed Oil to increased comfort when used to manage Dry Eye Syndrome.<sup>1</sup> Essential Fatty acids such as Flaxseed Oil work throughout the body to protect cell membranes. Omega-3 Fatty Acids (Flaxseed Oil) have a competitive inhibitory effect on the arachidonic acid (omega-6 derivative) inflammatory cascade and a modular effect on immune cells.<sup>2,3</sup> Flaxseed Oil also improves meibomian gland secretion by increasing its fluidity, thereby 'unplugging' the gland orifices. A recent study demonstrated that increased intake of Omega-3 fatty acids improved the profile of the polar lipid fraction of meibomian secretions in patients with Dry Eye Syndrome. By enhancing the lipid fraction of the tear film, evaporative loss will decrease.<sup>4</sup> Chronic blepharitis has associated meibum abnormalities that explain defects in the tear lipid layer that may result in a frankly unstable tear film and that explain the frequently associated evaporative dry eye.<sup>5</sup>

**Evening Primrose Oil** is an Omega-6 gamma linolenic acid (GLA) that is a downstream metabolite of Omega-6 linoleic acid. This compound is a necessary component in the downstream metabolism of Omega-6 fatty acid to the series one anti-inflammatory prostaglandins (PGE1s), which are associated with healthy mucosal tissue and tear film. The human body cannot metabolize Omega-3 fatty acids to these specific anti-inflammatory prostaglandins.<sup>6</sup> Omega-6 fatty acids that are successfully metabolized or those that have the metabolic advantage of containing GLA reduce inflammation after further metabolizing to dihomo-gamma-linolenic acid (DGLA), which also blocks, when appropriate, the pro-inflammatory arachidonic acid conversion. They also enhance the delta-6 and delta-5 desaturase enzymatic conversion of Omega-3 alpha-linolenic acid to EPA/DHA and the series 3 anti-inflammatory prostaglandins.<sup>7</sup> The body requires all of the essential fatty acids for optimal health. They are particularly important for the patient that has Dry Eye Syndrome because PGE1s from Omega-6 (EPO) interrupt the inflammatory loop associated with chronic Dry Eye Syndrome.

**Bilberry Extract** is a botanical source of an important bioflavonoid for eye health. Bioflavonoids are water-soluble plant-based antioxidants that have additional beneficial effects on eye health. The eyes are supplied with oxygen and nutrients through minute capillaries; bioflavonoids may increase the integrity of these blood vessels, enhancing their function. Research has also demonstrated improvements in patients with retinopathy by supporting blood vessels of the eyes and thereby reducing exudations (fluid seeping through blood vessels).

**OTHER INGREDIENTS:** Safflower Oil, Lecithin (Precept 8120), d-alpha Tocopheryl Acetate, Gelatin, Glycerin, Purified Water, Caramel Powder.

**CONTRAINDICATIONS:**

Should not be used by the patient without physician supervision, or in those persons showing hypersensitivity to any component of this preparation. Avoid taking at the same time with other medications and/or supplements. Pregnant women should not take Evening Primrose Oil due to increased risk of pregnancy complications. Evening Primrose Oil may lower the seizure threshold and precipitate seizures in patients taking phenothiazines.

**WARNINGS:**

Before taking, tell your doctor if you are pregnant or breastfeeding. Flaxseed Oil may cause ileus (intestinal blockage). Flaxseed Oil may cause a thyroid problem. Flaxseed Oil and Evening Primrose Oil reduce blood vessel platelet aggregation. If already taking aspirin or blood thinners consult your physician – you may need to have your clotting time checked. Evening Primrose Oil may lower the seizure threshold and precipitate seizures in patients taking phenothiazines.

**PRECAUTIONS:****Information for Patients:**

Keep out of the reach of children. In case of emergency contact a Poison Control Center Immediately. Avoid taking at the same time with other medications and/or supplements.

**Pregnancy Category C:** It is not known whether this Medical Food can cause fetal harm when administered to a pregnant woman or affect reproduction.

**Pediatric Use:**

Safety and effectiveness in children have not been established.

**ADVERSE REACTIONS:**

Other than the possibility for allergic reaction in susceptible individuals, no serious side effects are associated with consumption of normal amounts. Flaxseed Oil increases stool bulk and frequency of defecation, it is not recommended for those with bowel obstruction, irritable bowel syndrome or diverticular disease. Stop taking immediately and talk to your doctor if you have any of the following side effects: Breathing problems or tightness in your throat or chest, chest pain, skin hives, rash, or itchy or swollen skin, headache, GI upset, nausea.

**DOSAGE:**

Take 4 soft gels daily. May be taken directly or during meals or snacks. Avoid taking at the same time with other medications and/or supplements.

**HOW SUPPLIED:**

Tears Again® HYDRATE™ is supplied as 120 Soft Gels in a caramel color.

**STORAGE:**

Store at a controlled room temperature, 15 –30 degree Celsius (59-86 degree Fahrenheit) Keep container tightly closed.

**REFERENCES:**

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7. Barabino S, Rolando M, Camicione P, et al. Systemic linolenic and gamma linolenic acid therapy in dry eye syndrome with an inflammatory component. Cornea 2003 Mar; 22(2); 97-101

Based on package insert.

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