

Introduction: Celiac disease or gluten intolerance is an increasingly diagnosed disease affecting a large segment of the population. The only treatment for gluten intolerance is a strict avoidance of foods containing gluten (alpha-gliadin specifically). A gluten free diet involves the total elimination of foods containing wheat, barley, and rye and food ingredients derived from them. Many food products are derived from those common grains and it is often difficult for people to know which foods may have been contaminated with gluten. Many times gluten intolerant people must eat in places where they have no control over how the food is prepared. Even when they go to great trouble to insure they do not eat foods containing gluten, they may be exposed to it because those preparing the food are not as knowledgeable about what ingredients to avoid or because of cross-contamination (an example would be a gluten-free food being prepared on a table surface with small amounts of flour remaining from previous food preparation). GlutenAce™ is designed to help manage such accidental exposure to small amounts of gluten.

Dosage: This product should be used when eating a gluten-free meal that might be contaminated with small amounts of gluten. It does not permit gluten intolerant people to consume gluten containing foods. One capsule should be taken per meal. If needed 2 or 3 capsules can be taken with a meal, but often this will provide no additional benefit.

Active Ingredients: **BioCore DPP IV™** protease digestive enzymes from specially cultivated *Aspergillus oryzae* and *Aspergillus melleus*. Especially important is the activity for proteolytic cleavage of the GLY-PRO peptide bond which is a commonly occurring bond in the alpha-gliadin peptide.

Bromelain: A pineapple derived proteolytic enzyme that can also break down proteins, but also has anti-inflammatory properties.

Quercetin: An important plant bioflavonoid. Also has anti-inflammatory properties and is used in allergy formulas.

Inactive Ingredients: Inactive ingredients (excipients) present in **Daily GlutenAce™** are used to keep the active ingredients in an easy-to-use and accurately measured dosage form.

Vegetarian Capsules: Size 0, made from plant derived cellulose.

Microcrystalline Cellulose: A source of hypoallergenic dietary fiber made from the pulp of evergreen trees. Used to increase the bulk of the capsule and protect the active enzyme.

Silicon Dioxide: Hypoallergenic mineral that prevents moisture damage.

Magnesium Stearate: Vegetable oil product that helps maintain even flow and uniform dosage in the capsules.

Description: **Daily GlutenAce™** is a dry powdered supplement in a two piece size “0” vegetarian capsule. The capsule has an “off white” color and could be described as a “medium sized” encapsulated supplement. Each bottle contains 60 capsules (a 30-90 day supply). **Daily GlutenAce™** is packaged in a white HDPE bottle with an inner and an outer tamper-evident band. The lot number and expiration date are printed on the bottom of the bottle.

Precautions: **Daily GlutenAce™** should not be expected to allow gluten intolerant individuals to eat gluten containing foods. Wheat, barley, and rye contain large amounts of gluten and the enzymes in **GlutenAce™** can not neutralize them. Even the small amounts from accidental contamination frequently can not be fully neutralized by **GlutenAce™**. **GlutenAce™** also contains the pineapple enzyme, bromelain, and quercetin which are possible allergens in some people. The use of **GlutenAce™** should be discontinued if allergy symptoms are observed.

Managing Celiac Disease/Gluten Intolerance

Many people suffer from unexplained symptoms such as irritable bowel syndrome, gas and bloating, chronic skin problems, chronic fatigue and many other continuous or intermittent conditions with no clinical diagnosis or apparent remedy. Some of these people are experiencing what was once thought to be a rare inherited digestive disorder called celiac disease (also known as coeliac sprue or gluten intolerance). Celiac disease is still poorly understood, but it is known to be an auto-immune disease that is triggered by the presence of gluten in some people who are genetically susceptible¹. In the most extreme situation, children become gluten intolerant during the first two years of life and must endure a life-long avoidance of all foods containing gluten. There is some evidence that the age when gluten is introduced has some influence on the development of childhood onset celiac disease². The pathology of celiac disease is both direct and indirect. The direct pathology is a breakdown of the intestinal villi due to the apparent autoimmune response to proteins made by tissue transglutaminase from partially digested gluten³. The symptoms of the direct response would include irritable bowel, bloating, and stomach pain. Indirect pathology could result from nutritional deficiencies and the consequences of chronic inflammation. These symptoms would include headache, chronic fatigue and skin eruptions. The only way to manage celiac disease is a strict avoidance of foods containing gluten, but sometimes even that may not be enough. **Daily GlutenAce™** is designed to assist people who are following a strict gluten free diet by reducing the impact of food contamination with small amounts of gluten and by reducing intestinal inflammation with digestive enzymes and herbs that reduce inflammatory responses. **Daily GlutenAce™** is a digestive product designed to help break down gluten peptides and reduce intestinal inflammation using the following 3 ingredients.

BioCor^e DPP IV™ Digestive Enzyme

A group at Stanford University isolated a 33 amino acid peptide from partially digested gluten that appears to be the offensive part of gluten in celiac disease⁴. The 33 segment was especially rich in proline, leucine, and glutamine. BioCor^e DPP IV™ consists of 3 protein digesting enzymes from *Aspergillus oryzae* and *Aspergillus melleus* that have the ability to digest peptide bonds (protein linking chemical bonds) with proline and leucine. These enzymes are capable of digesting small amounts of the gluten peptide, hopefully rendering it harmless. It has been shown that the proline-glutamine bonds are especially resistant to digestive breakdown, but that adding additional enzymes can sometimes facilitate the process⁵. These enzymes have also been demonstrated to be able to break down tumor necrosis factor, a highly inflammatory product of immune cells.

Bromelain

Bromelain is a pineapple derived protein digesting enzyme. It is normally a crude extract containing a variety of proteolytic enzymes, many of which have anti-inflammatory properties⁶. Bromelain has been frequently used as a general digestive aid because of its ability to digest proteins. Hale, et al. from Duke University studied bromelain in a rat model of spontaneous ulcerative colitis in response to reports of remission of that disease in two patients who were refractory to standard treatments⁷. The rats taking oral bromelain had significantly less severe bowel inflammation than those not taking bromelain. Oral bromelain has also been shown to help restore normal gut function after abdominal surgery in rats⁸. Bromelain has not been shown to help celiac disease specifically, but indirect evidence shows that it has a good chance of reducing inflammation in the gut due to multiple causes.

Quercetin

Quercetin is one of the most important bioflavonoids in foods and is especially concentrated in green and black teas, onions, and apples. Quercetin is a potent antioxidant and anti-inflammatory agent⁹. The anti-inflammatory properties of quercetin have been demonstrated in several types of cells, and shown to have valuable protective effects^{10, 11}.

References

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