



## **Digest Gluten** Chewable

### Great-tasting formula that may help support gluten digestion<sup>^</sup>

- Features Tolerase® G Prolyl Endopeptidase, which has been clinically demonstrated • to help break down residual gluten in meals
- Ideal for gluten-sensitive individuals concerned about hidden gluten in food .
- Supports healthy digestive function
- Delicious, natural cherry berry-flavoured chewable tablet format .

Digest Gluten Chewable was specifically formulated for gluten-sensitive individuals who are trying to follow a gluten-free or gluten-reduced diet. Gluten is abundant in the Western diet in grains and processed foods, and can be present in non-food items such as medication, toothpaste, mouthwash and lipstick.<sup>12</sup> As people have less control over their food when travelling, during social visits or at restaurants, it may be difficult to intentionally limit gluten intake.<sup>3</sup> Furthermore, contamination of gluten-free foods may occur during processing, packaging or storage, and through sharing utensils or appliances.<sup>3</sup> Digest Gluten Chewable features Tolerase<sup>®</sup> G, a prolyl endopeptidase that has been clinically shown to help break down gluten peptides in the stomach.<sup>4,5</sup> In one study, Tolerase<sup>®</sup> G degraded nearly all of the gluten present in the stomach of participants within one hour of administering a liquid low- or high-calorie gluten-containing meal.<sup>4</sup> Additionally, this enzyme significantly degraded gluten in the stomach and duodenum of participants after consumption of gluten-containing porridge.<sup>5</sup> Preclinical research has found that Tolerase<sup>®</sup> G is active at the low-pH range of the stomach, resistant to pepsin degradation, and able to degrade the immunogenic peptides of gluten, further supporting its use as an effective enzyme.<sup>6</sup> Each delicious chewable tablet can be easily incorporated into the diet to help in the digestion of gluten-containing foods.4,5



#### EACH TABLET CONTAINS:

Tolerase<sup>®</sup> G Prolyl Endopeptidase (from Aspergillus niger).....144 mg/83520 PPI

Non-Medicinal Ingredients: D-Mannitol, xylitol, sunflower lecithin, natural organic berry and cherry flavours, organic acacia gum, citric acid

Tolerase<sup>®</sup> G is a trademark of DSM.

#### **Recommended Dose**

Adults: Chew 1 to 2 tablets up to 3 times daily before a glutencontaining meal, or as recommended by your healthcare practitioner.

**Product Size** 90 Chewable Tablets

NPN 80087516



**Product Code** 10563A

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^This product is not intended to replace a gluten-free diet, or to treat or prevent celiac disease.

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# **Digest Gluten Chewable**

## Scientific Rationale:

Gluten is a mixture of related proteins present in grains, such as wheat, barley and rye.<sup>1</sup>The primary proteins are gliadin and glutenin, which contain high levels of the amino acids glutamine and proline.<sup>1</sup> After gluten is consumed, it is partially degraded by proteases in the gastrointestinal tract.<sup>2</sup> However, as many proteases cannot break down gliadin due to its high content of proline, these long proline-rich peptides reach the small intestine intact.<sup>12</sup> In genetically predisposed individuals, exposure to these incompletely digested peptides in the intestines can trigger an immune response characterized by infiltration of lymphocytes, atrophy of the villi, and increased gut permeability.<sup>1</sup> In turn, these changes can result in pain, distension and altered bowel habits.3

Research suggests that Western diets typically provide an average gluten intake of 5-20 grams per day.<sup>1</sup> As they play an important role in determining the quality of dough, gluten proteins are commonly found in bread, pasta, pastries and other baked products.<sup>1</sup> Wheat bread is a primary source of dietary gluten, with each slice containing approximately 4 g.<sup>1</sup> Gluten is also used as fillers or coatings in medication and candy, and is commonly found in processed foods, including processed meat, ice cream, butter, seasonings and dressings.1

Although some individuals may try to limit or exclude gluten intake, adherence to these diets is challenging.<sup>3</sup> Intentionally limiting gluten intake is difficult due to the prevalence of gluten-containing grains in the Western diet; social pressures for gluten-containing diets; and higher cost or poor availability, palatability and nutritional content of gluten-free foods.<sup>4,5</sup>

Gluten may be unintentionally ingested due to the contamination of products believed to be gluten-free.<sup>5</sup> Cross-contamination may occur in the home through sharing utensils, countertops or appliances.<sup>5</sup> Furthermore, there is a greater chance of contamination when individuals eat outside of the house, such as when travelling, during social visits or at restaurants (especially buffets or salad bars).<sup>5</sup> Contamination may also occur in the fields, mills or processing lines when grains are grown and harvested, processed into flours, or packaged into final products; or where grains are sold in open bins.<sup>5</sup> Another concern is the difficulty of detecting gluten in prepared foods, as packaged and processed foods often use gluten-containing grain products as additives, preservatives and stabilizers.<sup>5</sup> Ingestible non-food items, such as medications and supplements, toothpaste, mouthwash, lipstick, and postage stamps may also contain traces of gluten.<sup>5</sup>

Due to the challenges associated with avoiding dietary gluten, researchers have investigated the ability of enzymes to promote gluten digestion by cleaving proline residues in the stomach. This would reduce the amount of gluten or residual peptides reaching the duodenum, where gluten-specific T cells are present to mount a potential immune response.<sup>6</sup> While early studies focused on bacterial-derived enzymes, their use may be limited if they are unstable at the low pH of the stomach, susceptible to pepsin digestion, and unable to degrade larger gluten proteins into harmless fragments.<sup>6</sup> One study reported that five commercially available digestive enzyme supplements did not effectively break down gluten peptides; however, Tolerase<sup>®</sup> G (a prolyl endopeptidase from Aspergillus niger) was reported to degrade all nine peptide sequences in the pH range of the stomach, with the majority of residual peptides too small to retain their immunogenic properties.7

Preclinical research has demonstrated that Tolerase<sup>®</sup> G is active at the low-pH range of the stomach and resistant to pepsin degradation.<sup>6</sup> It has been shown to effectively degrade gluten proteins into harmless fragments in vitro, as well as gluten-containing meals under conditions mimicking in vivo digestion.<sup>6,8</sup> Similarly, combined intake of Tolerase<sup>®</sup> G with a reduced-gluten barley in gluten-sensitive macaques led to greater immunological, histopathological and clinical improvements when compared to the intake of barley alone.<sup>9</sup> Combined intake decreased clinical diarrhoea scores, reduced apoptotic cell counts in the small intestine, and decreased the production of IFN-v and TNF by lymphocytes.9

Tolerase<sup>®</sup> G was reported to significantly promote gluten digestion in the stomach of healthy volunteers in a randomized, double-blind, placebocontrolled trial.<sup>10</sup> Participants received a liquid high- or low-calorie meal containing 4 g of gluten, with or without Tolerase® G.<sup>10</sup> The enzyme degraded nearly all gluten in the stomach within one hour, significantly decreasing the amount of gluten reaching the duodenum when compared to the placebo (regardless of caloric density).<sup>10</sup>

These results were confirmed in a randomized, placebo-controlled trial, where participants consumed porridge containing 0.5 g of gluten along with a placebo or Tolerase<sup>®</sup> G (166,600 PPI or 333,400 PPI).<sup>11</sup> Gluten levels were significantly reduced in the stomach and duodenum by both Tolerase® G concentrations when compared to the placebo, further demonstrating its beneficial effects as a digestive aid.<sup>11</sup> However, research suggests that the composition of a meal may influence the amount of Tolerase® G needed for complete gluten degradation.<sup>12</sup> Therefore, this enzyme should be used to support unintended gluten consumption, rather than replace a gluten-free diet.<sup>12</sup>

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