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Gluten-Free Drugs for Celiac Disease Patients

Celiac disease is a chronic autoimmune disorder caused by a genetic intolerance to gluten that occurs in about 1% of the population.¹ The main form of treatment is a lifelong gluten-free diet.

CELIAC DISEASE — Although originally described in young children as a malabsorption syndrome characterized by diarrhea, steatorrhea and failure to thrive, particularly after cereals are first introduced, presentations in older children, adolescents and adults with diarrhea or non-gastrointestinal signs and symptoms (such as iron-deficiency anemia, metabolic osteopathy, short stature, neurologic symptoms, type 1 diabetes and dermatitis herpetiformis) are now more common.² Potential complications of celiac disease include intestinal adenocarcinoma, enteropathy-associated T-cell lymphoma and refractory sprue. The trigger for these signs, symptoms and complications is exposure of the intestinal mucosa to gluten. The sensitivity of patients to gluten is variable³ but 50 mg per day appears to be the minimum dose required, at least in the short term, to produce measurable damage to the small intestinal mucosa.⁴

GLUTEN — Gluten is the entire protein component of wheat. Gliadin is the alcohol-soluble, toxic fraction of gluten. Gliadin, which is resistant to degradation by gastrointestinal enzymes, interacts with antigens in the cell wall to cause inflammation.

GLUTEN IN FOOD — Gluten is found not only in wheat (including spelt, kamut, semolina and triticale), but also barley (including malt) and rye. Gluten-free grains include rice, millet, corn, quinoa, amaranth, sorghum and buckwheat. Oats are also gluten-free, but commercially available forms may be contaminated by gluten-rich grains. Other originally gluten-free products may also become cross-contaminated with

gluten during the manufacturing process. Foods such as soups, sausages and ice cream may contain gluten as a filler. The FDA has proposed that foods containing <20 parts per million (ppm) of gluten may be labeled as “gluten free”⁵; foods containing that amount are unlikely to add up to 50 mg of gluten per day under most conditions of consumption.

GLUTEN IN DRUGS AND COSMETICS — The FDA does not require any mention of gluten in drug labels. Most of the gluten in drugs comes from **inactive ingredients** obtained from whole grains, grain flour or starch grain. Inactive ingredients such as starches that are derived from corn or potato sources should be acceptable (unless there is contamination with gluten); unspecified or “pregelatinized” starch, dusting powder or flour may be derived from wheat. The source of an inactive ingredient can be changed without changing the label.

Sweeteners used in pharmaceutical products may also be sources of gluten. Uncontaminated sucrose, honey, dextrose, fructose and corn syrup solids should not be problematic.

Fillers, thickening agents, and polymers used for liquid and solid dosage forms such as gums (e.g. acacia, agar, alginates, carrageenan, gellan gum, guar gum, xanthan gum), cellulose and its derivatives (e.g. hydroxy-propylcellulose, methylcellulose, microcrystalline cellulose, sodium carboxymethylcellulose), and other polymers (e.g. polyvinylpyrrolidone, crospovidone, croscarmellose sodium) should be acceptable if not contaminated with gluten.

Soaps, shampoos and lotions may also contain gluten and may accidentally be ingested. The source of **solvents** or **vehicles** should be evaluated; alcohol, polyethylene glycol, propylene glycol and glycerin generally do not cause problems for patients sensitive to gluten.⁶

WHAT MANUFACTURERS KNOW — Some pharmaceutical companies that responded to a survey pub-

lished in 2001 reported that they believed their products were gluten free but could not guarantee it, in part because the suppliers of the raw materials could not guarantee that their materials were gluten free.⁷

OBTAINING GLUTEN-FREE DRUGS — Information about the gluten content of pharmaceutical products can be found electronically on web sites such as www.glutenfreedugs.com.⁸ However, it may also be advisable to ask the manufacturer whether a specific product is or continues to be gluten free. In making these inquiries, providing the drug's lot number is generally helpful. If all else fails, a compounding pharmacy may be able to provide gluten-free products.

CONCLUSION — Gluten in drugs as well as in food and cosmetics can be a problem for patients with celiac disease. Drug labels may not be helpful because the source of inactive ingredients can be changed without changing the label. Even some manufacturers may not know whether their products are gluten free. □

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