

Editorial

The Impact of Celiac Sprue on Patients' Medication Choices

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Celiac sprue, a disease of malabsorption that occurs most frequently in people who are white and of European descent, affects more than 2 million people in the United States. Symptoms, which can appear in infancy through the eighth decade of life,^{1,2} typically include villous atrophy (found on intestinal biopsy), malabsorption of multiple nutrients, and consequences of nutrient depletion.² Although the etiology is unknown, it may be a combination of environmental, immunologic, and genetic factors. Specifically, environmental factors include an association with gliadin—a component of gluten found in wheat, barley, rye, and, in lesser amounts, oats—that causes mediation of an immune response whenever patients ingest or use products containing gluten. The immune response damages or destroys villi in the small intestine and, without villi, malnutrition ensues.^{1,2}

Primary treatment for celiac sprue includes complete avoidance of gluten-containing foods and products. Approximately 90% of patients have a good response to complete gluten restriction, with the remaining patients having either a response to soy restriction or glucocorticoid therapy and having “temporary” disease symptoms or fatal outcome. For those who have a response to complete gluten restriction, dietary restriction is not

enough because gluten can be hidden in other sources, including medications.

Gluten can be found in medications directly or indirectly; however, the US Food and Drug Administration currently does not require labeling of gluten content on package inserts or any precautionary statement for patients with celiac disease.³ Directly, gluten is often found in the inactive ingredients of products (such as starches or starch derivatives) that are listed in the package insert but that can be changed without updating the package insert. These inactive ingredients also are not well recognized by health care professionals or patients as potential sources of gluten. In addition, variations between brand and generic drugs, as well as between generic drugs by different manufacturers, can lead to hidden sources of gluten. Indirectly, gluten can be transferred through manufacturing processes. Manufacturers may not know how materials were obtained or processed if their ingredients are purchased from another company, and those ingredients previously may have come into contact with other materials containing gluten. See Table 1 for a list of manufacturers who do not use gluten.

Ultimately, because a “good” source does not exist, patients must double-check the content of every medication before ingestion,

which can be time consuming depending on the number of medications being taken and the availability of the information. Many patients consult their pharmacists, who may or may not have the time to double-check the content of the medications with the manufacturer. This results in many pharmacists relying on secondary resources or enlisting the aid of a drug information center. Transfer of patients with celiac sprue from community to acute-care settings poses additional safety issues because many institutional health care providers have set formularies that do not consider gluten-free status as primary criteria for selection.

The Web site glutenfreedrugs.com, which is maintained by a clinical pharmacist, is available for health care professionals and patients, but the information should always be double-checked with the manufacturer.³ Other resources include the Celiac Disease Foundation (www.celiac.org) and the Celiac Sprue Association/United States of America, Inc (www.csaceliacs.org); however, neither of these Web sites provides information about the gluten content of specific medications.

In addition to answering the questions of patients and health care professionals regarding the gluten content of medications, the University of Kansas Drug Information Center has compiled a list of gluten-free manufacturers. The list is a good starting point for practitioners when searching for a gluten-

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Table 1. Gluten-Free Manufacturers

A G Marin	Ellon Traditional Flower Remedies	Natren
Actelion	ETHEX Corporation ^a	Neurovites
Advanced Nutritional Technology, Inc	Everett Laboratories	NextWave Pharmaceuticals
AkPharma	Excellium Pharmaceuticals	Niche Pharmaceuticals
Allan Pharmaceutical, LLC	Ferring Pharmaceuticals	Nostrum Laboratories
Altaire Pharmaceuticals, Inc	Fluoritab Corp	Nutra/Balance Products ^b
Alto Pharmaceuticals	Fougera	Optics Laboratories
Alva-Amco Pharmaca Companies	Freeda Vitamins	Optimox Corp
Ambi Pharmaceuticals	G&W Laboratories	Oscient Pharmaceuticals Corp
Amerifit Brands	Gate Pharmaceuticals (Teva)	Otsuka America Pharmaceutical, Inc
Anchen Pharmaceuticals	Inverness Medical, Inc	PARI Respiratory Equipment, Inc
Apothecus Pharmaceuticals	Jaymac Pharmaceuticals, LLC	Pharmaceutical Associates, Inc
Aqua Pharmaceuticals	Jazz Pharmaceuticals	Pharmakon Labs, Inc
AR Scientific ^a	Karalex Pharma	Pharmascience Laboratories, Inc
Astellas Pharma	Kenwood Therapeutics	Procter & Gamble Pharmaceuticals Inc
Axcan Pharma	King Pharmaceuticals	Proper Nutrition, Inc
Barr Laboratories	Kirkman Laboratories	Purdue Pharma, LP
Beach Pharmaceuticals	KLI Corp	QOL Medical
Berna Products Corp	Konsyl Pharmaceuticals	Reckitt Benckiser Pharma
B.F. Ascher & Co	K-PAX Inc	Respa Pharm
BioMarin Pharmaceutical, Inc	Kramer Laboratories	Roche
Blairex Lab	KVK-Tech, Inc	Romark Pharm
Blu Pharmaceuticals, LLC	Laser Pharmaceuticals	RX Vitamins, Inc
Braintree Lab	Leitner Pharmaceuticals	Santarus
Brioschi, Inc	Llorens	Scandinavian Formulas, Inc
Capellon Pharmaceuticals	Loma Lux Laboratories	Scot-Tussin Pharm Co, Inc
Carlson JR	Major Pharmaceuticals	Sepracor, Inc
CarWin Associates	Mayor Pharmaceutical Laboratories	Shionogi USA, Inc
C.B. Fleet	McCoy's products	Solace Nutrition
Cera Products	MCR American Pharmaceuticals	SourceCF, Inc
Colorado Biolabs, Inc	Med Gen, Inc	Takeda Pharmaceuticals ^a
Consumer Choice Systems, Inc	Meda Pharmaceuticals	TAP Pharmaceuticals ^a
CorePharma, LLC	Med-Derm Pharmaceuticals	The Coromega Company
CutisPharma, Inc	Medical Nutrition USA	The T-Lite Company
CV Therapeutics, Inc	Medicis	Validus Pharmaceuticals
Dabur Pharma US, Inc	MedOp	Vertical Pharmaceuticals
Digestive Care	MGI Pharma	ViroPharma
DSE Healthcare Solutions	MiddleBrook Pharmaceuticals	Warner Chilcott
DUSA Pharmaceuticals	Midlothian Laboratories	Xttrium Lab
E5 Pharma	Mission Pharmaca	Yerba Prima
ECR Pharmaceuticals	Mylan Pharmaceuticals	

^aProducts are free of gluten-containing ingredients, but company cannot guarantee products as gluten free; ^bAll products are gluten free except the cookie.

free medication, but as stated previously, double-checking with the manufacturer regarding specific products as inactive ingredients and recognizing that manufacturing processes can change is essential.

The editors of *Hospital Pharmacy* are interested in how pharmacists currently provide patient care

plans for celiac sprue. Share your experiences with Dr. Dennis Cada (hospitalpharmacy@drugfacts.com).

REFERENCES

1. Celiac disease. National Digestive Diseases Information Clearinghouse (NDDIC) Web site. <http://digestive.niddk.nih.gov/ddiseases/pubs/celiac>. Accessed December 18, 2008.

2. Binder HJ. Disorders of absorption: celiac sprue. In: Kasper DL, Fauci AS, Longo DL, Braunwald E, Hauser SL, Jameson JL, eds. *Harrison's Principles of Internal Medicine*. 16th ed. New York, NY: McGraw Hill; 2005:1770-1772.

3. Plogsted S, Parish CR. Medications and celiac disease: tips from a pharmacist. *Pract Gastroenterol*. 2007;31(1):58-64. ■