



# RxTriad

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## GLUTEN SENSITIVITY

### FORMULATING FOR THE GLUTEN-SENSITIVE INDIVIDUAL

Gluten sensitivity or intolerance is a genetic disorder that affects as many as 2 million Americans.<sup>1</sup> The classic symptoms range from diarrhea, weight loss, and malnutrition to latent symptoms such as isolated nutrient deficiencies. Gluten-sensitive individuals are prone to a condition called dermatitis herpetiformis, a rashlike allergic reaction caused by deposition of amino acids in the skin.<sup>2</sup>

Once the condition is diagnosed, strict adherence to a 100% gluten-free diet can prevent almost all complications of the disease.<sup>3</sup> This means that the affected individual must avoid all products that contain wheat, rye, barley, and any of their derivatives for life. If a person with the disorder continues to eat foods containing gluten, his chance of developing gastrointestinal cancer increases by a factor of 40 to 100 times that of an unaffected individual;<sup>4</sup> his chance of developing gastrointestinal carcinoma or lymphoma is 15%.<sup>3</sup>



Continued on reverse

## IN THE LITERATURE

**Bloodworth D. Issues in opioid management.** *Am J Phys Med Rehabil* 2005; 84(3 Suppl): S42-S55.

The author is a physician from the Department of Physical Medicine and Rehabilitation, Quentin Mease Hospital, Houston, Texas. She reviews the literature dealing with the use of short- or long-term opioids in adults with chronic and nonmalignant pain and focuses on 26 studies where opioids demonstrated efficacy. The opioids studied were sustained-release morphine, controlled-release codeine, hydrocodone, extended-release morphine sulfate, sustained-release oxycodone, tramadol, sustained-release tramadol, controlled-release dihydrocodeine, sustained-release dihydrocodeine, and proxiphyne with paracetamol. The author highlights and discusses a variety of issues with the use of opioids in chronic nonmalignant pain. The issues discussed include the divergent views of patients and physicians concerning long-term opioid use; the effects of opioids on psychomotor skills, including driving and cognition; defining breakthrough pain for a patient; the use of patient treatment agreements to assist with patient compliance and aligning treatment goals; special considerations for the use of opioids in patients with chronic arthritis pain; postoperative pain management in patients taking long-term opioids for chronic pain; opioid withdrawal; addiction; and deciding whether to prescribe opioids for patients with chronic nonmalignant pain.

While the primary treatment of this disease is avoidance of gluten and does not involve administration of any medication, these individuals may require prescription or over-the-counter medications or nutritional and/or herbal supplements for the amelioration of their symptoms or for the treatment of other conditions. If you are presented with a patient with gluten intolerance, what options do you have for prescribing medications that are gluten free?

The grains in List I have been identified as containing gluten and should be avoided by the gluten-sensitive individual.<sup>5,6</sup> Grains and starches that are gluten free and thus good sources of gluten-free excipients are in List II.

List I: Sources to be avoided by gluten-sensitive individuals

Barley, Farina, Kamut, Rye, Spelt, Triticale, Wheat (durum or semolina)

List II: Sources acceptable for use in gluten-sensitive individuals

Amaranth, Arrowroot, Beans, Corn\*, Millet, Nuts, Potato, Quinoa, Rice, Sorghum, Soy, Tapioca

\* Note: Corn does contain gluteins, but corn gluteins do not contain the antigenic amino acid sequence found in wheat. Thus, corn can be used in gluten-free formulations.

Other ingredients that should have their source verified are sweeteners and solvents. Gluten-sensitive individuals have a higher-than-usual prevalence of lactose intolerance; lactose should be used with caution in these individuals.

Solid dosage forms generally contain a lubricant (e.g., magnesium stearate,

stearic acid). If the lubricant specified in a formulation originates from a vegetable source, check that the source is acceptable before using it in a gluten-free product.

The only treatment for gluten-sensitive individuals is complete avoidance of substances containing gluteins (primarily starches derived from wheat, barley, and rye). Plenty of alternatives are available to provide them with gluten-free prescriptions through your compounding pharmacist.

**References**

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Excerpted from Cacace JL. Formulating for the gluten-sensitive individual. *International Journal of Pharmaceutical Compounding* 2005; 9(5): 357–358.

**WHAT TYPES OF DRUGS ARE FOUND IN TOPICAL PREPARATIONS?**

Compounding pharmacists have far more options than commercial medicine provides, and transdermal pain management can include a number of drugs that include, but are not limited to, those listed below. Some of these are identical to the oral dosage forms. When applied topically, these drugs often have fewer systemic side effects than the oral forms.

Although transdermal treatment allows for many different options, certain classes of drugs are most widely formulated in transdermal preparations. Most compounded topical preparations for treatment of pain include a combination of two or more of the following classes of drugs:

- **Nonsteroidal anti-inflammatory drugs (NSAIDs):** While NSAIDs have quick-acting pain-relieving properties, their real therapeutic purpose is to minimize inflammation or swelling in joints and tissues which can affect mobility in some cases. Examples of common NSAIDs are ibuprofen, piroxicam, and ketoprofen.
- **Anesthetics:** Anesthetics or pain relievers act specifically to reduce pain, and when used topically can be directed to a specific problem area. The most commonly used topical pain relievers are lidocaine, benzocaine, ketamine, and tetracaine.
- **Muscle relaxants:** Muscle relaxants reduce the contractility of the muscle by blocking the transmission of nerve impulses. Common prescription examples include carisoprodol, baclofen, and cyclobenzaprine.
- **Adjunct pain relievers:** A nonanesthetic medication can be used to reduce pain by transmitting a nerve blocker that alters a pain signal on its pathway to the brain. Widely used examples include antidepressants such as amitriptyline or an opioid receptor agonist such as loperamide.
- **Steroids:** Steroids reduce inflammation that accompanies a variety of conditions such as poison ivy or oak, psoriasis, bee stings, allergic reactions, rashes of unknown origin, sprains, and arthritis. The most commonly used is dexamethasone.
- **Antiepileptic agents:** These agents are used to control some types of seizures, and they have been found to also help alleviate chronic nerve pain. Agents used frequently are gabapentin, phenytoin, and lamotrigine.

**UNAPPROVED DRUGS, WHAT'S THE BIG DEAL?**

What do the following drugs have in common?

- Acetaminophen, Codeine Phosphate, and Caffeine capsules and tablets
- Amobarbital Sodium capsules
- Amyl Nitrate inhalant
- Chloral Hydrate capsules, syrup, and suppositories
- Codeine Phosphate injection, oral solution, and tablets
- Codeine Sulfate tablets
- Colchicine injection and tablets
- Digitoxin tablets
- Digoxin elixir and tablets
- Ephedrine Sulfate capsules and injection
- Ergonovine Maleate injection and tablets
- Ergotamine Tartrate tablets
- Hydrocodone Bitartrate tablets
- Hydrocodone Bitartrate, Aspirin, and Caffeine tablets
- Hydromorphone Hydrochloride suppositories
- Levothyroxine Sodium for injection
- Morphine Sulfate oral solution and tablets
- Nitroglycerin sublingual tablets
- Opium tincture
- Oxycodone tablets
- Oxycodone Hydrochloride oral solution
- Paregoric
- Phenazopyridine Hydrochloride tablets
- Phenobarbital capsules, elixir, and tablets
- Phenobarbital Sodium injection
- Pilocarpine Hydrochloride ophthalmic solution
- Potassium Bicarbonate effervescent tablets for oral solution
- Potassium Chloride oral solution
- Potassium Gluconate elixir and tablets
- Potassium Iodide oral solution
- Quinine capsules
- Quinine Sulfate tablets
- Salsalate capsules
- Sodium Fluoride oral solution and tablets
- Thyroid tablets

The answer is...they are examples of “pre-1938” products that have never been approved by the US Food and Drug Administration (FDA). They were all “grandfathered in” and allowed to remain on the market without further regulatory approval if they were labeled with the same conditions of use.

Some of the most important drugs on the market today are unapproved by the FDA, including these pre-1938 drugs, compounded preparations, intravenous admixtures, and others. Patients depend upon FDA-unapproved drugs every day. In fact, any manipulation of an FDA-approved drug outside the FDA-approved labeling changes it to an FDA-unapproved drug.