

Should I care about gluten in medications?

Dr. M Ines Pinto-Sanchez & Professional Advisory Council Canadian Celiac Association

A minimal amount of gluten, a protein found in wheat, rye and barley, is sufficient to induce inflammation and lead to complications in people with celiac disease¹. Gluten can be found in food and non-food sources including prescribed or over-the-counter medications, vitamins and supplements².

Gluten can be part of the non-medicinal ingredients in medications, and the most common form is as excipients which are used to bind pills together. *Modified starch and pregelatinized starch of unclear origin, dextrates, dextrin, dextrimaltose and colouring* are some of the excipients that may contain gluten.

Gluten-free claims on packaged foods are regulated by Health Canada³, with a required cut-off of less than <20 mg/kg (20 ppm) of gluten to be labelled as gluten-free. Unfortunately, similar laws are not in place for labelling of gluten content in medications. There are currently no requirements for labelling gluten or common allergens found in drug ingredients in Canada. Therefore, getting answers about gluten content in medication may be challenging.

How Much Gluten Can a Medication Contain?

The good news is that the majority of medications contain no gluten or very low gluten. In the cases where gluten may be present, it can be estimated based on drug formulation information that wheat starch and other ingredients derived from wheat would contribute no more than 0.5 mg gluten in each pill or tablet⁴. This amount is extremely low, although, the total daily amount will depend on the number of medications taken and other sources containing gluten.

If the medication contains wheat starch, you should ideally avoid using the product. However, if there is no gluten in the list of ingredients, or added excipients like starch, then the amount of gluten is probably very low and unlikely to produce a reaction in people with celiac disease. It is unlikely that any excipient other than starch contains gluten.

Sugar alcohols, such as mannitol, sorbitol, sorbitan, maltitol, xylitol, lactitol, erythritol, and hydrogenated starch hydrolysates are highly processed sugars that contain no gluten and will not cause a problem. Another misrepresented ingredient is wheat maltodextrin, or plain maltodextrin. The ingredient maltodextrin is gluten free even when derived from wheat, due to the way it is processed and is considered safe for people with celiac disease.

How can I know if my medication contains gluten?

Every medication or supplement taken by mouth must be checked to ensure it is gluten free. Probiotics are one type of supplement that may contain added gluten but may get overlooked.



Although information about the gluten content of some medications is available through Internet-based listings and other publications⁵, currently there is no universally accepted source of reliable information⁶. Therefore, it is important to get information from your **physician, pharmacist and the drug manufacturer**. There are some lists available online from the US, for example the one found in GlutenFreeDrugs.com; however, these lists of medications may not apply to Canada. In addition, these lists need constant updating to be correct, because manufacturers can change their ingredients any time and without warning. There is a need for regulations indicating the gluten content of non-prescription products on the package labelling, which would help patients with celiac disease and other individuals wishing to avoid ingesting gluten.

What should I do if I suspect that my medication may contain gluten?

- 1- Contact your physician to let them know about your concern or reaction to the medication. Do not stop taking prescription medicine without talking to your doctor first.
- 2- Bring your list of medications to your pharmacists and inform the pharmacist that you are diagnosed with celiac disease and should follow a very strict gluten-free diet.
- 3- Discuss with the pharmacists hidden sources of gluten, such as excipients.
- 4- You or the pharmacists can contact the manufacturer and ask about gluten content in medication, whether the medication is produced in facility that process gluten, and whether they test their products for gluten.
- 5- If wheat, rye and barley are not found within the ingredients and excipients, the amount of gluten, if any present, may be very low and likely safe for people with celiac disease.

Although medications will likely contain none or very low amount of gluten, when several medications and supplements are taken on a daily basis, the gluten content may potentially become a problem if the total gluten amount goes above tolerated limits. Until new regulations come effective in Canada, it is important that people with celiac disease work with their doctor and pharmacist⁷ to make sure their medications do not contain sources of gluten. Contacting the manufacturer can also help you determine if the medication you will be taking is gluten-free or not. The Canadian Celiac Association and Professional Advisory Council will continue supporting and advocating for the good of our gluten-free community.



References

- 1- Lebwohl B, Sanders DS, Green PH. Coeliac disease. Lancet 2018;
- 2- Maltin V, Charabaty A, Mangione R. Medications: a hidden source of gluten. Practical Gastroenterology. 2009;33(8):32–8.
- 3- Health Canada's position on gluten free claims. <https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/food-allergies-intolerances/celiac-disease/health-canada-position-gluten-free-claims.html>
- 4- Gluten in medication. Food and Drug Administration. <https://www.fda.gov/drugs/ensuring-safe-use-medicine/medications-and-gluten>
- 5- Mangione R et al. Determining the gluten content of non-prescription drugs: Information for patients with celiac disease. J Am Pharm Assoc. 2011;51:734–737.
- 6- King AR. Gluten content of the top 200 medications of 2008: a follow-up to the impact of celiac sprue on patients' medication choices. Hosp Pharm. 2009;44:984–92.
- 7- Mangione RA, Patel PN. Caring for patients with celiac disease: the role of the pharmacist. J Am Pharm Assoc. 2008;48:e125–35.