

Gluten and Lactose in Medicines

Gluten and lactose may be present in medicines as excipients. Excipients are intended to be pharmacologically inactive ingredients, and include binders, absorbents, protectants and colouring agents. Some patients need to, or choose to, avoid gluten or lactose. This bulletin summarises what to consider when prescribing or dispensing medicines for these patients.

Gluten

Gluten is a protein found in cereals such as wheat, barley and rye. Patients with coeliac disease **must** avoid gluten in their diet, as consumption causes autoimmune-mediated damage to the small intestine. The most likely source of gluten in medicines is **wheat starch**, which can be used as a binder in tablets or capsules. Pharmaceutical quality wheat starch is highly processed to remove proteins, and this, combined with the relatively small weight of a tablet or capsule, means there are likely only trace amounts of gluten in medicines that do contain wheat starch. However, in New Zealand, a product can only be labelled gluten-free if the content is less than 3 parts per million, and many manufacturers have not tested their medicines for gluten. The total exposure of gluten needed to trigger either symptoms or asymptomatic intestinal damage is not exactly clear, and differs between people. Therefore, most patients with coeliac disease will choose to avoid any products containing wheat starch. The gluten content of some of the more common excipients is shown below:

| | |
|--------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Contains gluten | •Wheat starch |
| May contain gluten (if starch source not specified) | •Sodium starch glycolate, pre-gelatinised starch, hydroxypropyl starch |
| Gluten-free | •Starch from corn, maize, potato, rice or tapioca •Cellulose, maltose, glucose, dextrose, maltodextrin, mannitol, sorbitol, xylitol, caramel colour (even if derived from wheat) |

Lactose

Lactose is a natural sugar found in milk, and is hydrolysed in the small intestine by the enzyme lactase. People with reduced or absent lactase activity have lactose intolerance, and this can result in gastrointestinal symptoms such as bloating, flatulence, cramps and diarrhoea. In contrast to coeliac disease, no damage to the intestine occurs. Most medicines do not contain enough lactose to cause symptoms, unless the patient has a severe intolerance. The dose of lactose in pharmaceuticals seldom exceeds 2 g per day. Several studies have shown that almost all people with lactose intolerance can consume this small amount without symptoms.

How do I find out if a medicine contains gluten or lactose?

Medsafe website

- Data sheet:** www.medsafe.govt.nz/Medicines/infoSearch.asp
 - The data sheet should state the included excipients in section 6.1.
 - From March 2021, Medsafe requires that the data sheet for all new medicine applications includes information on the presence of allergens. Data sheets for medicines containing gluten or lactose must state: “contains gluten from [specify source]” or “contains lactose”. Manufacturers of existing medicines have until March 2024 to update their data sheets.
- Product/Application Search:** www.medsafe.govt.nz/regulatory/dbsearch.asp
 - This part of the website contains the ‘product detail’, which always includes the excipients, even if they are not in the data sheet. Medicines that don’t have a current data sheet are also often listed in this section.
- Consumer Medicine Information:** www.medsafe.govt.nz/Medicines/infoSearch.asp
 - These usually list the excipients and sometimes state specifically if the product is gluten or lactose-free.

Manufacturer

- If you can’t find the information via Medsafe, or are unsure, contact the manufacturer of the medicine directly. Contact information for the manufacturer (or ‘sponsor’) is listed towards the end of data sheet (section 8).