

RGH Pharmacy E-Bulletin

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A joint initiative of the Patient Services Section and the Drug and Therapeutics Information Service of the Pharmacy Department, Repatriation General Hospital, Daw Park, South Australia. The RGH Pharmacy E-Bulletin is distributed in electronic format on a weekly basis, and aims to present concise, factual information on issues of current interest in therapeutics, drug safety and cost-effective use of medications.

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Gluten and oral prescription medicines

In people with coeliac disease the immune system reacts abnormally to gluten, causing small bowel damage resulting in gastrointestinal and malabsorptive symptoms.

Gluten is a mixture of two plant proteins - gliadin (a prolamine) and glutenin, and is found in wheat flour and to a lesser extent in barley and rye. People with coeliac disease should avoid products containing gluten. While oats (uncontaminated) do not contain gluten, they do contain avenin, which is a prolamine. Avenin is toxic to the intestinal mucosa of avenin-sensitive individuals, and can trigger a reaction in these coeliacs. The question is often raised as to the content and significance of gluten in oral prescription medicines.

According to the Australian Therapeutic Goods Administration (TGA) there are no active ingredients that are incorporated in prescription medications registered in Australia that contain gluten. However, it is not necessarily the case that the same degree of confidence may be applied with respect to the many complementary and alternative medicine products that are in widespread use in the community.

Although it is recognised that the formulation of medicines do not usually specify the inclusion of gluten as a separate excipient, it is possible that some gluten may be present in the form of wheat starch, which is sometimes added to the tablet formulation to make tablets easier to handle or swallow. The TGA regards medicines as 'gluten-free' if the product contains no detectable gluten and contains no oats or barley malt. However, in practice it is not possible to test to confirm a zero gluten content, but research has shown that people with coeliac disease are able to safely tolerate a small amount of gluten, in keeping with the amount that may be present in pharmaceutical products that have been labelled as 'gluten-free'. It is a requirement of the TGA that all oral medicines that contain > 0.3% gluten require to be labelled as such, and with the source of the gluten (e.g. wheat starch) specified.

Where the excipient is subject to the standard of a specific monograph in one of the various pharmacopoeias, raw materials must comply with those standards. For example, according to the European Pharmacopoeia the content of protein for pharmaceutical grade wheat starch should be < 0.3%. Thus, wheat starch is highly refined with only 'trace amounts' of gluten and is considered to be safe for use by patients with coeliac disease. In the United Kingdom, the Medicines and Healthcare Products Regulatory Agency therefore deems that pharmaceutical grade wheat starch is effectively gluten free, and for this reason all oral prescription medicines licensed in the UK are considered to be gluten-free.

Those with concerns regarding gluten sensitivity are best advised to contact the manufacturer of the medication in question to seek specific advice about the content of gluten or avenin contained in the product. Contact details for the various manufacturers of pharmaceutical products can be found in the consumer medicines information for the product, or in various standard drug information resources.

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FOR FURTHER INFORMATION – CONTACT THE PHARMACY DEPARTMENT ON 82751763 or email: chris.alderman@rgh.sa.gov.au
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