

Prescribing...

- ✚ Medicinal products contain not only active drugs but also other ingredients included for a variety of purposes.
- ✚ It is important to distinguish between allergies to these ingredients, which are relatively uncommon and intolerances which are more common and less serious.
- ✚ This second bulletin considers prescribing issues for people with Coeliac Disease and those with Peanut allergies.

Coeliac disease

Coeliac disease is an autoimmune condition associated with chronic inflammation of the small intestine, which can lead to malabsorption of nutrients. Its prevalence on the islands seems to be increasing, so it is important that clinicians are aware of the evidence if asked for gluten-free products.

Dietary proteins (glutens), which are present in wheat, barley and rye activate an abnormal mucosal immune response. Clinical and histological improvements usually follow when gluten is excluded from the diet. Population screening studies suggest that 1 in 100 people in the UK are affected. The total exposure needed to trigger symptoms is not known and may differ between people. It is suggested that consumption of less than 10mg of gluten per day is highly unlikely to trigger disease activity.

Pharmaceutical starch, which is extracted from plant sources such as wheat, corn (maize) and potato, is used primarily in oral solid-dosage formulations where it acts as a binder, diluent and disintegrant. Wheat starch could be problematic for people with coeliac disease. However, the Medicines and Healthcare products Regulatory Agency (MHRA) has advised Coeliac UK that **wheat starch of pharmaceutical quality is highly processed and very low in gluten (containing no more than 100ppm).**

If a product contains wheat starch, this will be indicated in the product information and in the accompanying patient information leaflet (PIL): "Suitable for people with coeliac disease. Patients with wheat allergy (different from coeliac disease) should not take this medicine". Where wheat starch has not been used in a medicinal product, the product can be regarded as gluten-free.

A search of the MHRA database in 2014 identified only 20 marketing authorisations that mention wheat starch as one of the excipients in the medicinal product; therefore, **the vast majority of prescribed medicines are gluten-free.**

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Peanut allergy

Peanut (*Arachis hypogaea*) is a member of the legume (bean) family, which also includes soya beans, lentils and garden peas. Allergy to peanut and tree nuts is estimated to affect 1 in 50 young infants.

Peanut or arachis oil is included in some products as a solvent for sustained-release intramuscular injections, vitamins and hormones, and as a vehicle for topical preparations. Therapeutically, emulsions containing peanut oil have been used in nutrition regimens, in enemas as a faecal softener and in otic drops to soften ear wax. Adverse reactions to peanut oil in foods and pharmaceutical formulations have been reported extensively. In 2003, the then Committee on the Safety of Medicines (CSM) reviewed allergic reactions associated with medicinal products containing peanut oil. It noted that pharmaceutical grade peanut oil is refined and, therefore, the peanut protein should be removed during the manufacturing process. However, a study has demonstrated that very small amounts of peanut protein may remain in refined peanut oil. The CSM advised that there was insufficient evidence to conclude that exposure to medicinal products containing peanut oil leads to sensitisation to peanut protein. However, although the risk of an allergic reaction is low, it advised as a precaution that patients known to be allergic to peanuts should not use medicines containing peanut oil. As there is a possible relationship between peanut allergy and soya allergy, patients allergic to soya should also avoid medicinal products containing peanut oil. All medicines containing peanut oil are required to include an appropriate warning in the labelling.

The summary of product characteristics (SPC) for medicines that contain arachis oil warn that they should not be used in patients with peanut allergy (e.g. Cerumol, naseptin nasal cream, Abidec multivitamin drops, Sustanon injection, Colpermin IBS relief capsules, dimercaprol injection). The SPCs also advise that patients with soya allergy should avoid products containing arachis oil (e.g. isotretinoin capsules), although it is rare for a person with peanut allergy to react to soya or other beans and legumes and most people with peanut allergy can eat soya quite safely, and vice versa.

In summary

- Pharmaceutical grade starch is in some solid dose products, but is very highly purified and includes less than 100 parts per million of gluten.
- Therefore the majority of products are effectively gluten-free.
- A limited number of products, listed above, containing arachis oil should be avoided in people allergic to peanuts.

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