

# Prescribing...

- ✚ Medicinal products contain not only active drugs but also other ingredients included for a variety of purposes.
- ✚ People who wish to avoid a specific substance because of an allergy or intolerance may ask about the constituents of a product and alternatives.
- ✚ This first of three bulletins provides an overview of the pharmaceutical issues that need to be considered , as well as a summary lactose intolerance.

### Background

- A food allergy is an adverse immune response and food intolerance is a non-immunological reaction that can be caused by enzyme deficiencies, pharmacological agents and naturally occurring substances.
- It is estimated that between 1% and 10% of adults and children have some form of food allergy or intolerance.
- The reason why a person has intolerance to a certain type of food is often not clear. However, as many as 20% of the population experience reactions to foods which make them believe that they have a food intolerance or hypersensitivity.
- For children, the most common food allergens include cows' milk, chicken eggs, shellfish, fish, soy, peanuts, wheat and tree nuts. The most common type of enzymatic food intolerance is lactose intolerance.
- Excipients in medicinal products may not be suitable for all people with a dietary intolerance or allergy, but in many cases the levels are too low to cause problems.

### Dietary intolerances and pharmaceutical considerations

#### Lactose intolerance

Lactose is a natural disaccharide present in the milk of most mammals. Symptoms of lactose intolerance arise from its malabsorption resulting from low or absent lactase activity. Although it is commonly confused with cows' milk allergy, lactose intolerance is not immunological in origin. The frequency of lactose intolerance varies with ethnic origin with the lowest rates in Caucasians (5% in a British population). There is considerable intraindividual and interindividual variability in the severity of gastrointestinal symptoms

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according to the amount of lactose ingested and the patient's ability to digest it. The minimum dose of lactose that will cause symptoms has not been unequivocally established. It has been suggested that adults and adolescents with a diagnosis of lactose intolerance can ingest up to 12g of lactose in a single dose (equivalent to the lactose content in 1 cup of milk) with no or only minor symptoms. A systematic review found that, for people with lactose intolerance and malabsorption, symptoms become more prominent with doses above 18g; single doses of 24g usually result in substantial symptoms; and consumption of 50g of lactose induced symptoms in most individuals. However, gastrointestinal symptoms have been reported after ingestion of smaller doses of lactose, and in clinical practice it is common to find lactose maldigesters who believe that the ingestion of a minimal amount (e.g. in a white coffee) can produce symptoms. The onset of such symptoms after ingestion of a lactose-containing drug in lactose maldigesters has been described only in a limited number of case reports, and population studies are lacking.

Commercially, lactose is produced from the whey of cows' milk and is widely used as a filler and diluent in tablets and capsules. As cows' milk proteins have been filtered in the manufacture of pharmaceutical grade lactose, allergic reactions are considered highly unlikely in most allergic individuals, and thus product information leaflets do not warn of the possibility of allergic reactions to cows' milk protein in lactose-containing medicines. The dose of lactose in most pharmaceutical products seldom exceeds 2g/day. It is unlikely that severe gastrointestinal symptoms can be attributed to the lactose in a conventional oral solid-dosage form, especially in adults who have not previously been diagnosed as severely lactose-intolerant. In a study of 77 lactose maldigesters with intolerance, the administration of capsules containing 400mg of lactose did not produce changes in hydrogen breath excretion and gastrointestinal symptoms at 8 hours compared with placebo. The researchers suggest that these results indicate that gastrointestinal symptoms can at times be mistakenly attributed to lactose in drugs, thus influencing medication adherence and may result in the use of alternative, and possibly less effective, therapeutic approaches. They suggest that lactase deficiency should no longer be considered a contraindication to the use of medications with similar or lower doses of lactose. However, there have been anecdotal reports of drug-induced diarrhoea due to lactose intolerance following administration of pharmaceutical preparations containing lactose.

### In summary

- The British National Formulary also advises that the lactose content in most products is too small to cause problems in most lactose-intolerant patients.
- However, in people with severe lactose intolerance, lactose content of a medicinal product should be determined before prescribing.

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