

Proceeding Paper

# Cow's Milk Protein Allergy: The Hidden Danger of Medicines' Excipients †

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**Abstract:** In patients with a cow's milk protein allergy, the presence of these allergens in medicines, even in trace amounts, can trigger serious allergic reactions. The study of milk-related excipient prevalence in 165 antiasthmatic medicines, based on the information included in the Summary of Product Characteristics, revealed the presence of lactose in more than one third of these medicines. Since lactose may suffer cross-contamination with cow's milk protein, these results are an alert to health professionals.

**Keywords:** excipients; lactose; cow's milk protein allergy



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## 1. Introduction

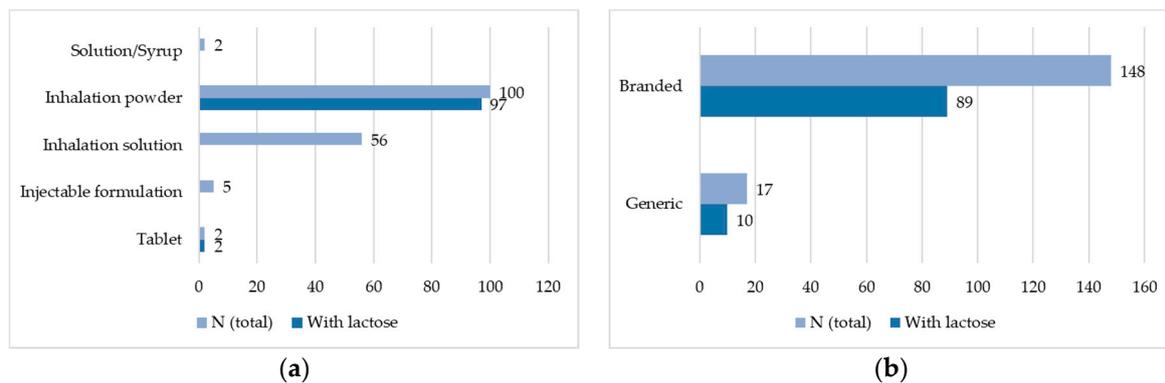
Food allergies are increasingly common, as well as a public health issue with a great impact. Cow's milk protein (CMP) allergy is one of the most common pediatric allergies [1]. CMP allergy may occur at any age. However, it is more prevalent in children under the age of three. In Europe, the reported prevalence ranges from 2% to 7.5% in the first year of life [2]. It is characterized by an immune response to proteins that are present in cow's milk [1]. The symptoms include cutaneous, gastrointestinal and respiratory effects. It is also one of the most common causes of anaphylaxis in children up to 2 years old [3]. Patients with this allergy should exclude milk from their diet [1]. Even dairy products that do not directly contain CMP can trigger an allergic reaction in sensitive patients due to cross-contamination. The intake of medicines containing milk-related excipients, such as lactose, may originate symptoms in allergic patients. This study aimed to evaluate the prevalence of milk derivatives as excipients in antiasthmatic medicines available in Portugal.

## 2. Materials and Methods

The presence of milk-related excipients was evaluated in 165 antiasthmatic medicines based on the Summary of Product Characteristics (SmPC). Selection criteria of medicines included: marketing authorization approved in Portugal, with the SmPC available on the human medicinal products database (INFOMED), for adult and/or pediatric use, in any dose or dosage form, branded or generic.

## 3. Results and Discussion

From a total of 165 medicines studied, 99 included lactose as an excipient, as stated in the SmPC, mainly inhalation powders and tablets (Figure 1a). Lactose was the only allergen derived from milk mentioned in the list of excipients. Regarding the presence of the allergen in generic (N = 17) and branded (N = 148) medicines, there is lactose in both groups (Figure 1b), with a similar prevalence (60.1% and 58.8%, respectively).



**Figure 1.** Presence of lactose as excipient according to: (a) dosage form; (b) generic or branded.

This study revealed a high prevalence of lactose (60%) in antiasthmatic medicines, which may represent a high risk to patients allergic to milk. The presence of milk derivatives as excipients in pharmaceutical products could induce an allergic reaction in patients with CMP allergy. Since respiratory symptoms, such as wheezing, shortness of breath, chest tightness, coughing, and breathing difficulties, are common in allergic patients, antiasthmatics are frequently prescribed medicines.

Lactose, although it is not a milk protein, can also trigger adverse reactions in patients with CMP allergy, due to the risk of cross-contamination by traces of CMP [4]. In the pharmaceutical industry, lactose is widely used as an excipient in medicines [5]. It is used in capsules and tablets as a volume expander or for direct compression, and also as a vehicle in dry powder inhalers, facilitating the delivery of the drug down to the smallest airways [5].

It is essential that the presence of food allergens is highlighted in the composition of the medicines, because even in trace amounts, they can trigger serious reactions in allergic patients. It is also imperative that healthcare professionals have easy access to the detailed composition of medicines, in order to provide a safe prescription and counseling.

**Institutional Review Board Statement:** Not applicable.

**Informed Consent Statement:** Not applicable.

**Data Availability Statement:** Data available in a publicly accessible repository, the data presented in this study are openly available in <https://extranet.infarmed.pt/INFOMED-fo/>.

**Conflicts of Interest:** The authors declare no conflict of interest.

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