Study Finds Common Medicines Contain Hidden Gluten and Soy

A recent study published assessed the presence of soy- and gluten-derived excipients in medicinal products authorized in Portugal.

Food allergies are a major public health concern, and their prevalence has risen in recent decades. Gluten is a protein found in barley, rye, and wheat, and it can cause adverse reactions in individuals with gluten sensitivity. Gluten ingestion causes three clinical disorders: celiac disease (CD), wheat allergy, and non-celiac gluten sensitivity, which have distinct symptoms and characteristics.

Some excipients are used in various pharmaceutical forms, including sodium starch glycolate, starch, and pregelatinized starch, while others are derived from sources such as rye, barley, oats, and wheat. Potato starch and corn starch are also used, as they are gluten-free, making them safe for individuals with gluten-related disorders. As a common excipient, starch is a major source of gluten. However, when "starch" is listed without a specified botanical origin, it complicates allergen identification, as it may derive from wheat or gluten-free sources.

Furthermore, soy is among the top food allergens, frequently causing allergic reactions in children. Soy contains several distinct proteins with varying risks for severe reactions. Besides, soy allergies can manifest as urticaria, oral allergy syndrome, asthma, angioedema, and anaphylaxis. Currently, soy or gluten allergies lack a definitive cure, and the best treatment is to avoid these allergens altogether in diet and medicinal products. However, analyses on the presence of gluten or soy in medicinal products are scarce.

Even trace amounts of allergens in excipients like soy lecithin or starches derived from wheat may be clinically relevant in highly sensitive individuals despite their low protein content.

Study

In the present study, researchers investigated the prevalence of soy- and gluten-derived excipients in medicinal products in Portugal. First, the Summary of Product Characteristics (SmPC) database was searched for human medicines to identify soy- and gluten-derived excipients. They focused on therapeutic classes most commonly prescribed for adults and children, including non-steroidal anti-inflammatory drugs (NSAIDs), antipyretics and analgesics, as well as anti-asthmatics and bronchodilators.

Paracetamol and ibuprofen were selected because of their high national sales volumes, making the study relevant to public health priorities in Portugal.

All medicinal products authorized for marketing in Portugal, with a linked SmPC in the online database (INFOMED), were eligible for inclusion. Branded and generic products, excluding injectables, were considered in all formulations and dosages. Since the dose or quantity of allergen was not specified in the SmPC, the team focused on identifying whether gluten, soy, and related substances were present.

Medicinal products were categorized as non-gluten-free based on the presence of xanthan gum, oats, starch, glucose syrup, wheat, rye, semolina, bran, barley, malt, sodium carboxymethyl starch, gelatinized starch, and pregelatinized starch. Similarly, products were classified as non-soy-free if they contained soy, lecithin, tocopherols, phytosterols, or xanthan gum.

Xanthan gum was treated as a risk factor for both allergens due to its potential production from soy—or gluten-containing sources, and thus, it was included in both classifications by the precautionary principle.

Further, Fisher's exact and chi-squared tests were performed to assess the associations between the presence of excipients and pharmacotherapeutic groups.

Results

A total of 308 medicinal products were analyzed. These included 108 antipyretics and analgesics, 115 bronchodilators and anti-asthmatics, and 85 NSAIDs. Sodium carboxymethyl starch and pregelatinized starch were the predominant gluten-derived excipients, while xanthan gum and soy were the most common soy-derived excipients. Xanthan gum and soy were almost exclusively present in NSAIDs, antipyretics, and analgesics.

Pharmacotherapeutic groups were significantly associated with the presence of soy- or gluten-derived excipients. Gluten excipients were more prevalent in antipyretics and analgesics than in NSAIDs, while soy excipients were more prevalent in NSAIDs than in antipyretics and analgesics. None of the 115 anti-asthmatic and bronchodilator inhalation products contained any soy- or gluten-derived excipients.

Among paracetamol-based antipyretics and analgesics, 51.2% of solid oral forms and 40% of liquid oral forms were not gluten-free, with gluten found most commonly in film-coated tablets (61.1%) and regular tablets (60%).

In contrast, only 4.4% of solid oral NSAIDs contained gluten, and gluten was primarily found in their liquid oral forms (26.7%).

Soy-derived excipients were found in 30% of liquid oral formulations and 33.3% of rectal suppositories of antipyretics and analgesics.

In the NSAID group, 11.8% of solid oral forms and 26.7% of liquid oral forms contained soy, with soft capsules and film-coated tablets being key contributors.

Additionally, there was no correlation between the presence of gluten and the classification of medicines as branded or generic.

However, a significant association was found between the branded or generic classification and the presence of soy-derived excipients ($p < 0.05$), reflecting formulation differences across manufacturers.

None of the solid oral forms of antipyretics and analgesics contained soy, whereas 30% of the liquid oral forms did, particularly syrups (60%). Among NSAIDs, nearly 12% of solid oral forms and 27% of liquid oral forms contained soy.

Conclusion

The findings reveal varying prevalences of soy and gluten in medications between dosage forms and therapeutic classes. These results have significant safety implications for susceptible consumers. Individuals with gluten sensitivity or celiac disease (CD) should exercise caution when using solid oral antipyretics and analgesics. Individuals with soy allergies should exercise caution when using liquid oral formulations and suppositories.

Liquid formulations and rectal suppositories may offer safer alternatives for individuals with gluten sensitivities, while solid oral NSAIDs may be a lower-risk option for soy-sensitive individuals.

Furthermore, healthcare providers should be aware of the potential presence of these allergens and advise individuals with sensitivities accordingly.

The study authors highlight the need for clearer allergen labeling on medicinal products and caution that reliance on SmPCs alone may not fully reveal hidden allergen sources. They also note that potential cross-contamination during manufacturing cannot be ruled out without direct confirmation from manufacturers, representing a key limitation of the study.

Moreover, manufacturers should clearly label the presence of these allergens to inform consumers and healthcare providers, and explore formulations that eliminate or minimize their presence. In particular, the study emphasizes that excipients listed generically as “starch” should be accompanied by the declared botanical source, such as wheat, corn, or potato, to enable safe selection for allergic individuals.

Proper labeling and increased awareness can help mitigate risks and ensure safer medication use for those with gluten and soy sensitivities.

Overall, the findings highlight the need for more transparency regarding excipients in medicines.

Source:

https://www.news-medical.net/news/20250401/Common-medicines-contain-hidden-gluten-and-soy-study-finds.aspx