

ALLERGENS IN MEDICINES: SOYBEAN AND GLUTEN



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INTRODUCTION

In recent decades, **food allergies and intolerances** have been **increasing** all over the world. **Wheat and soy** are among the foods with the most allergenic ingredients.

Both gluten and soy derivatives can be **found in medicines as excipients**, which can trigger adverse reactions in individuals with celiac disease, sensitivity to gluten and allergy to wheat.

OBJECTIVES

Analysis of the information contained in the Summary of Product Characteristics (SmPC) to assess the existence of gluten and/or soy as excipients in medicines marketed in Portugal.

MATERIALS AND METHODS

The presence of gluten and/or soy was evaluated in the complete **excipient list** of medicines based on SmPC.

Inclusion criteria:

- antibacterials, antiasthmatics, bronchodilators, or medicines with paracetamol or acetylsalicylic acid;
- any dosage and pharmaceutical form, generic and branded, mandatory prescription or over-the-counter;
- Marketing Authorization approved in Portugal and SmPC available at the National database of medicines for human use (INFOMED).

RESULTS

From the **552 SmPC evaluated**:

- **11.6%** referred the presence of **starch**, not always specifying its origin, which may indicate the presence of gluten (wheat starch)
- **4.5%** included **soy** or soy derivatives
- **1.3%** contained gluten and soy

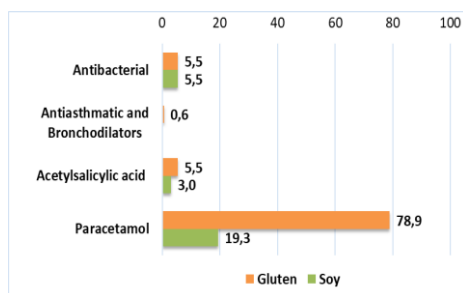


Figure - % Gluten and Soy in some drug classes

The **prevalence of gluten and soy allergens** was higher in medicines with **paracetamol**.

CONCLUSIONS

- ✓ 17.4% medicines revealed the **presence of gluten or soy** in the SmPC;
- ✓ The **origin of excipients** is not always explicit in the SmPC, which can raise doubts among prescribers and consumers and increases the risk of allergic reaction;
- ✓ Information about the **presence of food allergens in medications should be emphasized and readily accessed**, because even in trace amounts they can trigger severe reactions in allergic/intolerant patients.

References

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