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POTENTIALLY HARMFUL EXCIPIENTS IN NEONATAL AND PEDIATRIC PATIENTS

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BACKGROUND

Excipients → quality, stability, bioavailability, and patient acceptability of medicines

Potentially harmful excipients (PHE) for vulnerable group of patients like children younger than 4 years old

OBJECTIVES

Assess the exposure to potentially harmful excipients

Determine if the amount of them exceed the **Acceptable Daily Intake (ADI)** in these patients

MATERIALS and METHODS

- Retrospective
- Descriptive

All neonates and children <4years old treated with oral medicines during 1 year

By the literature

ADI

PHE

- Propylparaben
- Propylene glicol
- Sodium benzoate
- Sorbitol
- Ethanol
- Sulphites

Different oral drugs — Total dose received

The amount of studied excipients → Pharmaceuticals Laboratories

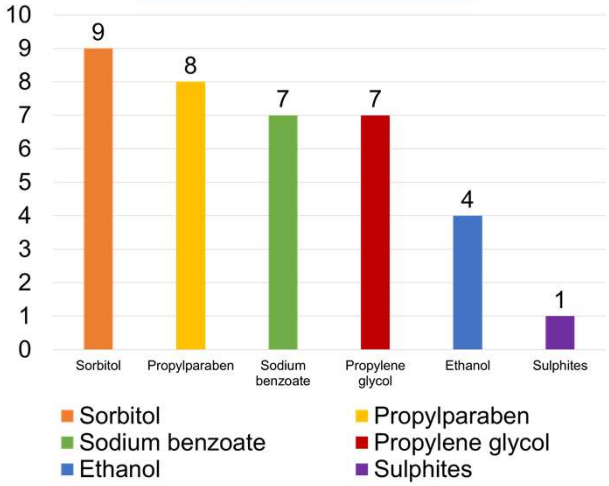
RESULTS

609 patients → 98 different drugs

At least one excipient studied → 28.6% of drugs

26% patients were exposed to PHE

Drugs quantity with PHE



26 **Cases the ADI was exceeded:**

- **34.6%** Sodium benzoate ADI was exceeded
- **34.6%** Sorbitol ADI was exceeded
- **11.5%** Sulphites ADI was exceeded
- **11.5%** Ethanol ADI was exceeded
- **7.6%** Propylene glicol ADI was exceeded

6 **Drugs the ADI was exceeded:**

- Calcium phosphate solution
- Potassium bicarbonate tablets
- Domperidone suspension
- Rifampicin suspension
- Clonazepam solution
- Diazepam solution

CONCLUSIONS

- The percentage of patients who exceeded the ADI of the PHE was low, although it shouldn`t exceed in any case.
- Quantitative information about excipients should be available to health professionals in order to take into account excipients issues when selecting medicines for this vulnerable group.

Conflict of interest: nothing to disclose

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