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

By the literature

ADI

PHE

Propylparaben
Propylene glycol
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 glycol ADI was exceeded

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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