DESCRIPTIVE STUDY OF MARKETED MEDICINES CONTAINING ASPARTAME

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BACKGROUND AND IMPORTANCE

IARC International Agency for Research on Cancer

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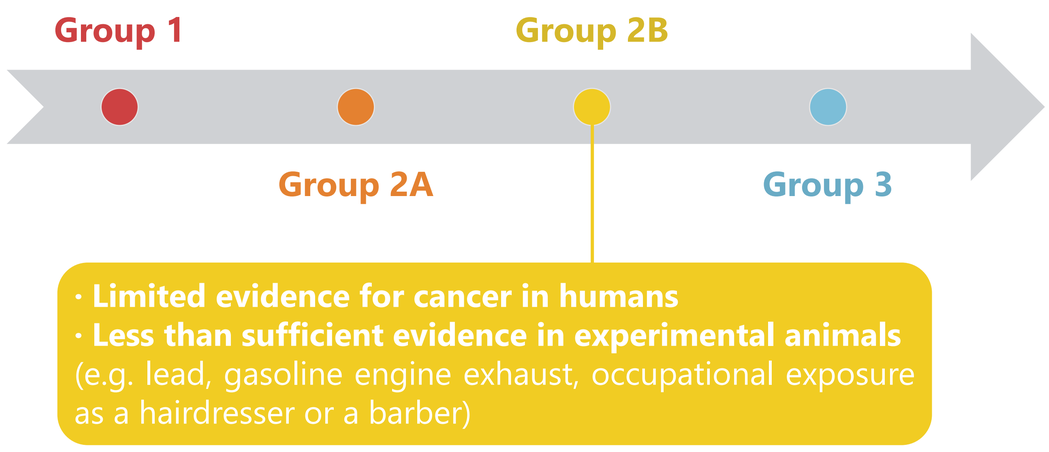
Aspartame classified as
possibly carcinogenic to humans (Group 2B)



World Health Organization + Food and Agriculture Organization of the United Nations

Joint WHO/FAO Expert Committee on Food Additives **(JECFA)**:
Safety threshold = 40 mg/kg body weight/day

AIM AND OBJECTIVES

❶ Compare the **maximum daily intake of aspartame (MDIa)** for every oral medicine marketed in our country with the safety threshold

❷ Analyse the **main features of these medicines** containing aspartame

MDIa was defined as the daily amount of aspartame taken if using the maximum dose of the corresponding drug according to its label dosage recommendations

MATERIAL AND METHODS

Bibliographic study

Collected variables	Medicine name
	Active drug
	Dosage form
	Authorised indication(s)
	Miligrams of aspartame per unit (solid dosage forms)
	Miligrams of aspartame per mililitre (liquid dosage forms)

RESULTS

370 medicines declared containing aspartame

222 **(60.0%) medication for chronic use**

148 **(40.0%) acute care drugs**

283 **(76.5%) fast disintegrating tablets**

68 **(40.0%) oral solutions/suspensions or powders for oral solution/suspension**

19 **(5.1%) other**

Median dose of aspartame was 3.0mg/unit (1.3–8.0) for solid forms and 12.5mg/mL (5.0–30.0) for liquid forms

For the total population of study, **median MDIa was 9.0mg per unit or mL (3.0–20.8) and the absolute largest observation was 420.0mg/mL**

Specifically, **median MDIa for solid forms was 8.0mg/unit (2.1–11.2) and for liquid forms was 75.0mg/mL (30.0–90.0)**;
the difference between these medians was statistically significative ($p<0.001$)

CONCLUSION AND RELEVANCE

All medicines marketed in our country containing aspartame have a **MDIa remaining under the threshold established by the JECFA for most adult population**. However, since liquid forms contain considerable amounts, their suitability as chronic treatments should be reconsidered for children during medication review, specially if polymedicated.

These results should be **comparable to the rest of European countries**.

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