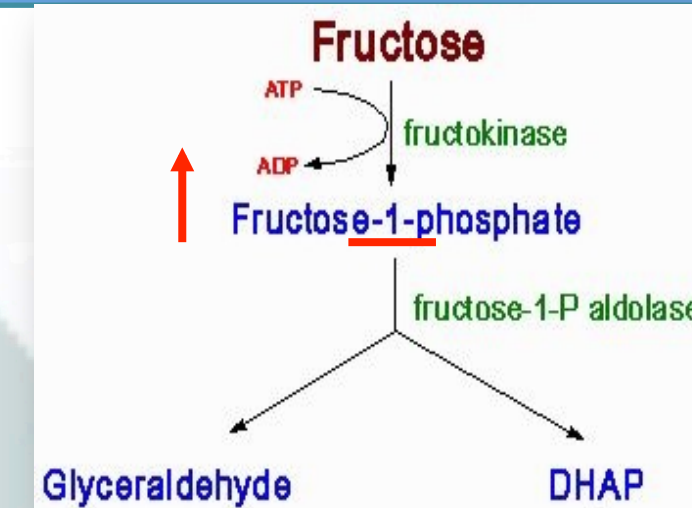


EXCIPIENTS IN PATIENTS WITH HEREDITARY FRUCTOSE INTOLERANCE

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BACKGROUND: Hereditary Fructose Intolerance (HFI) is an autosomal recessive disorder caused by aldolase B deficiency. Treatment consists of elimination of fructose, sucrose and sorbitol from the diet. There are a lot of medicines with sweetener but there is disagreement with their tolerance.



PURPOSE: Our purpose is to provide information to health professional (pharmacist and doctors) and patients about excipients for HIF patients. The work was conducted in close collaboration with the Spanish association of HFI patients.

MATERIAL AND METHODS: We reviewed Spanish and European legislation about excipients and dietary recommendations for HIF patients.

RESULTS: We reviewed the European Guidelines (Excipients in the label and package leaflet of medicinal products. EMA. 2003) and Spanish legislation (Circular 2/2008) and classify the excipients listed in allowed, contraindicated or in which special caution is advised:

CONTRAINDICATED:

Fructose, sucrose, invert sugar and sorbitol are a significant source of fructose and in label must appear an alert:

“Patients with rare hereditary problems of fructose intolerance should not take this medicine”

High fructose corn syrup, sucromalt or tagatose (metabolized by aldolase B) are not used in the pharmaceutical industry but they should avoid.

CAUTION: Evaluate benefit and risk according patient and excipient characteristics (purity, metabolism and quantity)

1. Legislation does not recommend: **MALTITOL, LACTITOL, ISOMALTITOL** (polyols: sorbitol disaccharides) but the dietary recommendation is not unanimous. Because of low affinity of the disaccharidases the sorbitol releases in the intestine is low and variable.

2. Legislation does not alert about **MANNITOL** (unknown hepatic metabolism), **INULIN** (fructose polysaccharide), **POLYDEXTROSE** (10% of sorbitol) and **POLYSORBATES**. Also, they could release a few fructose or sorbitol.

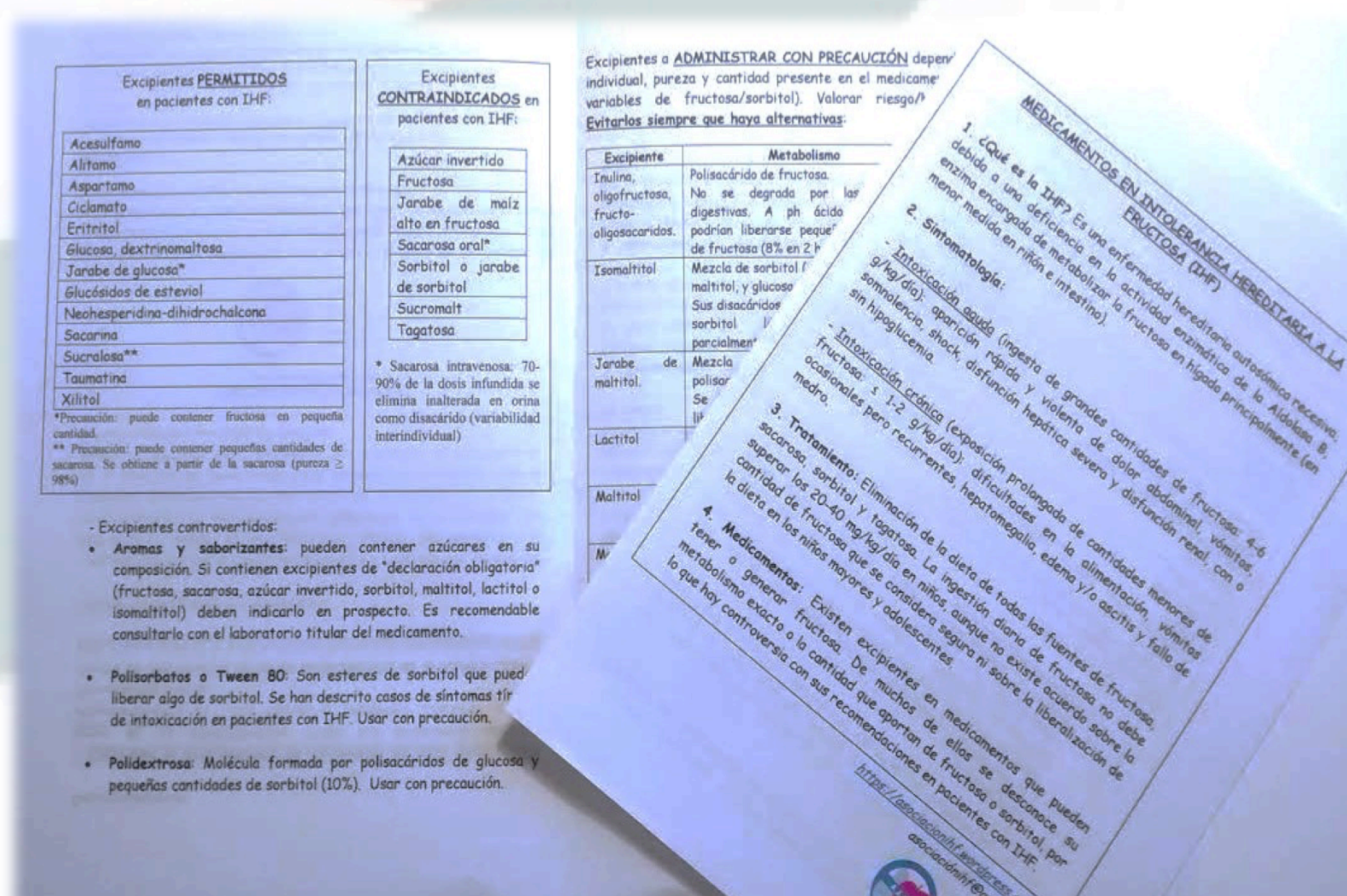
ALLOWED: there is not alert on the label for HIF patients:

Dextrinomaltose and glucose syrup, synthetic sweeteners (**acesulfame, aspartame or saccharin**), **sucralose, erythritol and xylitol**.

CONCLUSION:

Excipients and sweeteners recommendations (especially polyols) do not match between legislation (contraindicated) and references. Furthermore, excipients legislation does not warn about mannitol, inulin, polydextrose and polysorbates.

Because of there are not unanimous recommendations we develop information material for health professionals in collaboration with HIF Spanish association.



References and/or Acknowledgements:

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