

Date: 05.10.2026

Urgent Field Safety Notice

Withdrawal from distribution chain

Isla Junior Sirop de tuse

Send by:

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For Attention of:

HALMED, Distribution chain down to pharmacies (not end-user)

Identification of the medical devices concerned:

The product in concern is *isla junior Sirop de tuse*. It is a throat liquid for children from 1 year exclusively sold in pharmacies.

Batch number: 506004

Expiration date: 04/2029

Composition (English):

Icelandic Moss Spissum Extract (3.3%), Xanthan Gum, Sorbitol, Water, Fructose, Citric Acid, Polysorbate 80, Potassium Sorbate, Zinc Sulphate, Strawberry Flavour

Composition (Romanian):

Extract de mușchi islandez (3,3 %), gumă xantan, sorbitol, apă, fructoză, acid citric, polisorbit 80, sorbat de potasiu, sulfat de zinc, aromă de căpșuni

Description of the problem, including the identified cause:

We hereby inform you that **batch 506004** of the medical device "**isla Junior Sirop de tuse**" is being withdrawn from the Croatian market because it is labelled in Romanian.

Background: During September 2026, the isla junior Syrup 100 ml was launched simultaneously in several European Union markets, including Croatia. Due to a shipping error, one pallet of products packaged for the Romanian market, bearing a different batch number, was delivered to Croatia together with the packs intended for the Croatian market. A small number of packages intended for the Romanian market (batch number 506004) were brought to the Croatian market before the error was detected. The batch intended for the Croatian market (number 506003B) is correctly labelled and is not affected from this recall.

Risk: The risk to the end-user lies in the incomprehensible instructions for use due to the Romanian labelling which could result in incorrect use of the product. The product has an extremely low risk profile. A wrong usage, such as an overdose of the product could result into a laxative effect or in case of use in children it could lead to diarrhoea or flatulence. Furthermore, the warning regarding incompatibility with individual ingredients cannot be understood.

Risk for end-users already treated: The risks are identical to the section above.

Assessment of the risk:

The error is apparent and can be noticed easily by pharmacies as well as by patients or users. The composition of the product for the Croatian and the Romanian market are the same. Despite the readability and the possibility of medication errors if used without understanding the instructions for use, there is no special risk with the Romanian labelled product.

What measures must the addressed party take?

Please immediately initiate the following actions in accordance with your standard operating procedures:

- Check your stock and block any further sale of batch 506004 (labelled in Romanian) in Croatia, if found in stock
 - o The stock check must be performed by physically inspecting the packaging and the actual batch number printed on the pack, irrespective of the batch number recorded in your system or stated on the delivery documentation.
- Return all packages of batch 506004, if found in stock, to Salveo d.o.o. Zavrtnica 17, 10000 Zagreb, Croatia

Please note:

The batch intended for the Croatian market is **506003B (expiry date 04/2029)**, is labelled in Croatian, and may continue to be distributed.

Sharing the information described here:

Please ensure within your organisation that all partners of the above-mentioned products and any other relevant parties are made aware of this Urgent Security Notice. If you have supplied the products to third parties, please forward a copy of this notice to them or inform the contact person listed below.

Please keep this information for at least as long as it takes to complete the measure.

HALMED received a copy of this FSN.

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