Laboratoires Urgo Healthcare
42, rue de Longvic
21300 Chenôve - France

FSN Ref: LUH-2022-1449 FSCA Ref: SUKLS248042/2022

Date: 22/11/2022

Urgent Field Safety Notice

URGO FILMOGEL Cracks 3.25 ml

For Attention of patients and Healthcare professionals

Contact details of local representative (name, e-mail, telephone, address etc.)*
Laboratoires Urgo Healthcare Caroline Soupe PCVRR – QA/ RA Director 42 rue de Longvic 21300 CHENOVE – FRANCE E-mail : c.soupe@fr.urgo.com Cell : +33608778169 **MagnaPharm CZ s.r.o.** Karol Michalák QA Manager CZ/SK and Qualified Person Karla Engliše 3201/6, Smíchov, 150 00 Prague E-mail: Karol.Michalaksr@magnapharm.eu Cell: +421 905 400 526

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Urgent Field Safety Notice (FSN)
Device Commercial Name
Risk addressed by FSN

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	"URGO CRACKS FILMOGEL" is a Medical Device class IIa. It is a filmogel intended to be used on cracks on feet and hands. GMDN code: 47763 - wound hydrogel dressing, non-sterile.
1.	2. Commercial name(s)
	URGO FILMOGEL Praskliny 3.25 ml
1.	3. Unique Device Identifier(s) (UDI-DI)
	Basic UDI-DI: 3664492LUHUS0031PC.
1.	4. Primary clinical purpose of device(s)*
	"URGO CRACKS FILMOGEL" is indicated to protect and treat cracks, chaps and minor cuts in order to relieve the pain they cause and promote their healing. It fills cracks, thus preventing their re-opening and bleeding. The product is ready for use.
1.	5. Device Model/Catalogue/part number(s)*
	600860 (finished product article code for Laboratoires Urgo Heathcare).
1.	6. Software version
	Not applicable.
1.	7. Affected serial or lot number range
	Batch number : 16956 - Expiration date 2024-11-30.
1.	8. Associated devices
	Not applicable.

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	A complaint has been received, on November 9th 2022 by the Manufacturer Laboratoires Urgo Healthcare from the distributor MagnaPharm CZ/SK, in order to advise that one unit of "URGO FILMOGEL Praskliny 3.25 ml" (batch 16956) has been found, by a local distributor in Slovakia, with a card (external packaging glued with the folding box) mentioning the name of "URGO MOUTH ULCERS FILMOGEL".  The complaint was recorded under the reference LUH-2022-1449.
2.	2. Hazard giving rise to the FSCA*
	This FSCA is related to a mix up between labellings of two different medical devices and a risk of confusion. In case of confusion and without having the extent of the non-compliance, the distributor MagnaPharm CZ/SK has decided to take immediately measures on this batch 16956, in order to prevent harm to the patient. They decided to withdraw units from the market at the level of pharmacies and local distributors, in Czech Republic and in Slovakia (because this batch 16956 was distributed in Czech Republic and is Slovakia).
2.	3. Probability of problem arising
	Further to the discovery of this issue, Laboratoires Urgo Healthcare asked to their different distributors having received and distributed this batch 16956 to confirm if they were front of the same issue. As it was confirmed that there was only one complaint for 5 084 units produced and distributed, the probability is assessed at (1/5084)x100 = 0.02%.
2.	4. Predicted risk to patient/users
	This FSCA is related to a mix up between labellings of two different medical devices. Further to the discovery of this issue, a toxicological / clinical assessment was performed. The conclusion is that even if the device "URGO CRACKS FILMOGEL" is used instead of "URGO MOUTH ULCERS FILMOGEL" for the treatment of mouth ulcers, the safety of the patient is not compromised: no systemic risk is expected and, although unlikely, only an application site reaction with transient and spontaneously reversible oral mucosa irritation may happen. A transient and spontaneously reversible discomfort or pain at application may be expected due to the presence of alcohol in the URGO CRACKS FILMOGEL solution.
2.	5. Further information to help characterise the problem
	Not applicable.

2.	6. Background on Issue
	The use of the device “URGO FILMOGEL Praskliny 3.25 ml” according to the label on the bottle, the Instruction For Use and the labelling of the box, which are compliant, won’t allow a misuse for the treatment of mouth ulcers.
2.	7. Other information relevant to FSCA
	Not applicable.

	3. Type of Action to mitigate the risk*	
3.	**1. Action To Be Taken by the User***	
	☐ Identify Device ☐ Quarantine Device ☒ Return Device ☐ Destroy Device ☐ On-site device modification/inspection ☐ Follow patient management recommendations ☐ Take note of amendment/reinforcement of Instructions For Use (IFU) ☐ Other ☐ None The distributor MagnaPharm CZ/SK has requested to receive returned devices from the users. After December 1st, 2022, MagnaPharm CZ/SK will deal with returned goods from the field.	
3.	2. By when should the action be completed?	December 2022
3.	3. Particular considerations for: Choose an item. Is follow-up of patients or review of patients’ previous results recommended? No	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	No
3.	**5. Action Being Taken by the Manufacturer**	
	☒ Product Removal ☒ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None Action plan on-going : - Withdrawal of the batch 16956 in Czech Republic and in Slovakia. - Sorting, in the distribution sites of other countries where the batch 16956 was commercialized, of all the units not sold. - Investigation performed on the manufacturing site with implementation of corrective actions.	
3	6. By when should the action be completed?	December 2022
3.	7. Is the FSN required to be communicated to the patient /lay user?	No

3	8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?
	Not applicable.

	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	Not applicable
4.	**3.** For Updated FSN, key new information as follows:	
	Not applicable	
4.	4. Further advice or information already expected in follow-up FSN? *	No
4	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	Not applicable.	
4	6. Anticipated timescale for follow-up FSN	December 2022
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Laboratoires Urgo Healthcare
	b. Address	42 rue de Longvic - 21300 CHENOVE – FRANCE
	c. Website address	https://urgo.fr
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. No	
4.	9. List of attachments/appendices:	Not applicable.
4.	10. Name/Signature	Caroline SOUPE PCVRR – QA/ RA Director

	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

	Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback..*

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.