Date : 19 june 2026

Urgent Field Safety Notice (FSN)

BLEPHADEMODEX

For Healthcare professionals: Pharmacists, Physicians and Opticians

Contact details of local representative (name, e-mail, telephone, address etc.)*
Laboratoires Thea Pharma Srl, Calea 13 Septembrie nr. 90, Complexul Grand, Camerele 2.19 - 2.20, Bucharest, Romania

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BLEPHADEMODEX

	1. **Information on Affected Devices***
1	1. Device Type*
	BLEPHADEMODEX is a sterile wipe, impregnated with a lotion for the daily hygiene of eyelids when there is Demodex infection. For use on the skin only, do not put directly into the eye.
1	2. Commercial name(s)
	BLEPHADEMODEX
1	3. Unique Device Identifier(s) (UDI-DI)
	3662042006180T3
1	4. Primary clinical purpose of device(s)*
	BLEPHADEMODEX is recommended: for daily hygiene of the eyelids when there is Demodex infection, to relieve the symptoms of an eyelid infection or inflammation (blepharitis) caused by Demodex. BLEPHADEMODEX cleans away crusts, eyelash dandruff, impurities and infectious agents on eyelids and eyelashes. BLEPHADEMODEX improves symptoms linked to Demodex infection, such as itching, burning, dryness and lid margin inflammation. Eyelid redness and foreign body sensations are reduced.
1	5. Device Model/Catalogue/part number(s)*
	T1172
1	6. Software Version
	NA
1	7. Affected serial or lot number range
	NA
1	8. Associated devices
	NA

	2 Reason for Field Safety Corrective Action (FSCA)*
	1. Description of the product problem*

	A significant and persistent increase in reports from several European countries concerning inappropriate use of BLEPHADEMODEX has been observed. These reports primarily involve off-label use, use in pediatric populations, and confusion with another of our medical devices, BLEPHACLEAN.
	3. Hazard giving rise to the FSCA*
	There is no immediate risk to health. The increasing frequency of these errors in use or dispensing has led us to implement targeted communication as a preventative measure.
	5. Probability of problem arising
	No associated problems have been identified. This is considered a precautionary measure to be carried out.
	6. Predicted risk to patient/users
	Off-label use, use in the paediatric population, or use of BLEPHADEMODEX instead of BLEPHACLEAN may lead to: Product ineffectiveness, infection (eyes and/or eyelids)
	7. Further information to help characterise the problem
	BLEPHADEMODEX is a sterile wipe, impregnated with a lotion for daily eyelid hygiene in case of Demodex infection, while BLEPHACLEAN is recommended for daily eyelid hygiene.
	8. Background on Issue
	During the preparation of the latest PSUR relating to our Class IIa medical device, BLEPHADEMODEX, covering the period from February 29, 2024 to February 28, 2026, we observed a significant and continuous increase in the frequency of reports related to incorrect use of BLEPHADEMODEX.
	9. Other information relevant to FSCA
	No additional information.

	3. Type of Action to mitigate the risk* *
3.	**Action To Be Taken by the User****
	☐ Identify device ☐ Retum Device ☐ Quarantine device
	☐ Destroy device
	☐ On-site device modification/inspection

	☐ Follow patient management recommendations ☐ Take note of amendment/reinforcement of Instructions For Use (IFU) ☒ Other ☐ None Ensure that BLEPHADEMODEX is used for daily eyelid hygiene in cases of Demodex infection, only and in adult patients	
3.	1. By when should the action be completed?	Not applicable
3.	2. Particular considerations for : Is follow-up of patients or review of patients' previous results recommended? **No** Provide further details of patient-level follow-up if required or a justification why none is required	
3.	3. **Is customer Reply Required? ***	**No**
3.	**4. Action Being Taken by the Manufacturer** ☐ **Product removal** ☐ **Modification/inspection du dispositif sur site** ☐ **Software upgrade** ☐ **IFU or labelling change** ☐ **Other** ☒ **None**	
3	5. **By when should the action be completed?**	NA
3.	6. **Is the FSN required to be communicated to the patient /lay user?**	**No**
3	7. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?	

	4. General Information*	
4.	1. FSN Type*	**New**
4.	2. For updated FSN, reference number and date of previous FSN	**None**
4.	**3.** For Updated FSN, key new information as follows:	
	None	
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:	
	No follow-up is expected	
4	6. Anticipated timescale for follow-up FSN	**None**
4.	**7.** Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	
	b. Address	
	c. Website address	
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	**None**
4.	10. Name/Signature	**Daniela Matiesanu** **Local Safety Officer** Digitally signed by MATIESANU DANIELA Date: 2026.06.22 17:45:06 +03'00'

	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.