Rev 1: September 2018

FSN Ref: CAPA2024-020 FSCA Ref: Irritated Eye Mist

Ref. Ares(2018)5836250 -

15/11/2018 Manufacturer's ref number

Date: 23:FEB:2024.

Urgent Field Safety Notice Device Commercial Name

For Attention of*:

Health Products Regulatory Authority
Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, IE - Dublin 2

Contact details of local representative (name, e-mail, telephone, address etc.)*
Kirrendeep Johal (Head of Compliance) Unit 1 Rothley Lodge Loughborough Road Rothley, Leicestershire LE7 7NL Office: 08081 643 076 Mob: 07498 319482

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Company Name/Logo

Manufacturer's ref number

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

1. Information on Affected Devices*

1.1. Device Type(s)*

Medical Device Type I MDD Non-Sterile (DOC Attached, Attachment 1)

1.2. Commercial name(s)

Vizulize Irritated Eye Mist
Pollenase Allergy Eye Mist

1.3. Unique Device Identifier(s) (UDI-DI)

5037154IRRITVT

1.4. Primary clinical purpose of device(s)*

The intended purpose of the product is to provide additional volume of isotonic solution to cleanse, moisturise and provide relief to uncomfortable eyes.

1.5. Device Model/Catalogue/part number(s)*

Part/Catalogue Number – IRRIT
Description/Name - Calendula and Hammamelis Formula

1.6. Software version

N/A

1.7. Affected serial or lot number range

Month	Quantity	Country (customer)	Product	B/N
Mar 23	600	Ireland (Pharmaher)	Vizulize Irritated Eye Mist	EM233783
Jun 23	360	Ireland (Pharmaher)	Pollenase Allergy Eye Mist	EM233920 EM233915

Additional sales through Boots have been sent to Ireland in addition to those listed above. Batches sent to boots are the following (unknown at this point which batch sent into Ireland from these batches);
EM223723 EM233777 EM233783 EM233821 EM233824 EM233851 EM233915 EM233941

1.	8. Associated devices
	Within context of the FSCA eg for IVD reagents and platforms. N/A

	2 Reason for Field Safety Corrective Action (FSCA)*
2.	1. Description of the product problem*
	A complaint was raised by (Sainsbury's) JS regarding EMP Allergy Eye Mist product batch EM233915 (manufactured in May 2023) whereby high microbial count was detected when performing surveillance testing on off the shelf products. JS report high yeast & mould counts of greater than 3 x103 cfu/g and high aerobic mesophilic counts of greater than 3 x103 cfu/g when testing Allergy Eye Mist batch EM233915, Exp Apr-26. Subsequent testing in February 2024 has more accurately quantified the yeast/mould count to be 4.7 x105 cfu/g and the aerobic mesophilic count to be 3.7 x107 cfu/g. Colony characterization has been performed which has identified Pandoraea norimbergensis, Pseudomonas fluorescens and Achromobacter spp.. These have both been identified as potential opportunistic pathogens, particularly in immunocompromised individuals, with the former linked to respiratory infections in patients with cystic fibrosis. Furthermore, testing by EM Pharma on retained samples has identified similar contamination on the same product manufactured around the same time (EM233920 and EM233941) with Pseudomonas species also confirmed present. The boundary at this point until further investigation can take place will be IRRTMIST batches manufactured from Jan 2023 to Dec 2023. Testing on other products manufactured on the same equipment around the same time has come back negative for contamination, showing that this problem is isolated to this product.
2.	2. Hazard giving rise to the FSCA*
	Independent Health Hazard Evaluation performed on the bacteria growth observed and has indicated that this incident will not cause Serious Adverse Health Consequences however there is a reason probability that this may cause medically reversible or transient adverse health Consequences. (Attachment 2).
2.	3. Probability of problem arising
	Sterile filling processes are highly manual, personnel within the sterile manufacturing (SM) area are trained and competent in all related processes. All sterile personnel are subject to environmental monitoring including contact plates and finger dabs as per validated processes. All equipment was operational as expected, all equipment used within the sterile manufacturing area is serviced and calibrated on a scheduled frequency. The cleanroom facility is subject to qualification on a 6-monthly basis as per ISO 14464. No deviations were reported from calibration or servicing performed at the time of the incident. All batches are subject to sterility and chemical assay and were all compliant upon release to market.
2.	4. Predicted risk to patient/users
	In decreasing order of likelihood – Eye infection (e.g., conjunctivitis), respiratory infection (e.g. pneumonia) or skin infection.
2.	5. Further information to help characterise the problem
	As of 24th Feb 2024, 1 complaint for adverse reaction for this product type has been logged and communicated to EMP.
2	6. Background on Issue

.	A complaint was raised by (Sainsbury's) JS regarding EMP Allergy Eye Mist product batch EM233915 (manufactured in May 2023) whereby high microbial count was detected when performing surveillance testing on off the shelf products. This then led EMP to investigate.
2	7. Other information relevant to FSCA
.	See Attachment 3

Manufacturer's ref number

	3. Type of Action to mitigate the risk*	
3.	**1. Action To Be Taken by the User*** ☐ Identify Device ☐ Quarantine Device X Return Device X Destroy Device ☐ On-site device modification/inspection ☐ Follow patient management recommendations ☐ Take note of amendment/reinforcement of Instructions For Use (IFU) ☐ Other ☐ None Provide further details of the action(s) identified.	
3.	2. By when should the action be completed?	asap
3.	3. Particular considerations for: Choose an item. Is follow-up of patients or review of patients' previous results recommended? N/A Provide further details of patient-level follow-up if required or a justification why none is required	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	No
3.	**5. Action Being Taken by the Manufacturer** X Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None Provide further details of the action(s) identified.	
3	6. By when should the action be completed?	Ongoing, all customers and relevent authorities are being notified. Feb 2024
3.	7. Is the FSN required to be communicated to the patient /lay user?	N/A All customers have already been notified.
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?	

	N/A notify end user just to be return or discarded any batches which has been detailed in recall letter.

Manufacturer's ref number

	4. General Information*	
4.	1. FSN Type*	Choose an item.
4.	2. For updated FSN, reference number and date of previous FSN	N/A
4.	**3.** For Updated FSN, key new information as follows:	
	N/A	
4.	4. Further advice or information already expected in follow-up FSN? *	N/A
4	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	N/A	
4	6. Anticipated timescale for followup FSN	For provision of updated advice.
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Only necessary if not evident on letter-head.
	b. Address	Only necessary if not evident on letter-head.
	c. Website address	Only necessary if not evident on letter-head.
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * Yes- MHRA	
4.	9. List of attachments/appendices:	If extensive consider providing web-link instead.
4.	10. Name/Signature	**Kirrendeep Johal** KJohal 24 Feb 2024

	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.