Rev 2: February 2020
FSN Ref: CO26271 FSCA Ref: CO26271

Date: 2023-12-20

Field Safety Notice
Viscopaste PB7

For Attention of*: All users of Viscopaste PB7

Contact details of local representative (name, e-mail, telephone, address etc.)*
Janine Davies, UK Clinical Sales & Marketing Manager – Wound and Skin Care Evolan Pharma, email: janine.davies@evolan.se, telephone: +44-(0)-7554 133321

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Field Safety Notice (FSN)
Viscopaste PB7
Incorrect content in Viscopaste PB7 boxes

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	Viscopaste PB7 is a paste bandage containing zinc oxide.
1.	2. Commercial name(s)*
	Viscopaste PB7
1.	3. Unique Device Identifier(s) (UDI-DI)
	-
1.	4. Primary clinical purpose of device(s)*
	Viscopaste PB7 is indicated to assist the management of venous leg ulcers. Viscopaste PB7 is also suitable for use in the management of chronic eczema/dermatitis.
1.	5. Device Model/Catalogue/part number(s)*
	4948
1.	6. Software version
	-
1.	7. Affected serial or lot number range
	D300381
1.	8. Associated devices
	-

2. Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	It has been identified that part of batch D300381 of the product Ichthopaste has been incorrectly packed in Viscopaste PB7 pre-printed folding boxes and distributed as Viscopaste PB7. The product inside the folding box, packed in a labelled pouch, is correctly labelled with Ichthopaste.
2.	2. Hazard giving rise to the FSCA*
	Due to the incorrect labelling on the folding box, there is a risk that Ichthopaste is used on a patient instead of Viscopaste PB7.
2.	3. Probability of problem arising
	-
2.	4. Predicted risk to patient/users
	-
2.	5. Further information to help characterise the problem
	-
2.	6. Background on Issue
	-
2.	7. Other information relevant to FSCA
	-

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 Identify and return devices of Viscopaste PB7 with batch number D300381.	
3.	2. By when should the action be completed?	2024-01-12
3.	3. Particular considerations for: - Is follow-up of patients or review of patients' previous results recommended? - -	
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 The concerned batch has been stopped for further distribution. Product returned from customers will be destroyed.	
3.	6. By when should the action be completed?	-
3.	7. Is the FSN required to be communicated to the patient /lay user?	Yes
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?	
	No	Not appended to this FSN

	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	-
4.	3. For Updated FSN, key new information as follows:	
	-	
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:	
	-	
4.	6. Anticipated timescale for follow-up FSN	-
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Evolan Pharma AB
	b. Address	Svärdvägen 19, 182 33 Danderyd, Sweden
	c. Website address	www.evolan.se
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	-
4.	10. Name/Signature	Ulrika Bernhardt QA/RA Medtech Manager, PRRC Evolan Pharma AB
		

	Transmission of this Field Safety Notice
	This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. 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.