Rev 2: February 2020

FSN Ref: FSN-CH-2022-01 FSCA Ref: FSCA-CH-2022-01

Date: 2022:07:13

Field Safety Notice
BENTRIO™

For Attention of*: Distributors of the Medical Device BENTRIO™

Contact details of local representative (name, e-mail, telephone, address etc.) *
Eric LOISEL, Qualified Person, Management Representative, Person Responsible for Regulatory Compliance
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France

Field Safety Notice (FSN)
BENTRIO™
Risk addressed by FSN

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	BENTRIO™ is a gel emulsion which is applied as a nasal spray for self-protection.
1.	2. Commercial name(s)*
	BENTRIO™
1.	3. Unique Device Identifier(s) (UDI-DI)
	NA
1.	4. Primary clinical purpose of device(s)*
	BENTRIO™ helps to: • Reduce the viral load and risk of infection from airborne viruses such as SARS-CoV-2, the cause of COVID-19; • Prevent the onset and alleviate allergic symptoms caused by airborne allergens such as pollen, house dust mites or animal dander.
1.	5. Device Model/Catalogue/part number(s)*
	NA
1.	6. Software version
	NA
1.	7. Affected serial or lot number range
	All batches.
1.	8. Associated devices
	NA

2. Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	Following the request of the French National Competent Authority (ANSM), the following indication for use: "*Reduce the viral load and risk of infection from airborne viruses such as SARS-CoV-2, the cause of COVID-19*" has been withdrawn. The ANSM considered that the clinical evidence was not sufficient regarding this indication.
2.	2. Hazard giving rise to the FSCA*
	According to the ANSM, this claim could lead, during the COVID-19 pandemic, some patients to neglect the application of barrier measures or to encourage them not to be vaccinated, even if it is stated in the instruction for use that "*BENTRIO™ is intended to be used together with standard preventive measures against viral infections such as personal hygiene or use of protective masks and is no substitute for antiviral vaccinations or medical treatment*". However, there is no safety issue arising from the use of this product and the other claims of this product regarding allergy remain valid.
2.	3. Probability of problem arising
	Very low given the low quantity of the product remaining on the market. No batches have been produced having this claim since April 2022. All advertising has been stopped regarding this claim. Moreover, it is clearly stated in the instruction for use that "*BENTRIO™ is intended to be used together with standard preventive measures against viral infections such as personal hygiene or use of protective masks and is no substitute*

	for antiviral vaccinations or medical treatment". However, there is no safety issue using the product and the other claims of this product remain valid.
2.	4. Predicted risk to patient/users
	The risk is to decrease the respect level of standard preventive barrier measures.
2.	5. Further information to help characterise the problem
	Post-production and vigilance data. No incident has been reported to the manufacturer.
2.	6. Background on Issue
	The withdraw of this claim is related to a technical documentation review from the ANSM.
2.	7. Other information relevant to FSCA
	NA

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 User: to be interpreted as all operators in the distribution chain	
3.	2. By when should the action be completed?	As soon as receiving this FSN- July 2022; BENTRIO™'s inventory was put into blocked status at the distributors as of the date of 30 June 2022.
3.	3. Particular considerations for: NA Choose an item. Is follow-up of patients or review of patients' previous results recommended? NA Choose an item. 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*** ☐ 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?	July 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? NA
	Choose an item. Choose an item.

4. General Information*		
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	NA
4.	3. For Updated FSN, key new information as follows:	
	NA	
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:	
	NA	
4.	6. Anticipated timescale for follow-up FSN	NA
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Laboratoires CHEMINEAU
	b. Address	93 Route de Monnaie, 37210, VOUVRAY, France
	c. Website address	https://chemineau-anjac.com/
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * Yes	
4.	9. List of attachments/appendices:	NA
4.	10. Name/Signature	Eric LOISEL Qualified Person, Management Representative, Person Responsible for Regulatory Compliance

	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.