Borgundveien 340

NO-6009 Aalesund

NORWAY

Urgent Field Safety Notice

Viiral Nose Spray

For Attention of Swedish Distributors

Contact details of local representative:
Avia Pharma, Svärdvägen 3B, 182 33 Danderyd, Sweden, Avia@srs.se

Company Name/ Logo

viiral®

Urgent Field Safety Notice (FSN)

Viiral Nasal Spray

Risk addressed by FSN

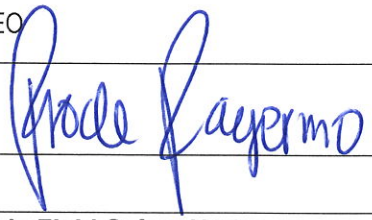
	1. Information on Affected Devices*
1.	1. Device Type(s)*
	Viiral Nasal Spray
1.	2. Commercial name(s)
	Viiral Nasal Spray
1.	3. Primary clinical purpose of device(s)*
	Viiral Nasal Spray is a non-invasive device used for prevention of common colds and for dry mucous membrane.

	2 Reason for Field Safety Corrective Action (FSCA)*
2.	1. Description of the product problem*
	Clinical effect is not formally documented during re-assessment of clinical data for support of intended use for CE-marking
2.	2. Hazard giving rise to the FSCA*
	The greatest hazard from using the product is lack of efficacy in preventing common colds – the safety profile of the substances is such that there is no risk connected to using the product. The product is withdrawn from the market until clinical evidence of effect has been re-assessed and formally documented.
2.	3. Background on Issue
	A change in clinical background data.
2.	4. Other information relevant to FSCA
	The safety profile is such that the use of the product poses no risk to the patient.

	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 in this case is the Swedish distributor and the pharmacies. Due to the safety profile of the product we suggest no action to the users that already have the product.	
3.	2. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes
3.	**3. Action Being Taken by the Manufacturer** ☒ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None	
3	4. By when should the action be completed?	February 28, 2020
3.	5. Is the FSN required to be communicated to the patient /lay user?	No

	4. General Information*	
4.	1. FSN Type*	New
4.	2. Further advice or information already expected in follow-up FSN? *	No
4.	3. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Viiral AS
	b. Address	Borgundveien 340, Alesund, Norway
	c. Website address	Viiral.no
4.	4. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	5. List of attachments/appendices:	**FSN response temlate**

4.	6. Name/Signature	Frode Fagermo CEO 

	Transmission of this Field Safety Notice
	Please transfer this notice to other organisations on which this action has an impact. (As appropriate) 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..*