Date: 06/10/2022

Field Safety Notice
Hyalubrix 30 mg/2 mL, acido ialuronico sale sodico 1,5%, soluzione per iniezione intrarticolare

For Attention of*: Client/Healthcare professional

Contact details of local representative (name, e-mail, telephone, address etc.)*
Fidia farmaceutici S.p.A., Via Ponte della Fabbrica 3/A, 35031, Abano Terme (PD), Italy tel +39 049 823 2111; fax +39 049 823 2398; mail: phv@fidiapharma.it; PEC: affariregolatori@pec.fidiapharmapec.it

URGENT FIELD SAFETY NOTICE
URGENTE AVVISO DI SICUREZZA

Dear Customer,
as manufacturer of the medical device subject to this safety notice, please, take note of the information reported and give us your feed-back, promptly.

Spett.le Cliente,
in qualità di fabbricante del dispositivo medico oggetto di questo avviso, si prega di prendere in considerazione quanto riportato e di fornirci riscontro tempestivamente.

Fidia farmaceutici S.p.A. Via Ponte della Fabbrica 3/A, 35031 Abano Terme (PD) Italia - T +39 049 8232111 - F +39 049 810653 - info@fidiapharma.it PEC DL@pec.fidiapharmapec.it - www.fidiapharma.com - Iscr. Reg. Imp. PD - CF/P.IVA 00204260285 - Codice Destinatario: **SN4CSRI** - Cap.Soc. € 36.120.000 int. vers. CCIAA PD n. 80793

Field Safety Notice (FSN)
Hyalubrix 30 mg/2 mL, acido ialuronico sale sodico 1,5%, soluzione per iniezione intrarticolare

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	HYALUBRIX è una soluzione viscoelastica sterile prodotta con acido ialuronico sale sodico ottenuto per fermentazione batterica da una frazione ad alto peso molecolare. Il dispositivo è fornito in una siringa pre-riempita da 30 mg/2 ml, sigillata in un blister. Il contenuto della siringa viene sterilizzato con calore umido.// HYALUBRIX is a sterile, viscoelastic solution, manufactured with hyaluronic acid sodium salt obtained by bacterial fermentation from a fraction of high molecular weight. The device is provided as a 30mg/2ml pre-filled syringe sealed in a blister. The content of the syringe is sterilized using moist-heat.
1.	2. Commercial name(s)*
	HYALUBRIX
1.	3. Unique Device Identifier(s) (UDI-DI)
	Complete when this becomes available.
1.	4. Primary clinical purpose of device(s)*
	HYALUBRIX è indicato per il trattamento del dolore e il miglioramento della funzionalità articolare in pazienti affetti da artropatia degenerativa o meccanica del ginocchio, dell'anca, della spalla, della caviglia e dell'articolazione trapezio-metacarpale. Il prodotto è indicato nel trattamento del dolore persistente dopo iniziale fallimento degli analgesici o in caso di fallimento o intolleranza ai farmaci antinfiammatori non steroidei. // HYALUBRIX is indicated for the treatment of pain and the improvement of joint functionality in patients affected by degenerative or mechanical arthropathy of the knee, hip, shoulder, ankle and trapezio-metacarpal joint. The product is indicated in the treatment of persistent pain after initial failure of analgesics or in case of failure or intolerance to non-steroidal anti-inflammatory drugs.
1.	5. Device Model/Catalogue/part number(s)*
	Device model: EQ47-01-1C (HYALUBRIX 30mg/2mL, 1 siringa preriempita – ster. Vapore - HYALUBRIX 30mg/2mL, 1 prefilled syringe – moist-heat ster.) /// Internal codes: 10000825 - 10000950 – 10000952 - 11000236
1.	6. Software version
	N.A.
1.	7. Affected serial or lot number range
	F12150; F12160; F16670; F19180; F20960; F21680; F22110; F12010
1.	8. Associated devices
	N.A.

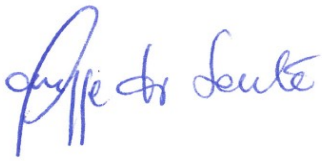
2. Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	Dal monitoraggio della sicurezza del prodotto sul mercato, abbiamo ricevuto un numero di segnalazioni di effetti indesiderati superiore a quello precedentemente osservato (vedi Trend Report inviato in data 3/10/2022). Tali effetti indesiderati sono prevalentemente rappresentati da dolore e gonfiore a livello dell'articolazione del ginocchio oggetto del trattamento per

	infiltrazione intra-articolare con intensità clinica variabile e comunque tutti definiti non seri sulla base delle informazioni raccolte. Inoltre,gli effetti indesiderati riportati sono noti per le iniezioni intrarticolari di acido ialuronico e sono descritti nel foglietto illustrativo di Hyalubrix.// From monitoring the safety of the product on the market, we have received more reports of undesirable effects than previously observed (see Trend Report sent on 03/10/2022). These undesirable effects are mainly represented by pain and swelling at the level of the knee joint subject to treatment for intra-articular infiltration with variable clinical intensity and, in any case, all defined as not serious events on the basis of the information collected. In addition, side effects are known for hyaluronic acid intra-articular injections and are already described in the Hyalubrix package insert.
2.	2. Hazard giving rise to the FSCA*
	In via cautelativa per preservare la sicurezza del paziente. // As a precaution to preserve patient safety.
2.	3. Probability of problem arising
	Provide an indication (from incident data or prospective modelling) of the likelihood the problem will arise.
2.	4. Predicted risk to patient/users
	From the output of the Health Hazard Evaluation indicate the anticipated risk (product of severity x probability) of patient/end user harm (direct or indirect).
2.	5. Further information to help characterise the problem
	Include any further relevant statistics to help convey the seriousness of the issue.
2.	6. Background on Issue
	Eg how the manufacturer became aware; brief details of relevant incidents; root cause if known; rationale for containment of problem to only affected devices; other risk mitigation or longer-term preventative action etc.
2.	7. Other information relevant to FSCA
	Paesi coinvolti nel recall//Countries involved in the recall: DE, IT, HR, GR, PL

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 Provide further details of the action(s) identified.	
3.	2. By when should the action be completed?	Al momento dell'identificazione del prodotto/ As soon as the device identification

3.	3. Particular considerations for: Implantable device Is follow-up of patients or review of patients' previous results recommended? Yes Follow the outcome of the undesirable effects	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes (7 October 2022)
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?	Specify where critical to patient/end user safety.
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?	
	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	Provide reference and date of previous FSN if relevant.
4.	3. For Updated FSN, key new information as follows:	
	Summarise any key difference in devices affected and/or action to be taken.	
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:	
	Eg patient management, device modifications etc.	
4.	6. Anticipated timescale for follow-up 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	Fidia farmaceutici S.p.A
	b. Address	Via Ponte della Fabbrica 3/A, 35031, Abano Terme (PD),
	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	

4.	9. List of attachments/appendices:	If extensive consider providing web-link instead.
4.	10. Name/Signature	Giuseppe di Sante, MD Head, Safety Surveillance Unit
		

	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.