RAPID ALERT NOTIFICATION OF A QUALITY DEFECT / RECALL

IMPORTANT -- DELIVER IMMEDIATELY

	Reference Number: **42/2023**
(add letter head of sender):	
1. To: (see list attached, if more than one)	
2. Product Recall Clas of Defect: (I) II	3. Falsification / Fraud (specify):
4. Product: **LIPOVON capsules, dietary supplements.**	5. Marketing Authorisation number: **N/A** For use in **humans** / animals (Select as required):
6. Brand / Trade name: **LIPOVON**	7. INN o generic name: **N/A**
8. Dosage form: **Capsules**	9. Strength: **N/A**
10. Batch number (and bulk , if different): **All batch number**	11. Expiry date: **All expiry dates**
12. Pack size and Presentation: **Bottle with 30 capsules**	13. Date manufactured: **N/A**
14. Marketing Authorisation holder: **N/A**	
15. Manufacturer: **LIPOVON LTD. Mexico** Contact person: Telephone:	16. Recalling firm (if different) Contact person: Telephone:
17. Recall number assigned (if available):	
18. Details of defect / Reason for recall: **The product is labeled as a dietary supplement; however, the analysis conducted by international agencies has identified the presence of Sibutramine, a substance banned since 2010; on the other hand, the Hoodia Gordonii and Garcinia cambogia was not allowed by this Cofepris for use in the formulation of dietary supplements.**	
19. Information on distribution including exports (type of costumers, e.g. hospitals): **Unknown information**	
20. Action taken by issuing Authority: **Sanitary Alert Published on the Cofepris website and notify to the Federal System for the intentional search.**	
21. Proposed action:	
22. From (issuing Authority): **Federal Commission for the Protection Against Sanitary Risk Comission of Evidence and Risk Management**	23. Contact person: **alertas@cofepris.gob.mx** Telephone: **+52 55 5080 5200 ext. 11257**
24. Signed	25. Date: **06/12/2023** / 26. Time: **14:10**

LINK https://www.gob.mx/cms/uploads/attachment/file/873625/Alertas_Sanitarias_Lipovon_29112023.pdf

MINISTERIO DE SANIDAD

agencia española de medicamentos y productos sanitarios

IMPORTANT DELIVER IMMEDIATELY

Rapid Alert Notification of a Quality Defect / Recall

	Reference Number : Quality Defect Alert VDC 1/2022

QUALITY DEFECT RAPID ALERT	
1. To: Quality defect rapid alert contacts(see list attached, if more than one)	
2. Product Recall Class of Defect: (circle one): **TYPE I**	3. Counterfeit / Fraud (specify)*
4. Product: **Veterinary Medicinal Products**	5. Marketing Authorisation Numbers: 3145 ESP For use in animals
6. Brand/Trade Name: **MILOXAN**	7. INN or Generic Name: *Clostridium perfringens type B, Clostridium perfringens type D, Clostridium septicum, Clostridium novyi type B, Clostridium tetani, Clostridium sordelii, Clostridium chauvoei (inactivated)*
8. Dosage Form: **Injectable suspension**	9. Strength:
10. Batch number (and bulk, if different): **L496957, D87447 y E42127 (content 50 ml) and E43535, E43536, L498023, E03412 y L498020 (content 250 ml)**	11. Expiry Date: 2024
14. Marketing Authorisation Holder: BOEHRINGER INGELHEIM ANIMAL HEALTH c/ Prat de la Riba Sant Cugat del Vallés (Barcelona)- Spain Contact person: **E-mail:** marta.dalmases@boehringer-ingelheim.com	
15. Manufacturer: CZ Vaccines S.A.U. La Relva s/n Porriño (Pontevedra)	16. Recalling Firm (if different):
18. Details of Defect/Reason for Recall: The AEMPS was informed by the MAH that a quality defect regarding to an out of specifications on the antigen *Clostridium novyi*. Therefore, the MAH proposed a recall of all the batches affected. Other affected batches have been released in PT, AT, FR, SE, IT	
20. Action taken by Issuing Authority: **Approved recall by MAH to veterinarian level.**	
21. Proposed Action: **Approved recall by MAH to veterinarian level.**	

22. From (Issuing Authority): **AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS, AEMPS.**	23. Contact Person: **Ramiro Casimiro** **Telephone: 34 918225433** **Email: rcasimiro@aemps.es**

24. Signed:	25. Date:20 **December 2022**	26. Time: *

RAPID ALERT NOTIFICATION OF A QUALITY DEFECT/RECALL
IMPORTANT – DELIVER IMMEDIATELY

	Reference Number
[add letter head of sender]	
1. To: (see list attached, if more than one)	
2. Product Recall Class of Defect: (I) II (circle one) Not yet classified, potential class	3. Falsification / Fraud (specify)*
4. Product: ADVANCED GLUCOSE SUPPORT Dietary Supplement Capsules	5. Marketing Authorisation Number: * For use in humans
6. Brand/Trade Name: Dr. Ergin's SugarMD, ADVANCED GLUCOSE SUPPORT	7. INN or Generic Name:
8. Dosage Form: N/A	9. Strength: N/A
10. Batch number (and bulk, if different): LOT#22165-003	11. Expiry Date: N/A
12. Pack size and Presentation: 60,120 & 180-count bottles	13. Date Manufactured: N/A
14. Marketing Authorisation Holder*: N/A	
15.	16. Recalling Firm (if different): SUGARMDS LLC 11470 Schenk Dr Maryland Heights, MO, 63043-3417
15.2 Where the defect is attributed to a manufacturing site, site where defect occurred (if different from 15.1):	
17. Recall Number Assigned (if available): RES 93394	
18. Details of Defect/Reason for Recall: Marketed Without an Approved NDA/ANDA- FDA analysis has found the product to be tainted with glyburide and metformin.	
19. Information on distribution including exports (type of customer, e.g., hospitals): Nationwide and online websites.	
20. Action taken by Issuing Authority: FDA issued a Consumer Health Warning on its website (11.3.2023). Firm issued press (11.8.2023) Recall was initiated or 11.13.2023.	
21. Proposed Action: U.S. Food and Drug Administration is monitoring this recall.	

22. From (Issuing Authority): U.S. Food and Drug Administration		23. Contact Person: Telephone: 301-796-3323
24. Signed: C. Howard	25. Date: 11/28/2023	26. Time: 0900

* Information not required, when notified from outside EU.

REPUBLIC OF BULGARIA
MINISTRY OF AGRICULTURE AND FOOD
BULGARIAN FOOD SAFETY AGENCY

IMPORTANT DELIVER IMMEDIATELY

Rapid Alert Notification of a Quality Defect / Recall

	Reference Number : Quality Defect Alert BG/I/02/23

QUALITY DEFECT RAPID ALERT	
1. To: Quality defect rapid alert contacts(see list attached, if more than one)	
2. Product Recall Class of Defect: (circle one): **TYPE I**	3. Counterfeit / Fraud (specify)*
4. Product: **Veterinary Medicinal Products**	5. Marketing Authorisation Numbers: 0022-1649 For use in animals
6. Brand/Trade Name: **OXYTETRACYCLIN hydrochloride-NGP 22/ 1,020 g comprettae spumescentes**	7. INN or Generic Name:
8. Dosage Form: **intrauterine tablet**	9. Strength:
10. Batch number (and bulk, if different): **22-010123**	11. Expiry Date: 01/2025
14. Marketing Authorisation Holder: **NGP Pharm EOOD** 10 Hadji Angel Str., 5400, Sevlievo, Republic of Bulgaria Contact person:	
15. Manufacturer: **SEVEREN VETERINAREN DILAR-SVD" OOD,** 10 Hadji Angel Str., 5400, Sevlievo, Republic of Bulgaria	16. Recalling Firm (if different):
18. Details of Defect/Reason for Recall: After routine sampling major inconsistencies have been identified relating to the text on the batch product labelling (e.g. withdrawal period and target species).	
20. Action taken by Issuing Authority: **Order for recall of the affected batch to vet. level.**	
21. Proposed Action: **No batch distribution outside of Bulgaria.**	
22. From (Issuing Authority): BULGARIAN FOOD SAFETY AGENCY	23. Contact Person: **Miroslav Georgiev** **Telephone:** **Email: mg_georgiev@bfsa.bg**
24. Signed:	25. Date: 29 November 2023 / 26. Time: * UB

RAPID ALERT NOTIFICATION OF A QUALITY DEFECT/RECALL
IMPORTANT – DELIVER IMMEDIATELY

	Reference Number
[add letter head of sender]	
1. To: (see list attached, if more than one)	
2. Product Recall Class of Defect: (I) II (circle one) Not yet classified, potential class	3. Falsification / Fraud (specify)*
4. Product: Dietary supplements	5. Marketing Authorisation Number: * For use in humans
6. Brand/Trade Name: Kuka Flex Forte, Reumo Flex (caplets), and Artri King (tablets)	7. INN or Generic Name: N/A
8. Dosage Form: Caplets and Tablets	9. Strength: N/A
10. Batch number (and bulk, if different): All batches	11. Expiry Date: all
12. Pack size and Presentation: Artri king in the bottles with 100 tablets. Kuka Flex in the bottles with 30 caplets. Reumo flex in the boxes with 30 caplets.	13. Date Manufactured: *
14. Marketing Authorisation Holder*: N/A	
15. 1 Manufacturer: Contact Person: Telephone:	16. Recalling Firm (if different): Botanical-Be Telephone: (915) 412-6237 or by e-mail at botanical.be@gmail.com
15.2 Where the defect is attributed to a manufacturing site, site where defect occurred (if different from 15.1): Contact Person: Telephone:	
17. Recall Number Assigned (if available): 93257	
18. Details of Defect/Reason for Recall: Due to the Presence of Undeclared Diclofenac.	
19. Information on distribution including exports (type of customer, e.g. hospitals): These products were distributed nationwide via the internet.	
20. Action taken by Issuing Authority: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/botanical-be-issues-voluntary-nationwide-recall-kuka-flex-forte-reumo-flex-caplets-and-artri-king#:~:text=of%20Undeclared%20Diclofenac-,Botanical%2DBe%20Issues%20Voluntary%20Nationwide%20Recall%20of%20Kuka%20Flex%20Forte,announcement%20as%20a%20public%20service.	
21. Proposed Action: U.S. Food and Drug Administration is monitoring this recall.	

22. From (Issuing Authority): U.S. Food and Drug Administration		23. Contact Person: Telephone: 301-796-3130
24. Signed: Beatriz Caceres-gentile -S Digitally signed by Beatriz Caceres-gentile -S Date: 2023.11.28 09:25:57 -05'00'	25. Date:	26. Time: *

* Information not required, when notified from outside EU.

MINISTERIO DE SANIDAD

agencia española de medicamentos y productos sanitarios

IMPORTANT DELIVER IMMEDIATELY

Rapid Alert Notification of a Quality Defect / Recall

	Reference Number : Quality Defect Alert VDC 3/2023

QUALITY DEFECT RAPID ALERT	
1. To: Quality defect rapid alert contacts(see list attached, if more than one)	
2. Product Recall Class of Defect: (circle one): **TYPE II**	3. ~~Counterfeit / Fraud~~ (specify)* For use in animals
4. Product: **FISIOVET solución para perfusión**	5. Marketing Authorisation Numbers: 1162 ESP.
6. Brand/Trade Name: **FISIOVET solución para perfusión**	7. INN or Generic Name: *Sodium chloride*
8. Dosage Form: **Solution for infusion**	9. Strength: 0.9 g Sodium Chloride per 100 ml
10. Batch number (and bulk, if different): **Batch 21244402**	11. Expiry Date: 31.05.2024
14. Marketing Authorisation Holder: B.BRAUN VETCARE Ctra. Terrasa 121 Rubí (Barcelona) - 08191 Spain Contact person: **E-mail:** montserrat.sabate@bbraun.com	
15. Manufacturer: B. BRAUN MEDICAL S.A. Ctra Terrasa 121 Rubi (Barcelona) - 08191 Spain	16. Recalling Firm (if different):

18. Details of Defect/Reason for Recall:

The AEMPS was informed by the Marketing Authorisation Holder of a quality defect regarding a contamination during the final sterilisation process by autoclaving.

Detection of cross-contamination with traces of Midazolam in several batches of solutions for infusion manufactured by B. BRAUN MEDICAL, S.A. - Ctra. de Terrassa, 121., Rubi (Barcelona), 08191, Spain.

The cross-contamination has been detected between medicinal products terminally sterilized in the same autoclave. The root cause is the migration of API (in traces) through polyethylene containers, to the water of the autoclave, and ingression of the API in subsequent batches processed in the same autoclave.

B. Braun Medical has analysed potentially affected batches of Sodium Chloride 9 mg/ml solution and Glucose 5% solution. However, other medicinal products have not been possible to analyse due to the lack of a reliable method of analysis by the type of matrix. The company has estimated it if they can be affected.

All batches not expired yet that show a Midazolam concentration higher than PDE (Permitted Daily Exposure) of 2 µg./day confirmed by analysis and also batches of solutions for which no analysis is possible and where the company has estimated that can be affected, are included in this recall as a precautionary measure (please see attached annex).

The investigation is ongoing.
Information will be updated if necessary.

UB Держпродспожинслужба
№11.2.3-15/26869 від 21.12.2023

DRINGEND - BITTE SOFORT AUSLIEFERN! IMPORTANT - DELIVER IMMEDIATELY!

Rapid Alert Notification of a Quality Defect ± Recall

Sender: Regierungspräsidium Darmstadt V 54 64278 Darmstadt	HESSEN	**1. Reference no.:**	**DE_HE_04 / II / 2023 / 1 / 1**
		2. Recall no. assigned:	**DE_HE_04 / II / 2023 / 1 / 1**

3. To: ☐ BfArM ☐ BVL ☐ PEI ☐ OLGB ☒ OLVET

4. Files attached? yes — Productlist giving details to 15-17

5. For use in	**6a. Class of defect**	**7. Reason**
veterinary	**6b. Product recall?** yes	quality defect

I.	**8. Product**	**9. Strength**	**10. INN or Generic name**	**11. Pack size and presentation**
	Italy: Sodio cloruro 0,9 g/100 ml B. Braun Vet Care, soluzione per infusione per bovini, cavalli, pecore, capre, suini, cani e gatti;	0,9%	Sodium Chloride 0.9 g/100 ml B. Braun Vet Care solution for infusion for cattle, horse, sheep, goat, pig, dog and cat	20 x 100 ml, Ecoflac plus bottle

12. Brand/Trade name	**13. Dosage form**	**14. Marketing authorisation number**
See No. 8	<please choose> Solution for infusion	Italy: 104785011

15. Batch number(s) and bulk (if different)	**16. Date(s) manufactured**	**17. Expiry date(s)**
Italy: 21244401	17.06.2021	31.05.2024

18. Marketing authorisation holder		**19. Manufacturer**	
Name	B. Braun Melsungen AG	**Name**	B. Braun Medical, S.A.
Address	Carl-Braun-Str. 1, 34212 Melsungen, Germany	**Address**	Carretera de Terrassa 121, Rubi, Spain
E-mail	pharmacovigilance@bbraun.com	**E-mail**	anna.jimenez@bbraun.com
Phone	+495661715050	**Phone**	+34608876819

20. Recalling firm (if different)	**21. Site where the defect occurred** (where the defect is attributed to a manufacturing site and if different from 19)
Name	**Name**
Address	**Address**
E-mail	**E-mail**
Phone	**Phone**

22. Details of the defect/reason for the recall

Cross-contamination of Sodium Chloride 0.9 g/100 ml B. Braun Vet Care solution for infusion for cattle, horse, sheep, goat, pig, dog and cat with Midazolam. Traces of Midazolam in autoclave water from previously sterilised Midazolam batch may migrate into the veterinary medicinal products through the containers during the sterilisation process (autoclaving).

23. Information on distribution including exports (type of customer, including parallel distribution/importation)

24. Action taken by the issuing authority	**25. Proposed action**
Supervision of batch recall	Batch recall

26. Issuing authority

From (issuing authority)	Regierungspräsidium Darmstadt V 54 64278 Darmstadt	**Phone**	+49 6151 12 5071
Contact person	Dr. Thomas Reinle	**E-mail**	thomas.reinle@rpda.hessen.de
Signature			

27. Date/Time 26-07-2023, 15:00

Article No.	INN/generic name	Local Tradename	Strength	Dosage form	Pack Size	Registration Number	Marketing Authorization Holder	Country of Authorisation	Countries of	Batch	Manufacturing Date	Expiry Date	Release Date	Date of first delivery	Date of last delivery	Release Units
3574290	Sodium chloride	Sodio cloruro 0,9 g/100 ml	9mg/ml	Solution for infusion	100ml Ecoflac plus	104785011	B.Braun Melsungen AG	Italy (Veterinary)	IT	21244401	17.06.2021	31.05.2024	07.07.2021	15.07.2021	21.10.2021	4412
472777	Sodium chloride	FisioVet Solución Para Per	9mg/ml	Solution for infusion	100ml Ecoflac plus	1162 ESP	B.Braun Vetcare S.A.	Spain (Veterinary)	ES	21244402	17.06.2021	31.05.2024	08.07.2021	16.08.2021	08.11.2021	4440