ДЕРЖАВНА СЛУЖБА УКРАЇНИ З ЛІКАРСЬКИХ ЗАСОБІВ ТА КОНТРОЛЮ ЗА НАРКОТИКАМИ
(Держлікслужба)

проспект Берестейський, 120-А, м. Київ, 03115, тел/факс: (044) 422-55-77, e-mail: dls@dls.gov.ua,
https://www.dls.gov.ua Код ЄДРПОУ 40517815

_____ № _____ На № _____ від _____

Державна служба України з питань безпечності харчових продуктів та захисту споживачів

На виконання пункту 2.1. Меморандуму про партнерство та співробітництво між Державною службою з лікарських засобів та контролю за наркотиками та Державною службою України з питань безпечності харчових продуктів та захисту споживачів від 14.10.2022 року та з метою інформування та протидії поширенню неякісних препаратів, в тому числі ветеринарних препаратів, дієтичних добавок надаємо копії повідомлень, які надійшли до Держлікслужби в рамках міжнародної взаємодії та обміну інформацією:

№ п/п	Назва регуляторного органу, що надіслав термінове повідомлення	Назва препарату	Виробник/ Заявник	Неякісний або фальсифікат
1.	U.S. Food and Drug Administration, (FDA)	Vitality capsules	One Source Nutrition, Inc., U.S.A.	Препарат продається як дієтична добавка але містить незадекларовані фармацевтичні інгредієнти (силденафіл і тадалафіл).

Додаток: на 1 арк.

Голова **Роман ІСАЄНКО**

Марина ОПАНАСЕНКО
044 422-55-75

IMPORTANT – DELIVER IMMEDIATELY
Rapid Alert Notification of a Quality Defect / Recall

		Reference Number
[add letter head of sender]		
1. To: (see list attached, if more than one)		
2. Product Recall Class of Defect: I		3. Falsification / Fraud (specify)
4. Product: Vitality	5. Marketing Authorisation Number: For use in humans	
6. Brand/Trade Name: Vitality	7. INN or Generic Name: n/a	
8. Dosage Form: Capsules	9. Strength: n/a	
10. Batch number (and bulk, if different): n/a	11. Expiry Date: n/a	
12. Pack size and Presentations: 6-count bottles and individual packets containing 1 capsule.	13. Date Manufactured: n/a	
14. Marketing Authorisation Holder: N/A		
15. Manufacturer†: Contact Person: Telephone:	16. Recalling Firm (if different): One Source Nutrition, Inc, 19723 Interstate 30 S, Benton, AR 72015-8024 Telephone: 501-690-4894 Contact Person: Steven Pate	
17. Recall Number Assigned (if available): Recall not yet classified		
18. Details of Defect/Reason for Recall: Marketed without an approved NDA/ANDA: FDA analysis found the product to be tainted with sildenafil and tadalafil, which are ingredients in FDA approved products for treatment of male erectile dysfunction in the family of drugs known as phosphodiesterase (PDE-5) inhibitors. Products containing sildenafil and tadalafil cannot be marketed as dietary supplements.		
19. Information on distribution including exports (type of customer, e.g. hospitals): Nationwide in the USA.		
20. Action taken by Issuing Authority: Firm issued press notification on 02/20/2025 and issued an updated press on 03/03/2025. Firm issued letters on 02/27/2025.		
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: CDER Recalls Telephone: 301-796-3130
24. Signed:	25. Date: 03/05/2025	26. Time:

* Information not required, when notified from outside EU.

† The holder of an authorisation referred to under Article 40 of Directive 2001/83/EC or Article 44 of Directive 2001/82/EC and the holder of the authorisation on behalf of whom the Qualified Person has certified the batch for release in accordance with Article 51 of Directive 2001/83/EC or Article 55 of Directive 2001/82/EC if different.

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№ п/п	Назва регуляторного органу, що надіслав термінове повідомлення	Назва препарату/	Виробник/ Заявник	Неякісний або фальсифікат
1.	U.S. Food and Drug Administration	Lactated Ringers Injection, for animal use only, 5000 mL	Nova-Tech Inc., U.S.A.	Виявлено сторонні часточки в ін'єкційному продукті

Додаток: на 2 арк.

Голова **Роман ІСАЄНКО**

Марина ОПАНАСЕНКО
044 422-55-75

APPENDIX 2

RAPID ALERT NOTIFICATION OF A QUALITY DEFECT / RECALL

IMPORTANT -- DELIVER IMMEDIATELY

Reference Number	RES 96413
1. To: (see list attached, if more than one)	PIC/S members via US FDA Liaison
2. Product Recall Class of Defect: I ☒ II ☐ (circle one)	Class I Recall
3. Falsification / Fraud (specify)*	n/a
4. Product:	Lactated Ringers Injection, For Animal Use Only, 5000 mL
5. Marketing Authorisation Number: * For use in humans/animals (delete as required)	
6. Brand/Trade Name:	
7. INN or Generic Name:	n/a
8. Dosage Form:	Injectable
9. Strength:	5000 mL
10. Batch number (and bulk, if different):	
11. Expiry Date:	NOV 2026
12. Pack size and Presentation:	5-Liter
13. Date Manufactured: *	TBD
14. Marketing Authorisation Holder*:	Nova-Tech Inc. distributes this unapproved product
15. 1 Manufacturer:	Nova-Tech Inc.
Contact Person:	Teresa Grabowski
Telephone:	+1 (308) 381-8841
16. Recalling Firm (if different):	
15.2 Where the defect is attributed to a manufacturing site, site where defect occurred (if different from 15.1):	
Contact Person:	n/a
Telephone:	n/a
Contact Person:	n/a
Telephone:	n/a
17. Recall Number Assigned (if available)÷	RES 96413
18. Details of Defect/Reason for Recall:	Particulate in injectable product
19. Information on distribution including exports (type of customer, e.g. hospitals): *	
20. Action taken by Issuing Authority:	A class I recall has been initiated.
21. Proposed Action:	U.S. FDA is monitoring this recall. Product was distributed in USA only.

22. From (Issuing Authority):		23. Contact Person: Ruth Yowell
U.S. Food and Drug Administration		Telephone: +1(240) 402-5620
24. Signed:	25. Date: Mar 3, 2025	26. Time: *

* Information not required, when notified from outside EU.

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ДЕРЖАВНА СЛУЖБА УКРАЇНИ З ЛІКАРСЬКИХ ЗАСОБІВ ТА КОНТРОЛЮ ЗА НАРКОТИКАМИ
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На виконання пункту 2.1. Меморандуму про партнерство та співробітництво між Державною службою з лікарських засобів та контролю за наркотиками та Державною службою України з питань безпечності харчових продуктів та захисту споживачів від 14.10.2022 року та з метою інформування та протидії поширенню неякісних препаратів, в тому числі ветеринарних препаратів, дієтичних добавок надаємо копії повідомлень, які надійшли до Держлікслужби в рамках міжнародної взаємодії та обміну інформацією:

№ п/п	Назва регуляторного органу, що надіслав термінове повідомлення	Назва препарату/	Виробник/ Заявник	Неякісний або фальсифікат
1.	AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS, AEMPS.	REVOZYN 400mg/ml suspension inyectable para bovino	Eurovet Animal Health B.V., Netherland	Невідповідність специфікації за показником на ресуспендованість під час дослідження стабільності

Додаток: на 2 арк.

Голова **Роман ІСАЄНКО**

Марина ОПАНАСЕНКО
044 422-55-75

IMPORTANT DELIVER IMMEDIATELY

Rapid Alert Notification of a Quality Defect / Recall

Reference Number : Quality Defect Alert VDC 3/2025

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)*
4. Product: **REVOZYN 400 MG/ML SUSPENSION INYECTABLE PARA BOVINO**	5. Marketing Authorisation Numbers: 3625 ESP For use in animals
6. Brand/Trade Name: **REVOZYN 400 MG/ML SUSPENSION INYECTABLE PARA BOVINO**	7. INN or Generic Name: penetamate iodhydrate
8. Dosage Form: **Injectable suspension**	9. Strength: 308.8 mg penethamate equivalent to 400 mg of penethamate iodhydrate
10. Batch number (and bulk, if different): **23F274** **24B191** **24F053**	11. Expiry Date: May 26 Jan 26 Jun 25
14. Marketing Authorisation Holder: VIRBAC EUROVET ANIMAL HEALTH B.V. Handelsweg, 25 Bladel. Noord-Brabant, Netherlands Contact person (Spain): **E-mail: Carin.deLaat@dechra.com**	
15. Manufacturer: EUROVET ANIMAL HEALTH B.V.	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 to an out-of-specification result in the resuspendability test during a stability study.	

20. Action taken by Issuing Authority: **Approved recall by MAH to veterinarian level.**		
21. Proposed Action: **Approved recall by MAH to wholesaler 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: 27 February 2025	26. Time: *

ДЕРЖАВНА СЛУЖБА УКРАЇНИ З ЛІКАРСЬКИХ ЗАСОБІВ ТА КОНТРОЛЮ ЗА НАРКОТИКАМИ
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Державна служба України з питань безпечності харчових продуктів та захисту споживачів

У доповнення до листа Держлікслужби від 06.02.2025 № 1576-1.1/2.4/17-25 щодо ветеринарного лікарського засобу Cylanic та на виконання пункту 2.1. Меморандуму про партнерство та співробітництво між Державною службою з лікарських засобів та контролю за наркотиками та Державною службою України з питань безпечності харчових продуктів та захисту споживачів від 14.10.2022 року та з метою інформування та протидії поширенню неякісних препаратів, в тому числі ветеринарних препаратів, дієтичних добавок надаємо копії повідомлень, які надійшли до Держлікслужби в рамках міжнародної взаємодії та обміну інформацією:

№ п/п	Назва регуляторного органу, що надіслав термінове повідомлення	Назва препарату/	Виробник/ Заявник	Неякісний або фальсифікат
1.	Institute for State Control of Veterinary Biologicals and Medicines (USKVBL), Czech Republic	Cylanic 50 mg + 12.5 mg, tablets for dogs and cats	Livisto Int'l, S.L., Spain	Зовнішній вигляд таблеток у блістері не відповідає встановленим вимогам

Додаток: на 3 арк.

Голова **Роман ІСАЄНКО**

Марина ОПАНАСЕНКО
044 422-55-75

Appendix 3

Follow-up and Non-urgent Information for Quality Defects

"Confidential. For regulatory authority use only. Not intended for publication"

ÚSKVBL

Add letter head of sender

1. National Reference Number (when applicable)	CZ/VET/1/30/02
2. Recall Number Assigned	USKVBL/1253/2025/POD

+ -

Attach files

3. To: (see list attached, if more than one) All Rapid Alert Network

4.Files attached? Yes

+ Product - Product

	5. Product	6. Strength	7. INN or Generic name
1	CYLANIC 50 mg + 12.5 mg tablets for dogs and cats	50 mg + 12.5 mg	

8. Brand/Trade Name	9. Dosage form	10. Marketing Authorisation Number
	Tablet	96/051/21-C

+ Batch - Batch

	11. Batch number (and bulk, if different)
1.1	23E25

12. Marketing Authorisation Holder		13. Manufacturer	
Name	Livisto Int'l, S.L.	**Name**	
Address	Av. Universitat Autònoma, 29 Cerdanyola del Vallès (Barcelona) 08290, Spain	**Address**	
E-mail	paola.filippi@livisto.com; inma.zorilla@livisto.com	**E-mail**	
Phone	+39 0522 640724; 0034 93 470 62 70	**Phone**	

14. Subject title

FOLLOW UP of the case: On 04.02.2025 USKVBL sent RAN Nr. CZ/VET/1/30/01 regarding OOS in appearance of VMP CYLANIC 50 mg + 12.5 mg tablets for dogs and cats, batch 23E25 and informed about initiation of withdrawal of this batch from the market in the Czech Republic. USKVBL tested samples of the same batch which was taken from distributor and found that tested sample does not comply with the specification in the approved registration dossier. Parameters OOS: appearance, assay of amoxicilin, assay and identity of clavulanic acid and related substances. Related test report No. 17/2025 is attached.

15.Issuing Authority Contact Person

From (Issuing Authority)	Institute for State Control of Veterinary Biologicals and Medicines (USKVBL); Czech Republic				
Contact Person	Jiri Dobias, MSc.	**E-mail**	RAS@USKVBL.CZ	**16. Date/Time**	19.02.2025 / 13:29
Phone	00420720940693	**Signature**			

Test report No. 17/2025

Number of issues: 2	Issue No. 2	Supplements: 0
Request No.: USKVBL/1491/2025/INS	Date of receipt: 31.01.2025	Contract review No.: 17/2025
The sample has been provided by the applicant.	End of analysis: 11.02.2025	

Sample identification:

Name of sample:	**CYLANIC 50/12.5 mg tablets for dogs and cats**	
Applicant:	Inspection Department, ÚSKVBL	
Batch No.: 23E25	Expire date: 10/2025	
Date of manufacture: not specified	Quantity of sample: 3 × 100 tbl.	

Tests	Results	Specifications according to [1)]	SOP (Method of determination)
Appearance of tablet	light tablets: slightly yellow, round and convex tablet with a cross-shaped break line on one side, 8 mm in diameter dark tablets: brown mottled (different intensity and tone), round and convex tablet with a cross-shaped break line on one side, 8 mm in diameter	white to slightly yellow, round and convex tablet with a cross-shaped break line on one side, 8 mm in diameter	*
Thickness	light tablets: 2.40 mm dark tablets: 2.70 mm	2.3 – 2.8 mm	*
Average tablet weight	106.1 mg	101.5 – 112.2 mg	* (ČL 2.9.5)
Disintegration time	light tablets: all 6 tablets disintegrated within 2 min. dark tablets: all 6 tablets disintegrated within 7 min.	max. 15 min.	* (ČL 2.9.1)
Resistance to crushing	light tablets: 24 N dark tablets: 22 N	max. 60 N	* (ČL 2.9.8)
Identity amoxicillin base	conform to reference	conform to reference	* (HPLC)
Assay amoxicillin base	light tablets: 49.9 mg/tbl., U = 2.98 mg/tbl. dark tablets: 33.5 mg/tbl., U = 4.66 mg/tbl.	47.5 – 52.5 mg/tbl.	* (HPLC)
Identity clavulanic acid	light tablets: conform to reference dark tablets: do not conform to reference (< LOD)	conform to reference	* (HPLC)
Assay clavulanic acid	light tablets: 12.4 mg/tbl., U = 0.66 mg/tbl. dark tablets: < LOD (LOD = 0.0015 mg/tbl.)	11.2 – 13.1 mg/tbl.	* (HPLC)

Related substances Amoxicillin base/clavulanic acid	**Amoxicillin** light tablets: unknown highest impurity: 0.24%, U = 0.02 % total impurities: 0.66%, U = 0.05% dark tablets: unknown impurities: 4 impurities over 1.0%, highest 8.81%, U = 0.72% total impurities: 20.39%, U = 1.67% **Clavulanic acid** light tablets: unknown highest impurity: 0.76%, U = 0.06% total impuriies: 1.27%, U = 0.10% dark tablets: unknown impurities: 3 impurities over 1.0%, highest 1.55%, U = 0.13% total impurities: 6.38%, U = 0.52%	Any impurity: ≤ 1% Total impurities: ≤ 5%	* (HPLC)
Microbiological testing of non-sterile products – Enumeration of total viable microorganisms and detection of specified microorganisms	TAMC: <10 CFU/g TYMC: <10 CFU/g absence of E. coli in 1 g	TAMC: $<2\times10^3$ CFU/g TYMC: $<2\times10^2$ CFU/g absence of E. coli in 1 g	SOP 05

[1] approved registration dossier of the marketing authorisation holder, European /Czech Pharmacopoeia, etc.
* – test is out of scope of accreditation

Conclusion: The tested sample DOES NOT COMPLY with the specifications in the approved registration dosssier. Parameters out of specification: appearance, assay of amoxicillin, assay and identity of clavulanic acid and related substances.

Brno: 12.02.2025

The person responsible for the analysis:
PharmDr. Jaroslav Maxa, Ph.D.
MVDr. Pavla Novotná

Authorization: PharmDr. Mgr. Alžběta Kružicová, Ph.D.
Head of OMCL Department

---------- The end of the test report. ----------

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У доповнення до листа Держлікслужби від 26.03.2025 № 3304-1.1/2.4/17-25 щодо ветеринарного лікарського засобу REVOZYN та на виконання пункту 2.1. Меморандуму про партнерство та співробітництво між Державною службою з лікарських засобів та контролю за наркотиками та Державною службою України з питань безпечності харчових продуктів та захисту споживачів від 14.10.2022 року та з метою інформування та протидії поширенню неякісних препаратів, в тому числі ветеринарних препаратів, дієтичних добавок надаємо копії повідомлень, які надійшли до Держлікслужби в рамках міжнародної взаємодії та обміну інформацією:

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1.	AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS, AEMPS.	REVOZYN 400mg/ml suspension inyectable para bovino	Eurovet Animal Health B.V., Netherland	Невідповідність специфікації за показником на ресуспендованість під час дослідження стабільності

Додаток: на 2 арк.

Голова **Роман ІСАЄНКО**

Марина ОПАНАСЕНКО
044 422-55-75

IMPORTANT DELIVER IMMEDIATELY

Rapid Alert Notification of a Quality Defect / Recall

Reference Number : Quality Defect Alert VDC 3/2025

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)*
4. Product: **REVOZYN 400 MG/ML SUSPENSION INYECTABLE PARA BOVINO**	5. Marketing Authorisation Numbers: 3625 ESP For use in animals
6. Brand/Trade Name: **REVOZYN 400 MG/ML SUSPENSION INYECTABLE PARA BOVINO**	7. INN or Generic Name: penetamate iodhydrate
8. Dosage Form: **Injectable suspension**	9. Strength: 308.8 mg penethamate equivalent to 400 mg of penethamate iodhydrate
10. Batch number (and bulk, if different): **24F053** **24B212** **24B191** **23G043**	11. Expiry Date: May 26 Jan 26 Jan 25 Jun 25
14. Marketing Authorisation Holder: VIRBAC EUROVET ANIMAL HEALTH B.V. Handelsweg, 25 Bladel. Noord-Brabant, Netherlands Contact person (Spain): **E-mail: Carin.deLaat@dechra.com**	
15. Manufacturer: EUROVET ANIMAL HEALTH B.V.	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 to an out-of-specification result in the resuspendability test during a stability study. Initially, information was received regarding 3 batches; however, on March 5, a correction of the affected batches was received from the MAH. Therefore, this alert has been modified.		
20. Action taken by Issuing Authority: **Approved recall by MAH to veterinarian level.**		
21. Proposed Action: **Approved recall by MAH to wholesaler 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: 06 March 2025	26. Time: *

ДЕРЖАВНА СЛУЖБА УКРАЇНИ З ЛІКАРСЬКИХ ЗАСОБІВ ТА КОНТРОЛЮ ЗА НАРКОТИКАМИ
(Держлікслужба)

проспект Берестейський, 120-А, м. Київ, 03115, тел/факс: (044) 422-55-77, e-mail: dls@dls.gov.ua,
https://www.dls.gov.ua Код ЄДРПОУ 40517815

_____ № _____ На № _____ від _____

Державна служба України з питань безпечності харчових продуктів та захисту споживачів

На виконання пункту 2.1. Меморандуму про партнерство та співробітництво між Державною службою з лікарських засобів та контролю за наркотиками та Державною службою України з питань безпечності харчових продуктів та захисту споживачів від 14.10.2022 року та з метою інформування та протидії поширенню неякісних препаратів, в тому числі ветеринарних препаратів, дієтичних добавок надаємо копії повідомлень, які надійшли до Держлікслужби в рамках міжнародної взаємодії та обміну інформацією:

№ п/п	Назва регуляторного органу, що надіслав термінове повідомлення	Назва препарату/	Виробник/ Заявник	Неякісний або фальсифікат
1.	Institute for State Control of Veterinary Biologicals and Medicines (USKVBL), Czech Republik	REVOZYN RTU 400mg/ml	Produlab Pharma Production B.V., Netherlands	Невідповідність специфікації за показником на ресуспендованість під час дослідження стабільності

Додаток: на 2 арк.

Голова **Роман ІСАЄНКО**

Марина ОПАНАСЕНКО
044 422-55-75

Appendix 2

IMPORTANT: DELIVER IMMEDIATLY- Rapid alert notification of a Quality Defect/Recall

"Confidential. For regulatory authority use only. Not intended for publication"

ÚSKVBL

Add letter head of sender

1. Reference Number CZ/VET/II/31/01

2. Recall Number Assigned (if available) USKVBL/3013/2025/POD

\+ -

Attach file

3. To: (see list attached, if more than one) All Rapid Alert Network **4.Files attached?** No

5. For use in Veterinary **6. Product recall/class of defect** II **7. Reason** Quality defect

+ Product - Product

	8. Product	9. Strength	10. INN or Generic name	11. Pack size and Presentation
1	REVOZYN RTU 400 mg/ml inj. susp.	400 mg/ml		50 ml

12. Brand/Trade Name	13. Dosage Form	14. Marketing Authorisation Number
	Solution for dispersion fot injection/infusion	96/022/18-C

+ Batch - Batch

	15. Batch Number (and bulk, if different)	16. Date manufactured	17. Expiry Date
1.1	24F053		May-26

18. Marketing Authorisation Holder

Name	Eurovet Animal Health, B.V.
Address	Handelsweg 25, 5531 AE Bladel, Netherlands
E-mail	Carin.deLaat@dechra.com
Phone	

19. Manufacturer

Name	Produlab Pharma Production B.V.
Address	Forellenweg 16, NL-4941SJ Raamsdonksveer, Noord-Brabant
E-mail	
Phone	

20. Recalling Firm (if different)

Name	
Address	
E-mail	
Phone	

21. Site where the defect occurred (where the defect is attributed to a manufacturing site and if different from 19)

Name	
Address	
E-mail	
Phone	

22. Details of the Defect/Reason for the Recall

The USKVBL was informed by the Marketing Authorisation Holder of a quality defect regarding to an out-of-specification limit in the resuspendability test during a stability study. In the context of testing of retained samples was recently found out, that the batch 24F053 was also affected by this quality defect. Based on communication with distributor in the Czech Republic, we found out, that this batch was distributed to the Czech market.

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

24. Action Taken by the Issuing Authority

Approved recall to end user level.

25. Proposed Action

Recall to end user level.

26. Issuing Authority

From (Issuing Authority) Institute for State Control of Veterinary Biologicals and Medicines (USKVBL) **Phone** 00420720940693

Contact person Jiri Dobias, MSc.; Jiri Bures DVM (director) **E-mail** RAS@USKVBL.CZ

Signature

27. Date/Time 03.03.2025/14:30

UB Державна служба України з лікарських засобів та контролю за наркотиками

UB Державна служба України з лікарських засобів та контролю за наркотиками №3303-1.1/2.4/17-25 від 26.03.2025 КЕП: Ісаєнко Р. М. 26.03.2025 3FAA9288358EC00304000000064

UB Державна служба України з лікарських засобів та контролю за наркотиками №53/2.0.1-1/25 від 26.03.2025 КЕП: Ісаєнко Р. М. 26.03.2025 3FAA9288358EC00304000000064

ДЕРЖАВНА СЛУЖБА УКРАЇНИ З ЛІКАРСЬКИХ ЗАСОБІВ ТА КОНТРОЛЮ ЗА НАРКОТИКАМИ
(Держлікслужба)

проспект Берестейський, 120-А, м. Київ, 03115, тел/факс: (044) 422-55-77, e-mail: dls@dls.gov.ua,
https://www.dls.gov.ua Код ЄДРПОУ 40517815

_____ № _____ На № _____ від _____

Державна служба України з питань безпечності харчових продуктів та захисту споживачів

На виконання пункту 2.1. Меморандуму про партнерство та співробітництво між Державною службою з лікарських засобів та контролю за наркотиками та Державною службою України з питань безпечності харчових продуктів та захисту споживачів від 14.10.2022 року та з метою інформування та протидії поширенню неякісних препаратів, в тому числі ветеринарних препаратів, дієтичних добавок надаємо копії повідомлень, які надійшли до Держлікслужби в рамках міжнародної взаємодії та обміну інформацією:

№ п/п	Назва регуляторного органу, що надіслав термінове повідомлення	Назва препарату	Виробник/ Заявник	Неякісний або фальсифікат
1.	The Therapeutic Goods Administration (TGA) of Australia	Orthoplex MagGI Restore 300g; Orthoplex Pure Children's Essentials 250g	Bio Concepts Pty Ltd, Australia	Препарат може мати нерівномірний розподіл калію йодиду
2.	The Therapeutic Goods Administration (TGA) of Australia	EverNatal 60 capsules	Naternal Vitamins, Australia	Інгредієнт калію йодид, що входить до складу препарату, є більш кристалічним, ніж визначено технічною документацією

3.	The Therapeutic Goods Administration (TGA) of Australia	Preconception Multi for Women	NRC Nutrition Pty Ltd, Australia	Препарат може мати нерівномірний розподіл калію йодиду

Додатки: 11 файлі в ел. вигляді.

Голова **Роман ІСАЄНКО**

Марина ОПАНАСЕНКО
044 422-55-75

Bio Concepts Pty Ltd
19A Guardhouse Road,
Banyo, QLD 4014

31ST March 2025

CRITICAL [PRODUCT RECALL]

TGA Reference Number: RC- 2025-RN-00362-1
Orthoplex Pure Children's Essentials 250g and Orthoplex Mag GI Restore 300g powders

Orthoplex Pure Children's Essentials 250g powder Aust L 371280 Barcode 9319091978855 - Batch 43268 Expiry January 2027
Orthoplex MagGI Restore 300g powder Aust L 311634 Barcode 9319091979449 - Batch 42660 Expiry January 2027

Dear Customer,

Bio Concepts, following agreement with the Therapeutic Goods Administration (TGA), is conducting a product recall of the above products – Orthoplex Pure Children's Essentials 250g and Orthoplex MagGI Restore 300g powders.

The potentially affected product has been/may have been supplied to your organisation.

What is the problem?

The Risk Assessment completed by the Contract Manufacturer has identified a particle size problem with potassium iodide which might cause nonhomogeneous blend in the powder. Calculations show the potential iodine in these products may be low or well in excess of safety limits for iodine. In mild cases, excess iodine consumption can cause diarrhoea, burning sensation in the mouth, nausea and vomiting. In severe cases, iodine poisoning may involve swelling of airways, cyanosis, weak pulse or coma. There is also the potential for iodine deficiency if the product is lacking the active ingredient. This product recall has been classified as a critical Class I.

No adverse events have been reported to date.

This product recall does not affect any other batches, expiry dates or pack sizes of Orthoplex Pure Children's Essentials or Orthoplex MagGI Restore, or any other Bio Concepts Orthoplex products.

The affected batches have been distributed to distributors and customers since the following dates:

Orthoplex Pure Children's Essentials 250g: 23rd March 2025
Orthoplex MagGI Restore 300g: 27th February 2025

What should you do?

Inspect your stock **immediately** and quarantine affected stock on hand to prevent further use:

- Orthoplex Pure Children's Essentials 250g Aust L 371280 Barcode 9319091978855 - Batch 43268 Expiry January 2027
- Orthoplex MagGI Restore 300g Aust L 311634 Barcode 9319091979449 - Batch 42660 Expiry January 2027

Please stop consuming these products immediately.

Complete the attached Customer Response form **immediately, even if you do not have any affected stock** and return it to **info@bioconcepts.com.au** so we can reconcile this product recall.

Return affected stock on hand with the completed response form to your point of purchase. If this is not possible, please contact Bio Concepts to discuss alternative arrangements on **07 3868 0699.**

Head Office: +61 (0)7 3868 0699
19A Guardhouse Road, Banyo QLD 4014, Australia
info@bioconcepts.com.au
www.bioconcepts.com.au

Ensure relevant staff members are informed of this product recall, including all health care professionals, reception staff, interns and any other applicable staff members.
If you have supplied or transferred any potentially affected product to another facility or organisation, provide that facility with a copy of this letter **immediately.**
Place this letter in a prominent position for at least one month.

If you have any health concerns or further questions relating to this product, please contact Bio Concepts Clinical Support line on **1800 077 113.**

Please report any adverse events or complaints to use and the TGA via https://www.tga.gov.au/safety/reporting-problems/reporting-adverse-events

Replacement stock

No alternative stock is currently available. Please refer to your point of purchase for a full refund.

Bio Concepts is working with our contract manufacturer to ensure that these failures in their quality processes are never repeated and corrective action is implemented immediately.

Thank you for your assistance in helping us to manage this product recall.
Bio Concepts sincerely regrets any inconvenience caused to your organisation.

Michael Osiecki
Managing Director
Bio Concepts

Head Office: +61 (0)7 3868 0699
19A Guardhouse Road, Banyo QLD 4014, Australia
info@bioconcepts.com.au
www.bioconcepts.com.au

NOT FOR FURTHER DISTRIBUTION

Customer list for Market Action RC-2025-RN-00362-1

As this document may contain commercially sensitive information, please do not distribute to third parties.

The Sponsor has provided the following customer list to the TGA. For questions regarding its contents or accuracy, please contact the Sponsor directly.

SUMMARY: 27 facilities in ACT, NSW, QLD, VIC and WA with 20 private individuals

SPONSOR: Bio Concepts Pty Ltd

CONTACT INFORMATION: 1800 077 113 - Bio Concepts Contact Clinical Support

State	Customer	Suburb
ACT	Kingston Natural Therapies Centre	Canberra
NSW	Vitality Natural Grocers	Albion Park Rail
NSW	Mr Vitamins Chatswood - "394"	Chatswood
NSW	Integria Healthcare (Aust) Pty Ltd	Greystanes
NSW	Health Potential Pty Ltd	Lemon Tree Passage
NSW	Vital.ly	Mascot
NSW	Vital.ly	Mascot
NSW	Tiaan Alisia Naturopathy	North Sydney
NSW	My Compounding	Roselands
NSW	Sutherland Shire Naturopathic Clinic	Sutherland
NSW	Life on The Inside	Waverley
QLD	Healing Hands Natural Health Centre	Eastern Heights
QLD	Perpetual Wellbeing Natural Health Pty Ltd	Graceville
QLD	Living Valley Pty Ltd	Kin Kin
QLD	Katrina Ellis Natural Health Centre	Kirra
QLD	The Shift Clinic	Milton
QLD	Forever Fertile & Noosa Natural Medicine	Peregian Beach
QLD	Natural Health Clinic Toowoomba	Toowoomba
QLD	Ariya Health Pty Ltd	Townsville
QLD	Far North Qld Nutritionals - Cairns	Yungaburra
QLD	Agnes Water Naturopath	Agnes Water
Vic	Hamish Everard Natural Therapies	Pascoe Vale
VIC	Melbourne Natural Medicine Clinic	South Melbourne
WA	Rener Health Products	Canning Vale
WA	Rener Health Products	Canning Vale
WA	Lakstins-Adams Natural Health Clinic	Canningvale
WA	CH2 Oborne Health Supplies	Perth Airport

NOT FOR FURTHER DISTRIBUTION

Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

CRITICAL RECALL*

LEVEL: Consumer

CLASS: Class I

REFERENCE: RC-2025-RN-00362-1

DATE AGREED: 1/04/2025

PRODUCT:

Orthoplex MagGI Restore 300g
Batch: 42660
Expiry Date: January 2027
Product Code: OWMGL

Orthoplex Pure Children's Essentials 250g
Batch: 43268
Expiry Date: January 2027
Product Code: OWPCL

ARTG: 311634 & 371280

SPONSOR: Bio Concepts Pty Ltd

SPONSOR CONTACT INFORMATION: 1800 077 113 - Bio Concepts Contact Clinical Support

REASON:

The contract manufacturer has advised that two Bio Concepts Listed Medicine formulations may have a non-uniform distribution of potassium iodide.

The Risk Assessment completed by the Contract Manufacturer has identified a particle size problem with potassium iodide which might cause nonhomogeneous blend in the powder. Calculations show the potential iodine in these products may be well in excess of the safety limits for iodine or lack amount of iodine.
In mild cases, excess iodine consumption can cause diarrhoea, burning sensation in the mouth, nausea and vomiting. In severe cases, iodine poisoning may involve swelling of airways, cyanosis, weak pulse or coma.

There is also the potential for iodine deficiency if the product is lacking the active ingredient.

The affected products have been distributed since February 2025. No adverse events have been reported to date.

This product recall does not affect any other batches, expiry dates or pack sizes of Orthoplex Pure Children's Essentials or Orthoplex MagGI Restore, or any other Bio Concepts Orthoplex products.

PO Box 100 Woden ACT 2606 ABN 40 939 406 804
Phone: 02 6289 4613 Email: recalls@health.gov.au

PROPOSED CUSTOMER ACTIONS:	Customers are to immediately stop using this product and return affected stock to place of purchase for a refund. If this is not possible contact Bio Concepts Customer Service on 07 3868 0699 to reconcile the recall. No alternative stock is currently available.

The sponsor is expected to dispatch letters to all affected customers within two business days of the agreed date. **Please do not contact the sponsor for further information unless you believe that you have the affected goods and have not received a notification letter.**

Product Distribution: 27 facilities in ACT, NSW, QLD, VIC and WA with 20 private individuals

Product export status: New Zealand

This information has been published in the TGA's searchable database: https://apps.tga.gov.au/PROD/DRAC/arn-detail.aspx?k=RC-2025-RN-00362-1

*For further details about Market Actions, please refer to - https://www.tga.gov.au/safety/market-actions

Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

CRITICAL RECALL*

LEVEL: Consumer

CLASS: Class I

REFERENCE: RC-2025-RN-00366-1

DATE AGREED: 1/04/2025

PRODUCT: **EverNatal 60 capsules**

Batch number: 43311

Exp: 01/27

ARTG: 447572 - EverNatal

SPONSOR: Naternal Vitamins

SPONSOR CONTACT INFORMATION: 0420 972 736 - Naternal Vitamins

REASON: The ingredient potassium iodide included in the product was identified by the manufacturer as being more crystalline than usual which may result in a potential for a nonhomogeneous blend. This nonhomogeneous blend could lead to variability in dosing. The variability in dosing could lead to some units lacking the active ingredient while others may contain excessive amounts.

Symptoms of iodine poisoning can range from mild to severe, depending on the level of iodine in the body. Mild symptoms consist of gastrointestinal upset, nausea, vomiting, and diarrhea, which may progress to more severe manifestations such as delirium, confusion, lethargy, and shock.

There is also the potential for iodine deficiency if the product is lacking the active ingredient.

This batch has been distributed to customers since 17th February 2025. No adverse events have been reported to date.

This recall does not affect any other batches of EverNatal or any other Naternal Vitamin products.

PROPOSED CUSTOMER ACTIONS: Consumers:
- Stop taking this product immediately
- Return affected stock to the place of purchase for a refund or email Naternal Vitamins customer service on recall@naternalvitamins.com.au to

arrange a replacement of affected product.

Wholesalers/distributors:
- Destroy stock and provide evidence of this in the response form for a refund or replacement.

No alternative stock is available currently. Alternative stock is expected to be available in approximately 4 weeks from Naternal Vitamins.

The sponsor is expected to dispatch letters to all affected customers within two business days of the agreed date. **Please do not contact the sponsor for further information unless you believe that you have the affected goods and have not received a notification letter.**

Product Distribution: 17 facilities nationally excluding NT, TAS and WA, along with 1615 private individuals nationally

Product export status: New Zealand

This information has been published in the TGA's searchable database:
https://apps.tga.gov.au/PROD/DRAC/arn-detail.aspx?k=RC-2025-RN-00366-1

*For further details about Market Actions, please refer to - https://www.tga.gov.au/safety/market-actions

NOT FOR FURTHER DISTRIBUTION

Customer list for Market Action RC-2025-RN-00366-1

As this document may contain commercially sensitive information, please do not distribute to third parties.

The Sponsor has provided the following customer list to the TGA. For questions regarding its contents or accuracy, please contact the Sponsor directly.

SUMMARY: 17 facilities nationally excluding NT, TAS and WA, along with 1615 private individuals nationally

SPONSOR: Naternal Vitamins

CONTACT INFORMATION: 0420 972 736 - Naternal Vitamins

State	Customer	Suburb
ACT	The Allergy Centre	Canberra
NSW	Essentia Natural Health	Bankstown
NSW	Nourishing Apothecary	Liverpool
QLD	Maroochydore Whole Life Pharmacy & Healthfoods	Buderim
QLD	The Wholesome Store	Burleigh Heads
QLD	Balanced Beings	Burleigh Heads
QLD	The Wholesome Store	Burleigh Waters
QLD	New Life Midwifery	Ipswich
QLD	Noosa Natural Medicine	Peregian Beach
QLD	Healing Home and Body	Tallai
QLD	The Biomedical Naturopath	Tallebudgera
SA	Natural Good Life	Nangkita
VIC	The Otway Wellbeing Centre	Colac
VIC	Organic Instinct	Coolaroo
VIC	Superwell	Eltham
VIC	Corinne Hohenhaus	Officer South
VIC	Prahran Health Foods	South Yarra

NOT FOR FURTHER DISTRIBUTION

Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

CRITICAL RECALL*

LEVEL: Consumer

CLASS: Class I

REFERENCE: RC-2025-RN-00363-1

DATE AGREED: 1/04/2025

PRODUCT: **Preconception Multi for Women**

Batch: 42469

Manufacture Date: January 2025

Expiry: January 2027

Barcode: 0787099780029

Product Code: NPMW60V

ARTG: 457190 - Preconception Multi for Women

SPONSOR: NRC Nutrition Pty Ltd

SPONSOR CONTACT INFORMATION: 07 5448 2001 - NaturoBest

REASON: In one batch of Preconception Multi for Women it was identified that a new source of potassium iodide used in the manufacturing process had a larger, more crystalline particle size than specified.

This led to an uneven distribution of iodine in the blend, which may result in some capsules containing too much or too little iodine.

Potential symptoms of excess iodine (if consumed) may include:
· Burning in the mouth or throat
· Nausea, vomiting, or diarrhoea
· Rapid heart rate or other signs of hyperthyroidism (rare, and primarily in sensitive individuals)
·In severe cases, iodine poisoning may involve swelling of airways, cyanosis, weak pulse or coma.

There is also the potential for iodine deficiency if the product is lacking the active ingredient.

No adverse events have been reported to date.

PROPOSED CUSTOMER ACTIONS:	CONSUMERS: - Stop taking this product immediately. -Return the product to the place of purchase for a refund or call the sponsors customer service line (07 5448 2001) to arrange the return of affected product and a refund. WHOLESALERS and DISTRIBUTORS: - Cease distribution and quarantine the affected batch immediately. - Notify any downstream customers/ retailers or patients who may have received the affected product and provide them with a copy of the sponsors consumer letter which contains the instructions on what to do with affected stock . -Further instructions on how to return affected stock are provided in the customer letters.

The sponsor is expected to dispatch letters to all affected customers within two business days of the agreed date. **Please do not contact the sponsor for further information unless you believe that you have the affected goods and have not received a notification letter.**

Product Distribution: 18 facilities nationally excluding ACT, NT and TAS along with over 1000 private individuals nationally

Product export status: NZ, UK, US and Malaysia.

This information has been published in the TGA's searchable database:
https://apps.tga.gov.au/PROD/DRAC/arn-detail.aspx?k=RC-2025-RN-00363-1

*For further details about Market Actions, please refer to - https://www.tga.gov.au/safety/market-actions

Subject: **Critical Recall – *Preconception Multi for Women* (Batch 42469), AUST L 457190, TGA reference number RC-2025-RN-00363-1**

NaturoBest **is one of several vitamin and prenatal brands impacted** by a problem that occurred at one of our contract manufacturers.

As a result of this problem, NaturoBest are recalling the *Preconception Multi for Women*, batch 42469 (expiry: January 2027).

A full refund will be provided.

We understand this may cause inconvenience, but the health and well-being of our customers is paramount. We also want to assure you that this was not caused by any error on our part, and **no other NaturoBest products or batches are affected**.

Details:

The potassium iodide used in this batch was supplied in a **larger, crystalline form**, which was not approved for use in existing formulations. This affected the blending process and may have caused **uneven distribution of iodine** in the capsules.

As a result, some capsules may contain **too much iodine**, while others may contain **none at all**. Importantly, **we have not received any reports of adverse effects.**

If you have not had any adverse reaction, it suggests that the capsules you consumed are unlikely to have contained excess iodine.

Potential symptoms of excess iodine (if consumed) may include:

- Burning in the mouth or throat
- Nausea, vomiting, or diarrhoea
- Rapid heart rate or other signs of hyperthyroidism (rare, and primarily in sensitive individuals)
- In severe cases, iodine poisoning may involve swelling of airways, cyanosis, weak pulse or coma.

There is also the potential for iodine deficiency if the product is lacking the active ingredient

What to do:

1. **Stop taking this product immediately.**
2. **Advise if you still have the product and advise by return email that the product has now been destroyed, your order number and a photo of any remaining stock you have showing the batch number.**
3. **Upon receipt of your email confirmation, we will provide you with a refund.**

This manufacturing issue has been reported to the Therapeutic Goods Administration (TGA) and we are working closely with them and the manufacturer responsible for this error throughout the recall process. **Our contract manufacturer is updating its internal procedures**, including adding particle size testing to raw material specifications, to ensure this cannot happen again.

We deeply regret this situation. Once again, **no other NaturoBest product is affected**, and the issue was caused by a raw material supplied to the manufacturer – not by any fault in our formulation.

Please report any adverse events or complaints to us on the contact details below and to the TGA at https://www.tga.gov.au/safety/reporting-problems/reporting-adverse-events

If you feel unwell or have any questions, please contact your healthcare practitioner and get in touch with us at admin@naturobest.com or 07 5448 2001.

Nikki Warren

NOT FOR FURTHER DISTRIBUTION

Customer list for Market Action RC-2025-RN-00363-1

As this document may contain commercially sensitive information, please do not distribute to third parties.

The Sponsor has provided the following customer list to the TGA. For questions regarding its contents or accuracy, please contact the Sponsor directly.

SUMMARY: 18 facilities nationally excluding ACT, NT and TAS along with over 1000 private individuals nationally

SPONSOR: NRC Nutrition Pty Ltd

CONTACT INFORMATION: 07 5448 2001 - NaturoBest

State	Customer	Suburb
NSW	Healthy Life NSW	Auburn
NSW	Clifford Hallam Healthcare Beresfield NSW	Beresfield
NSW	Natural Chemist	Brookvale
NSW	Mung Bean Health	Charmhaven
NSW	Health Masters	Kincumber
NSW	Vital.ly	Mascot
QLD	Clifford Hallam Healthcare BNE	Brendale
QLD	Rener Health Supplies	Canning Vale
QLD	Livelife Pharmacy	Plainland
QLD	Healthy Life QLD	Stafford
QLD	Ariya Health Supplies Townsville	West End
SA	Bayside Pharmacy	Glenelg
SA	Healthy Life SA	Mile End
VIC	Clifford Hallam Healthcare Pty Ltd VIC	Keysborough
VIC	Jade Dragon Tradional Chinese Medicine	Narre Warren South
VIC	The Memo	South Yarra
VIC	Cocoon Acupuncture	Traralgon
WA	Healthy Life WA	Perth

NOT FOR FURTHER DISTRIBUTION

Distributor Recall Notification Letter

Subject: **Critical Recall – *Preconception Multi for Women* (Batch 42469), AUST L 457190, TGA reference number RC-2025-RN-00363-1**

NaturoBest **is one of several vitamin and prenatal brands impacted** by a problem that occurred at one of our contract manufacturers.

As a result of this problem, NaturoBest are recalling the *Preconception Multi for Women*, batch 42469 (expiry: January 2027).

A full refund will be provided.

We understand this may cause inconvenience, but the health and well-being of our customers is paramount. We also want to assure you that this was not caused by any error on our part, and **no other NaturoBest products or batches are affected**.

Details:

The potassium iodide used in this batch was supplied in a **larger, crystalline form**, which was not approved for use in existing formulations. This affected the blending process and may have caused **uneven distribution of iodine** in the capsules.

As a result, some capsules may contain **too much iodine**, while others may contain **none at all**. Importantly, **we have not received any reports of adverse effects.**

If you have not had any adverse reaction, it suggests that the capsules you consumed are unlikely to have contained excess iodine.

Potential symptoms of excess iodine (if consumed) may include:

- Burning in the mouth or throat
- Nausea, vomiting, or diarrhoea
- Rapid heart rate or other signs of hyperthyroidism (rare, and primarily in sensitive individuals)
- In severe cases, iodine poisoning may involve swelling of airways, cyanosis, weak pulse or coma.

There is also the potential for iodine deficiency if the product is lacking the active ingredient.

Immediate Action Required:

- Cease distribution of batch 42469 immediately.
- Quarantine any remaining stock and advise as soon as possible how many units you have remaining in stock.

- Notify any downstream customers/retailers provide them with a copy of the consumer letter where it instructs them to stop sale and use and return stock.
- Complete the customer response form attached.
- Return affected stock and invoice the cost of the freight and returns to NRC Nutrition Pty Ltd.

This recall has been reported to the Therapeutic Goods Administration (TGA). The **manufacturer is reviewing and strengthening their internal protocols**, including implementing particle size testing as part of raw material specifications to prevent recurrence.

We appreciate your cooperation and swift action to help protect customer safety and uphold regulatory compliance. Should you require assistance, please contact me.

Nikki Warren

Wholesale letter

Subject: **Critical Recall – *Preconception Multi for Women* (Batch 42469), AUST L 457190, TGA reference number RC-2025-RN-00363-1**

Dear practitioner,

NaturoBest **is one of several vitamin and prenatal brands impacted** by a problem that occurred at one of our contract manufacturers.

As a result of this problem, NaturoBest are recalling the *Preconception Multi for Women*, batch 42469 (expiry: January 2027).

A full refund will be provided.

We understand this may cause inconvenience, but the health and well-being of our customers is paramount. We also want to assure you that this was not caused by any error on our part, and **no other NaturoBest products or batches are affected**.

Details:

The potassium iodide used in this batch was supplied in a **larger, crystalline form**, which was not approved for use in existing formulations. This affected the blending process and may have caused **uneven distribution of iodine** in the capsules.

As a result, some capsules may contain **too much iodine**, while others may contain **none at all**. Importantly, **we have not received any reports of adverse effects.**

If you have not had any adverse reaction, it suggests that the capsules you consumed are unlikely to have contained excess iodine.

Potential symptoms of excess iodine (if consumed) may include:

- Burning in the mouth or throat
- Nausea, vomiting, or diarrhoea
- Rapid heart rate or other signs of hyperthyroidism (rare, and primarily in sensitive individuals)
- In severe cases, iodine poisoning may involve swelling of airways, cyanosis, weak pulse or coma.

There is also the potential for iodine deficiency if the product is lacking the active ingredient.

Required actions:

- Cease distribution and use of batch 42469 immediately.

- Notify any patients or customers who may have received this product and provide them with a copy of the attached consumer letter.
- Fill in our customer response form attached stating that the product has been quarantined and destroyed by yourself and your customer.

This recall has been submitted to the TGA. The manufacturer is reviewing and updating its internal QA processes, including the addition of particle size testing to relevant raw material specifications, to ensure this problem does not recur.

We appreciate your support in helping manage this recall. Again, this problem originated with the raw material supplied to the manufacturer, and **no other NaturoBest formulations have been affected.**

Please email admin@naturobest.com if you need assistance or further information.

Nikki Warren

Naternal
VITAMINS

2nd of April 2025

CRITICAL Recall

TGA Reference Number: RC-2025-RN-00366-1 [EverNatal 60 capsules: AUST L 447572

Batch: 43311
EXP: 01/2027
Date: 01/2025

Dear customer,

Naternal Vitamins, following agreement with the Therapeutic Goods Administration (TGA), is conducting a Recall of the above EverNatal, 60 capsules. Batch 43311; Expiry 01/2027.

The potentially affected product has been supplied to you.

What is the problem?

While no adverse events have currently been reported to either Naternal Vitamins or the TGA, we have received a Risk Assessment from the Australian manufacturer of the mentioned batch indicating the below:

- The ingredient potassium iodide included in the product is more crystalline than usual which may result in variability in dosing
- The variability in dosing could lead to some units lacking the active ingredient while others may contain excessive amounts
- Due to the potential for variability in dosing all the batch mentioned above (EverNatal, Batch 43311; Expiry 01/2027) is being recalled to prevent the potential of consumption of excessive iodine intake.
- In mild cases, excess iodine consumption can cause diarrhoea, burning sensation in the mouth, nausea and vomiting. In severe cases, may involve swelling of airways, cyanosis, weak pulse or coma.
- **No adverse events have been reported to date.**
- The onset of symptoms can vary but are generally experienced with a few hours of indigestion.

This Recall does not affect any other batches of EverNatal or any other Naternal Vitamin products. It is a stand alone incident affecting batch of EverNatal only.

This batch has been distributed to customers since 17th February 2025.

What should you do?

Stop taking or supplying this product and immediately and quarantine affected stock EverNatal, 60 capsules. Batch 43311; Expiry 01/2027 on hand to prevent further use.

Complete the attached Customer Response form immediately even if you do not have any affected stock and return it to ***recall@naternalvitamins.com.au*** so we can reconcile this recall.

Consumers are to return affected stock to the place of purchase for a refund or email our customer service on recall@naternalvitamins.com.au to arrange a replacement of affected product.

Wholesalers/Distributors

Distributors are to destroy stock and provide evidence in the response form of destruction this for a refund or replacement.

Replacement stock

No alternative stock is available currently. Alternative stock is expected to be available in approximately 4 weeks from Naternal Vitamins.

For further information please email recall@naternalvitamins.com.au

Please report any adverse events or complaints to us and the TGA via https://www.tga.gov.au/safety/reporting-problems/reporting-adverse-events

While we sincerely regret any inconvenience or concern this situation has caused, we take product quality, safety, and efficacy extremely seriously—as we have since our founding in 2021. Throughout these years, we've helped tens of thousands of women access premium prenatal supplements, and we remain committed to providing exceptional products to our valued customers going forward.

Customer care and safety are our highest priorities, which is why we took immediate action to inform you as soon as we were notified of this potential issue.

Thank you for your understanding and continued support. Please don't hesitate to reach out if we can assist you in any way.

Melanie Nolan

Director, Naternal Vitamins