



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

Reference Number : Quality Defect  
Alert VDC 2/2024

| QUALITY DEFECT RAPID ALERT   |  |
|--|--|
| 1. To: Quality defect rapid alert contacts(see list attached, if more than one)  |  |
| 2. Product Recall Class of Defect:<br>(circle one): <b>TYPE II</b>   | 3. <del>Counterfeit</del> / <del>Fraud</del> (specify)*                      |
| 4. Product:<br><b>SEMINTRA 4 MG/ML SOLUCION ORAL<br/>PARA GATOS</b>  | 5. Marketing Authorisation Numbers:<br>Nº EU/2/12/146/001 For use in animals |
| 6. Brand/Trade Name:<br><b>SEMINTRA 4 MG/ML SOLUCION ORAL<br/>PARA GATOS</b>   | 7. INN or Generic Name: <i>Telmisartan</i>                                   |
| 8. Dosage Form:<br><b>Oral solution</b>  | 9. Strength:<br>4 mg/ml  |
| 10. Batch number (and bulk, if different):<br><b>F56158</b>  | 11. Expiry Date:<br>Sept 2026  |
| 14. Marketing Authorisation Holder: BOEHRINGER INGELHEIM VETMEDICA GMBH<br><br>Binger Strasse, 173<br>Ingelheim am Rhein. Rhineland-Palatinate<br>D-55216- Germany<br>Contact person (Spain):<br><br><b>E-mail: <a href="mailto:marta.dalmases@boehringer-ingelheim.com">marta.dalmases@boehringer-ingelheim.com</a></b> |  |
| 15. Manufacturer: BOEHRINGER INGELHEIM   | 16. Recalling Firm (if different):   |
| 18. Details of Defect/Reason for Recall:<br><br>The AEMPS was notified of an alert issued by the MAH concerning out of specifications on pH and appearance during the stability studies. The MAH proposes the recall of all units of the affected batch. The AEMPS agrees with the proposal.                             |  |
| 20. Action taken by Issuing Authority: <b>Approved recall by MAH to wholesaler level.</b>  |  |
| 21. Proposed Action: <b>Approved recall by MAH to wholesaler level</b>   |  |

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|   |                            |   |
|---|----------------------------|---|
| 22. From (Issuing Authority):<br><b>AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS<br/>SANITARIOS, AEMPS.</b> |                            | 23. Contact Person:<br><b>Ramiro Casimiro</b><br><b>Telephone: 34 918225433</b><br><b>Email: rcasimiro@aemps.es</b> |
| 24. Signed:   | 25. Date: 15 February 2024 | 26. Time: *   |





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|   |                            |   |
|---|----------------------------|---|
| 22. From (Issuing Authority):<br><b>AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS<br/>SANITARIOS, AEMPS.</b> |                            | 23. Contact Person:<br><b>Ramiro Casimiro</b><br><b>Telephone: 34 918225433</b><br><b>Email: rcasimiro@aemps.es</b> |
| 24. Signed:   | 25. Date: 15 February 2024 | 26. Time: *   |



Appendix 2

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

Add letter head of sender

1. Reference Number AT/II/2024/02/01

2. Recall Number Assigned (if available) INS-640.001-4655

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

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

|   |   |                        |   |                                       |
|---|---|------------------------|---|---------------------------------------|
| 1 | <b>8. Product</b>                               | <b>9. Strength</b>     | <b>10. INN or Generic name</b>            | <b>11. Pack size and Presentation</b> |
|   | Semintra  | 4 mg/ml                | Telmisartan                               | n/a                                   |
|   | <b>12. Brand/Trade Name</b>                     | <b>13. Dosage Form</b> | <b>14. Marketing Authorisation Number</b> |                                       |
|   | Semintra 4 mg/ml Lösung zum Eingeben für Katzen | Oral solution          | EU/2/12/146/001-002                       |                                       |

1.1 15. Batch Number (and bulk, if different) F56910 16. Date manufactured 13-Oct-2023 17. Expiry Date 30-Sep-2026

|   |   |                         |   |
|---|---|-------------------------|---|
| <b>18. Marketing Authorisation Holder</b> |   | <b>19. Manufacturer</b> |   |
| <b>Name</b>                               | Boehringer Ingelheim Vetmedica GmbH         | <b>Name</b>             | Boehringer Ingelheim Promeco S.A. de C.V.   |
| <b>Address</b>                            | Binger Straße 173, 55216 Ingelheim, Germany | <b>Address</b>          | Calle de Maiz No. 49, Col. Barrio Xaltocan, C.P. 160090 Xochimilco, Mexico City, Mexico |
| <b>E-mail</b>                             | n/a   | <b>E-mail</b>           | n/a   |
| <b>Phone</b>                              | n/a   | <b>Phone</b>            | n/a   |

|  |   |   |     |
|--|---|---|-----|
| <b>20. Recalling Firm (if different)</b> |   | <b>21. Site where the defect occurred (where the defect is attributed to a manufacturing site and if different from 19)</b> |     |
| <b>Name</b>                              | Boehringer Ingelheim RCV GmbH & Co KG         | <b>Name</b>   | n/a |
| <b>Address</b>                           | Dr.-Boehringer-Gasse 5-11, 1121 Wien, Austria | <b>Address</b>  |     |
| <b>E-mail</b>                            | matthias.binder@boehringer-ingelheim.com      | <b>E-mail</b>   |     |
| <b>Phone</b>                             | n/a   | <b>Phone</b>  |     |

**22. Details of the Defect/Reason for the Recall**  
 During routine stability tests deviations from the specified values regarding appearance and pH value have been detected. For this reason batch F56910 of 'Semintra 4 mg/ml Lösung zum Eingeben für Katzen' is being recalled in Austria as a precautionary measure. According to the MAH the affected batch of the veterinary medicinal product was distributed to AT.

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

**24. Action Taken by the Issuing Authority** Recall in Austria **25. Proposed Action** Recall class II

**26. Issuing Authority**  
**From (Issuing Authority)** Austrian Federal Office for Safety in Health Care (BASG) **Phone** +43(0)505 55-36466  
**Contact person** Birgit Donabauer **E-mail** birgit.donabauer@ages.at  
**Signature** [Redacted] **27. Date/Time** 16-Feb-2024

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UB Держпротекторат з питань безпеки  
 № 1123-18/S970 від 27.02.2024  
 44/0/0020-1-2  
 арк.1



Donabauer Birgit  
am 16.2.2024



Dieses Dokument wurde amtssigniert.

Informationen zur Prüfung der elektronischen Signatur und des Ausdrucks finden Sie unter <http://www.basg.gv.at/amtssignatur>.

Bundesamt für Sicherheit im Gesundheitswesen  
Traisengasse 5, 1200 Wien

UB Держпродспоживслужба  
№11.2.3-15/3976 від  
27.02.2024

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