Date: 18 June 2025

# Urgent Field Safety Notice
## CAPHOSOL®

For Attention of*: Health Authorities, Distributors and retail Pharmacy

| Contact details of local representative (name, e-mail, telephone, address etc.)* |
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| **EU: Aurelie Therier E-mail: aurelie.therier@recordati.com Tel: +31 (0) 858 883207 Recordati Netherlands B.V., Beechavenue 54, 1119PW Schiphol-Rijk Netherlands** |

**Recordati Netherlands B.V.**
**Recordati Rare Diseases – Recordati Group**

Beechavenue 54
1119PW Schiphol-Rijk
The Netherlands
www.recordatirarediseases.com

Registered company number: 62352385

RECORDATI RARE DISEASES

18 June 2025

# Urgent Field Safety Notice (FSN)
# CAPHOSOL®
# Proposed recall of Caphosol due to Out of Specification pH of Caphosol B

## 1. Information on Affected Devices*

### 1. Device Type(s)*

Caphosol is a mouth rinse. It is classified as a Class I medical device.


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| 1. | 2. Commercial name(s) |
| | Caphosol ® |
| 1. | 3. Unique Device Identifier(s) (UDI-DI)* |
| | Weekly pack 5060146293099 & Monthly pack 5060146293105 UDI-DI 506014A0052685 |
| 1. | 4. Primary clinical purpose of device(s)* |
| | Caphosol is indicated for dryness of the mouth and oropharynx (hyposalivation, xerostomia), regardless of the cause and regardless of whether the condition is temporary or permanent. Caphosol is also indicated as an adjunct to standard oral care in the prevention and treatment of the mucositis that may be caused by radiation or high dose chemotherapy. Relief of dryness of the oral mucosa in these conditions is associated with amelioration of pain. |
| 1. | 5. Device Model/Catalogue/part number(s)* |
| | A00526 (Weekly) and A00527 (Monthly) |
| 1. | 6. Software version |
| | No applicable |
| 1. | 7. Affected serial or lot number range |
| | Batch: 23001W23101W – Batch: 23002W23102W – Batch: 23003W23103W |
| 1. | 8. Associated devices |
| | No applicable |

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| | 2 **Reason for Field Safety Corrective Action (FSCA)*** |
| 2. | 1. Description of the product problem* |
| | As a precautionary measure, Recordati Netherlands B.V. is proposing to initiate a voluntary recall of the medical device Caphosol. This recall concerns all batches of Caphosol. |
| 2. | 2. Hazard giving rise to the FSCA* |
| | An OOS has been observed for one of the components of Caphosol related to too low pH. The OOS pH levels could potentially affect the efficacy and safety of the product. However, if patients follow the instructions for use, mixing one sachet of Caphosol A with one sachet of Caphosol B, the pH of the treatment dose should remain unaffected.<br>Recordati investigated our pharmacovigilance and medical information databases, and found no adverse event reports that could be related to the OOS.<br>While based on the above the overall risk to patients appears low, Recordati has nevertheless as a precautionary measure decided to propose a voluntary Class II recall |
| | 3. Probability of problem arising |

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| 2. | If patients follow the labelling instruction, there should not be an adverse medical impact of the OOS of Caphosol B. According to the medical report and the investigation in our complaint and global medical information database, no case has been reported regarding the misuse of patients who didn't follow the labelling instruction. The probability of problem if patients don't follow the labelling instructions is estimated as Low. |
| 2. | 4. Predicted risk to patient/users |
| | While based on the above the overall risk to patients appears low, Recordati has nevertheless as a precautionary measure decided to propose a voluntary Class II recall |
| 2. | 5. Further information to help characterise the problem |
| | Health Care Professionals should not prescribe Caphosol to new patients nor to patients currently taking the product. |
| 2. | 6. Background on Issue |
| | An Out of Specification (OOS) issue with the pH of Caphosol B was identified during an ongoing stability study. This issue affects batches 23101W, 23102W, and 23103W. The pH results at T24 months/ 30°C/65%RH were 4.8, 4.7, and 4.8 respectively (specification: 5.0 – 7.0). This impacts all finished product batches packaged as A00526 (Weekly) and A00527 (Monthly). |
| 2. | 7. Other information relevant to FSCA |
| | This field may only contain additional information that is deemed necessary by the manufacturer to supplement information relevant to the FSCA. |

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| | **3. Type of Action to mitigate the risk*** | |
| **3.** | **1. Action To Be Taken by the User*** <br><br> ☒ Identify Device ☐ Quarantine Device ☒ Return Device ☒ Destroy Device <br><br> ☐ On-site device modification/inspection <br><br> ☐ Follow patient management recommendations <br><br> ☐ Take note of amendment/reinforcement of Instructions For Use (IFU) <br><br> ☐ Other ☐ None <br><br> Provide further details of the action(s) identified. | |
| 3. | 2. By when should the action be completed? | The proposed recall will be conducted at the retail level. Distributors will be instructed to destroy existing stocks of the impacted lots to the third-party logistics provider. Pharmacies will be notified by their distributors and instructed to destroy affected products. Action to be completed by end September 2025. |

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| 3. | 3. Particular considerations for: Choose an item.<br><br>Is follow-up of patients or review of patients' previous results recommended?<br>Choose an item.<br><br>Provide further details of patient-level follow-up if required or a justification why none is required | |
| 3. | 4. Is customer Reply Required? *<br>(If yes, form attached specifying deadline for return) | No |
| **3.** | **5. Action Being Taken by the Manufacturer**<br><br>☒ Product Removal ☐ On-site device modification/inspection<br>☐ Software upgrade ☐ IFU or labelling change<br>☐ Other ☐ None<br><br>.... | |
| 3 | 6. By when should the action be completed? | Voluntary product recall will be initiated with and expected reconciliation by end September 2025. |
| 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. | |

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| | **4. General Information*** | |
| 4. | 1. FSN Type* | Update |
| 4. | 2. For updated FSN, reference number and date of previous FSN | FSN-2/06/2025 |
| 4. | **3.** For Updated FSN, key new information as follows: | |
| | **Not applicable** | |
| 4. | 4. Further advice or information already expected in follow-up FSN? * | Not planned yet |
| 4 | 5. If follow-up FSN expected, what is the further advice expected to relate to: | |
| | Not expected | |
| 4 | 6. Anticipated timescale for follow-up FSN | Not applicable |
| 4. | 7. Manufacturer information<br>(For contact details of local representative refer to page 1 of this FSN) | |
| | a. Company Name | **Recordati Netherlands B.V.** |
| | b. Address | **Beechavenue 54 - 1119PW - Schiphol-Rijk** |
| | c. Website address | Only necessary if not evident on letter-head. |
| 4. | 8. The Regulatory Authority of your country has been informed about this communication to customers. * | |
| 4. | 9. List of attachments/appendices: | **Not applicable** |
| 4. | 10. Name/Signature | **Aurelie Therier – Person Responsible for Regulatory Compliance (PRRC) and Head of Regulatory, Oncology** |
| | | DocuSigned by: Aurelie Therier 52A979CE06FD478... |

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| | **Transmission of this Field Safety Notice** |
| | Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.<br>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. |