

**DRINGEND – BITTE SOFORT AUSLIEFERN! IMPORTANT – DELIVER IMMEDIATELY**

<b>Rapid Alert Notification of a Quality Defect / Recall</b>	
Meldende Stelle	
1. To / Empfänger:	
FAX/E-MAIL	
<input type="checkbox"/>	Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM)
0228 207-4636 poststelle@bfarm.de	
<input type="checkbox"/>	Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL)
030 18444-30409 poststelle@bvl.bund.de	
<input type="checkbox"/>	Paul-Ehrlich-Institut – Bundesamt für Sera und Impfstoffe – (PEI)
06103 77-1263 pei@pei.de	
2. Product Recall Class of Defect:    I            II (circle one)	
3. Counterfeit / Fraud (specify)*	
4. Product:	5. Marketing Authorisation Number:*
For use in humans/animals (delete as required)	
6. Brand/Trade Name:	7. INN or Generic Name:
8. Dosage Form:	9. Strength:
10. Batch/Lot Number:	11. Expiry Date:
12. Pack size and Presentation:	13. Date Manufactured:*
14. Marketing Authorisation Holder:*	
15. Manufacturer†:	16. Recalling Firm (if different):
Contact Person:	Contact Person:
Telephone:	Telephone:
17. Recall Number Assigned (if available)	
18. Details of Defect/Reason for Recall:	
19. Information on distribution including exports (type of customer, e.g. hospitals):*	

20. Action taken by Issuing Authority:		
21. Proposed Action:		
22. From (Issuing Authority):		23. Contact Person:  Telephone:
24. Signed:	25. Date:	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 released the batch in accordance with Article 51 of Directive 2001/83/EC or Article 55 of Directive 2001/82/EC if different.

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