

RAN-Formular (Rapid-Alert-Notification) zur Mitteilung über den RAS-Verteiler

DRINGEND - BITTE SOFORT AUSLIEFERN! IMPORTANT - DELIVER IMMEDIATELY

Rapid Alert Notification of a Medicinal Product Falsification

☐ **ASSUMED** ☐ **REASONABLY SUSPECTED** ☒ **VERIFIED**

Bezirksregierung Arnsberg
Seibertzstr. 1
59821 Arnsberg
Germany

1. To/Empfänger:		FAX
<input checked="" type="checkbox"/> Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM)		0228-207-4636
<input type="checkbox"/> Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL)		030-18444-30409
<input type="checkbox"/> Paul-Ehrlich-Institut/Bundesamt für Sera und Impfstoffe (PEI)		06103-77-1263
<input checked="" type="checkbox"/> Ministerium für Arbeit, Gesundheit und Soziales des Landes Nordrhein-Westfalen		0211-855-3683
2. Theft of 1650 packages Sildenafil beta 100mg	3. Falsification	
4. Product: Sildenafil beta 100mg 48 Filmtabletten Sildenafil beta 100mg 60 Filmtabletten	5. Marketing Authorisation Number: 83910.00.00 For use in humans	
6. Brand/Trade Name: Sildenafil beta	7. INN or Generic Name: Sildenafil	
8. Dosage Form: coated tablets	9. Strength: 100 mg	
10. Batch number (and bulk, if different): BSJ907C BSJ2001C BSJ907D	11. Expiry Date: 11/2022 12/2022 11/2022	
12. Pack size and Presentation: 48 or 60 coated tablets, German presentation	13. Date Manufactured: unknown	
14. Marketing Authorisation Holder: betapharm Arzneimittel GmbH		
15. Manufacturer†: Contact Person: Telephone:	16. Recalling Firm	
17. Rapid Alert Notification Reference Number: N/A		
18. Details: 1650 packages of Sildenafil beta 100mg were stolen from the NextPharma warehouse in Werne. The theft was presumably conducted in March 2021. Charges were already filed by NextPharma and investigations are ongoing.		
19. Information on distribution including exports (e. g. type of customer, e.g. hospitals): n/a		
20. Action taken by Issuing Authority: FOR YOUR INFORMATION		

21. Proposed Action: This RAN-Notification should inform the collegial authorities about the theft of medicinal products from betapharm Arzneimittel GmbH. The competent authority of the MAH (Regierung von Oberbayern) has already been informed.		
22. From (Issuing Authority): Bezirksregierung Arnsberg Seibertzstr. 1 59821 Arnsberg mail to: nina.makowski@bra.nrw.de		23. Contact Person: Dr. Nina Makowski Telephone: +49 2931 82-2365
24. Signed: gez. Dr. Makowski	25. Date: 19.11.2021	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.

This is intended only for the use of the party to whom it is addressed and may contain information that is privileged, confidential, and protected from disclosure under applicable law. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please notify us by telephone immediately and return it to us at the above address by mail. Thank you.