

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	
<input type="checkbox"/> ASSUMED <input type="checkbox"/> REASONABLY SUSPECTED <input checked="" type="checkbox"/> VERIFIED	
Landesverwaltungsamt Referat Gesundheitswesen, Pharmazie Referatsbereich Pharmazie Ernst-Kamieth-Straße 2 06112 Halle (Saale)	
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"/> <Oberste Landesbehörde>	0391-567-6912
2. Classification (not mandatory) ---	3. Falsification: Theft
4. Product: vardenafil film-coated tablets	5. Marketing Authorisation Number: * EU/1/03/248/010 For use in humans
6. Brand/Trade Name: Levitra 20 mg film-coated tablets	7. INN or Generic Name: vardenafil
8. Dosage Form: film-coated tablets	9. Strength: 20 mg
10. Batch number (and bulk, if different): BXJCR31	11. Expiry Date: 10/2021
12. Pack size and Presentation: 4 film-coated tablets, UK presentation	13. Date Manufactured: * 10/2018
14. Marketing Authorisation Holder: Bayer AG, 51368 Leverkusen, Germany	
15. Manufacturer†: Bayer AG, 51368 Leverkusen, Germany Contact Person: --- Telephone: ---	16. Recalling Firm
17. Rapid Alert Notification Reference Number: DE_	
18. Details: The manufacturer MPA Pharma GmbH (contract manufacturer of the parallel importer EMRAMed Arzneimittel GmbH in Germany) informed the responsible authority, that 45 packages of Levitra 20 mg have been stolen from the warehouse at the production site in Osterburg (Germany). The theft was detected on 19 th August 2020. All packages were marked with serial numbers. MPA Pharma GmbH submitted charge against unknown at the police. The serial numbers have been registered as stolen by MPA Pharma GmbH at the hub.	
19. Information on distribution including exports (e. g. type of customer, e.g. hospitals): * Not applicable	

20. Action taken by Issuing Authority: FOR YOUR INFORMATION		
21. Proposed Action: ---		
22. From (Issuing Authority): Landesverwaltungsamt Referat Gesundheitswesen, Pharmazie Referatsbereich Pharmazie Ernst-Kamieth-Straße 2 06112 Halle (Saale)	23. Contact Person: Kathrin Hoffmann Telephone: +49345 514 1286 Fax: +49345 514 1291 mail to: pharmazie@lvwa.sachsen-anhalt.de	
24. Signed: <i>Hoffmann</i>	25. Date: <i>02.09.2020</i>	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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