

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			
Regierungspräsidium Karlsruhe Referat 25 – Ärztliche und Pharmazeutische Angelegenheiten Markgrafenstr. 46 76133 Karlsruhe			
1. To / Empfänger:		FAX	
☒	Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM)	0228-207-4636	
☐	Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL)	030-18444-30409	
☐	Paul-Ehrlich-Institut / Bundesamt für Sera und Impfstoffe - (PEI)	06103-77-1263	
☒	Ministerium für Soziales und Integration Baden-Württemberg, Referat 53, Else-Josenhans-Str. 6, 70173 Stuttgart	0711-123-3816	
2. Classification (not mandatory)		3. Falsification	
4. Product: <table border="1"><tr><td>1. Vidlista ® 20 mg 2. Filitra ® 20 mg</td></tr></table>		1. Vidlista ® 20 mg 2. Filitra ® 20 mg	5. Marketing Authorisation Number: * 1. 0/25/1325 2. For use in humans/ (delete as required)
1. Vidlista ® 20 mg 2. Filitra ® 20 mg			
6. Brand/Trade Name: Vidlista ® 20 mg Filitra ® 20 mg		7. INN or Generic Name:	
8. Dosage Form: 1. Tablets 2. Sublingualtablets		9. Strength: 1. 20 mg Tadalafil 20 mg 2. Vardenafil	
10. Batch number (and bulk, if different): 1. 620032 2. 380006		11. Expiry Date: 1. 02/2023 2. 04/2023	
12. Pack size and Presentation: Blister 10 Stück Pack size unknown		13. Date Manufactured: 1. 09/2020 2. 05/2020	
14. Marketing Authorisation Holder: *			

15. Manufacturer†: 1. Centurion Remedies Indien 2. Fortune Health Care India Contact Person: Telephone:		16. Recalling Firm	
17. Rapid Alert Notification Reference Number: DE_			
18. Details:			
19. Information on distribution including exports (e.g. type of customer, e.g. hospitals): * Suspicion of the distribution of drugs through illegal distribution channels Jan Krol, Ciepla 4/12 00-862 Warszawa			
20. Action taken by Issuing Authority: FOR YOUR INFORMATION The goods were secured by the customs office			
21. Proposed Action:			
22. From (Issuing Authority): Regierungspräsidium Karlsruhe mail to: abteilung2@rpk.bwl.de		23. Contact Person: Sabine Hofsäss Telephone: +49 721 926 7641	
24. Signed: Sabine Hofsäss	25. Date: 14.05.2021	26. Time: *	

* Information not required, when notified from outside EU.

† The holder of an authorisation referred to under Article 40 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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