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**	
Landesverwaltungsamt Referat Gesundheitswesen, Pharmazie Referatsbereich Pharmazie Ernst-Kamieth-Straße 2 06112 Halle (Saale)	
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
☒ <Oberste Landesbehörde>	0391-567-6912
2. *Classification (not mandatory)* ---	3. Falsification: Theft
4. Product: esketamine hydrochloride solution for injection	5. Marketing Authorisation Number: * 1-22524 For use in humans
6. Brand/Trade Name: Ketanest S 5 mg/ml	7. INN or Generic Name: esketamine hydrochloride
8. Dosage Form: solution for injection	9. Strength: 5 mg/ml
10. Batch number (and bulk, if different): a) X63047 b) AW0433	11. Expiry Date: a) 04/2021 b) 07/2021
12. Pack size and Presentation: 10 x 5 ml ampoules, austrian presentation	13. Date Manufactured:* a) 04/2018 b) 07/2018
14. Marketing Authorisation Holder: Pfizer Corporation Austria Ges.m.b.H., Vienna, Austria	
15. Manufacturer†: Pfizer Manufacturing Belgium NV, Puurs, Belgium 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 eleven packages of Ketanest S 5 mg/ml (two packages of batch no. X63047, not marked with serial numbers; nine packages of batch no. AW0433, marked with serial numbers) have been stolen from the warehouse at the production site in Osterburg (Germany). The theft was detected on 13th August 2020. MPA Pharma GmbH submitted charge against unknown at the police. The serial numbers of batch no. AW0433 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: Hoffmann	25. Date: 02.09.2020	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.*