RAN-Formular für Risikoklasse I oder II

DRINGEND - BITTE SOFORT AUSLIEFERN! IMPORTANT - DELIVER IMMEDIATELY

Rapid Alert Notification of a Recall

Add Letter Head of Sender / Meldende Stelle
Landesamt für Arbeitsschutz, Verbraucherschutz und Gesundheit
Wünsdorfer Platz 3
15806 Zossen

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 Landesgesundheitsbehörde	
☐	Oberste Landesveterinärbehörde	

2. Product Recall Class of Defect: I II (circle one)	3. Falsification/Fraud (specify)* assumed burglary
4. Product: Esketamin Ethypharm 5 mg/ml	5. Marketing Authorisation Number: 2203482.00.00 For use in humans/~~animals (delete as required)~~
6. Brand/Trade Name: Esketamin Ethypharm 5 mg/ml	7. INN or Generic Name: Esketamin
8. Dosage Form: solution for injection/infusion	9. Strength: 5mg/ml
10. Batch number (and bulk, if different): 58931119	11. Expiry Date: 30.11.2021
12. Pack size and Presentation: 10 x 5ml	13. Date Manufactured: * -
14. Marketing Authorisation Holder: * 8174981 AS "Kalceks" Beiname: JSC "Kalceks" Krustpils iela 53 LV-1057 Riga	
15. Manufacturer†: Contact Person: Telephone:	16. Recalling Firm (if different): Ethypharm GmbH Mittelstraße 5/5a D-12529 Deutschland Contact Person: Telephone:
17. Recall Number Assigned (if available):n.a.	

18. Details of Defect/Reason for Recall: During incoming goods inspection it was detected that 610 packages of the medicinal product Esketamin Ethypharm 5 mg/ml are missing. It was confirmed the 610 packages were not lost during transport and it is assumed that the 610 packages are probably still in the warehouse, but cannot be located at the moment. Therefore the company decided to initiate a voluntary recall of the affected batch of the medicinal product. As there is also the possibility of theft of the 610 packages, the loss was also reported to the local criminal police as a precaution.
19. Information on distribution including exports (type of customer, e.g. hospitals): * Wholesalers within Germany
20. Action taken by Issuing Authority: LAVG monitors the initiated recall. The local authority at place of the the store house acts independently to reveal defects or faults.
21. Proposed Action: The company itself performes a recall of the affected batch to achieve a summary of the circulating packages, and to surround the unique identifiers.

22. From (Issuing Authority): Landesamt für Arbeitsschutz, Verbraucherschutz und Gesundheit (LAVG) Abteilung Gesundheit Dezernat G3 Apotheken, Arzneimittel, Medizinprodukte Wünsdorfer Platz 3 15806 Zossen Germany	23. Contact Person: Dr. Steffen Rodewald steffen.rodewald@lavg.brandenburg.de Telephone: *49331 8683 859

24. Signed:	25. Date: 20200303	26. Time: * 10:00

* 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 certifiedthe batch for release in accordance with Article 51 of Directive 2001/83/EC or Article 55 of Directive 2001/82/EC if different.