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 Landesamt für soziale Dienste Schleswig-Holstein Abteilung Gesundheits- und Verbraucherschutz Dezemat 31 Arzneimittelüberwachung Gartenstraße 24 24534 Neumünster Germany 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, Gesundheit, Jugend, Familie und Senioren des Landes Schleswig-Holstein 2. Classification: 1 3. Falsification: verified 4. Product: MENOGON® 75 IU 5. Marketing Authorisation Number: * 236209/98 (Lebanon/Middle East) For use in humans 6. Brand/Trade Name: MENOGON® 75 IU 7. INN or Generic Name: Menotrophin 8. Dosage Form: Powder and solvent for solution for injection 9. Strength: 75 IU 10. Batch number (and bulk, if different): 78432 11. Expiry Date: 30-01-2024 78432 12. Pack size and Presentation: 5 ampoules of powder and 5 ampoules of solvent 14. Marketing Authorisation Holder: Ferring GmbH, Wittland 11, 24109 Kiel, Germany 15. Manufacturer*: Ferring GmbH, Wittland 11, 24109 Kiel, Germany 16. Recalling Firm 17. Rapid Alert Notification Reference Number: not assigned 18. Not assigned 19. Rapid Alert Notification Reference Number: not assigned 19. Rapid Alert Notification Reference Number: not assigned 19. Rapid Alert Notification Reference Number: not assigned 10. Rapid Alert Notification Reference Number: not assigned 11. Rapid Alert Notification Reference Number: not assigned 12. Rapid Alert Notification Reference Number: not assigned 13. Rapid Alert Notification Reference Number: not assigned				
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18. Details:

The Lebanon Health Authority informed Ferring that the aboved mentioned batch and other expired batches (648742, 648953) were noticed during a pharmacy inspection. The presentation is in English and Arabic language. Ferring was asked to evaluate if the batches are genuine or not. Batch numbers/data are not known for this product and do not follow the coding system of Ferring. Furthermore, the packaging layout of the batches does not comply with the original artwork. The falsification was classified as verified.

19. Information on distribution including exports (e. g. type of customer, e.g. hospitals):*

The above-mentioned batches were not imported into Lebanon by the legal supply chain.

General information about the product:

Germany: currently no batch of the product in the market (last batch expired on 30th of June 2021)

Other European countries: marketing authorisations were de-registered. Other Arabic countries holding marketing authorisation with English/Arabic artwork: Bahrain, **Egypt**, Iran, **Iraq**, Jordan, Kuwait, **Libya**, **Oman**, Qatar, **Saudi Arabia**, **Sudan**, Syria, United Arabic Emirates, Yemen, Turkey (bold printed countries are those with the main supply)

20. Action taken by Issuing Authority: Issuance of RAN

- 21. Proposed Action: It is proposed that the BfArM forwards this notification to the Arabic Health Authorities.
- 22. From (Issuing Authority):
 Landesamt für soziale Dienste Schleswig-Holstein
 mail to:
 post.arzneimittelueberwachung@lasd.landsh.de

23. Contact Person:
Dr. Carsten Bode
Telephone: +49 4321 913 958

- 24. Electronically signed in internal
- 25. Date: 09th of August 2021

26. Time: *

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Quelle: 121110_F02_01 Seite 1/1

^{*} 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.