

<p>Rapid Alert Notification of a Medicinal Product Falsification</p> <p> <input type="checkbox"/> ASSUMED <input type="checkbox"/> REASONABLY SUSPECTED <input checked="" type="checkbox"/> VERIFIED </p>	
<p>Regierungspräsidium Darmstadt, 64278 Darmstadt</p>	
1. To/Empfänger:	FAX
<input 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"/> Hessisches Ministerium für Soziales und Integration, Referat V 3A	0611-817-3651
2. Classification (not mandatory) --	3. Falsification
4. Product: Pantogar	5. Marketing Authorisation Number: * -- For use in humans/animals (delete as required)
6. Brand/Trade Name: Pantogar	7. INN or Generic Name: Medicinal yeast Calcium-D-pantothenate Thiamin mononitrate L-cystine Keratin para-Aminobenzoic acid
8. Dosage Form: Capsules	9. Strength: n.a.
10. Batch number (and bulk, if different): 1923278 and 1923271	11. Expiry Date: 10/2022; 08/2022
12. Pack size and Presentation: various	13. Date Manufactured:* 10/2017; 08/2017
14. Marketing Authorisation Holder: Georg Simons GmbH	
15. Manufacturer†: Merz Pharma GmbH & Co. KGaA Ludwigstrasse 22 D-64354 Reinheim Contact Person: Dr. Philippa Bach (QP) Telephone: +4961628009806 Email: Philippa.Bach@merz.de	16. Recalling Firm
17. Rapid Alert Notification Reference Number: DE_HE_2019/705	
<p>18. Details:</p> <p>Pantogar Capsules were offered via Ebay platform (shop 'karas89'). Product purchased via Ebay was shipped from Greece. Only blisters without folding box or package leaflet were received.</p> <p>Later on, it was confirmed that the capsules were manufactured in Egypt by a licensee. The product has been distributed outside of the legal distribution chain.</p>	
<p>19. Information on distribution including exports (e. g. type of customer, e.g. hospitals):*</p> <p>Currently the medicinal product Pantogar is not distributed in EU / non-EU countries by Georg Simons or Merz affiliates (exception is Austria).</p>	

20. Action taken by Issuing Authority: Criminal complaint to prosecutor office was filed by Merz. Ebay was notified by Merz on illegal distribution of medicinal products. Information of RAS Network by issuing authority.		
21. Proposed Action: follow up by competent authority of Greece regarding Ebay shop 'ka-ras89'		
22.	23.	
24. Signed:	25. Date: 07.01.2020	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.

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