Baden-Württemberg
REGIERUNGSPRÄSIDIUM TÜBINGEN
LEITSTELLE ARZNEIMITTELÜBERWACHUNG

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**

<Letter Head of Sender/Meldende Behörde>	
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>	

2. *Classification (not mandatory)*	3. Falsification
4. Product: Neupro 4mg/24h	5. Marketing Authorisation Number: EU/1/05/331/005 For use in humans
6. Brand/Trade Name:	7. INN or Generic Name:
8. Dosage Form: transdermal patch	9. Strength: 4mg/24h
10. Batch number (and bulk, if different): 58033101	11. Expiry Date: 03/2022
12. Pack size and Presentation: 28 patches, Italian presentation	13. Date Manufactured:*
14. Marketing Authorisation Holder: UCB Pharma,B-1070 Bruxelles	
15. Manufacturer†: UCB Pharma S.A. B-1070 Bruxelles Contact Person: n.a. Telephone: n.a.	16. Recalling Firm
17. Rapid Alert Notification Reference Number: **DE_BW_01_RAS 290_2020**	
18. Details: During control of incoming goods parallel distributor ACA Mueller ADAG Pharma AG in 78244, Gottmadingen, Germany, noticed differences between purchased packages: UV sensitive fibers and the watermark are missing on the Bollini labels. The colour of the labels is white instead of cream-coloured. The number on the label is different to the number on the label pad. No recall by ACA is required as none of the packages were marketed. Suspected falsified goods are kept in separated area for rejected products.	
19. Information on distribution including exports (e. g. type of customer, e.g. hospitals): no distribution by the parallel distributor in Germany.	
20. Action taken by Issuing Authority: RA-Notification	

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21. Proposed Action: This is the first purchase of this batch by ACA. Therefore no falsified packages were marketed by ACA. UCB Pharma (40789, Monheim, Germany) was contacted by ACA whether they could check if it is a counterfeit.		
22. From (Issuing Authority): Regierungspräsidium Tübingen Leitstelle Arzneimittelüberwachung		23. Contact Person:
24. Signed:	25. Date: 18.08.2020	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.*

Neupro® 4 mg/24 h

cerotto transdermico
rotigotina

Ciascun cerotto rilascia 4 mg di rotigotina in 24 ore. Ciascun cerotto di 20 cm^2 contiene 9,0 mg di rotigotina.
Altri ingredienti: Poli(dimetilsilossano, trimetilsilil silicato)-copolimerizzato, povidone K90, E171, E223, E304, E307, fluoropolimero, poliestere, silicone, alluminio, pigmenti (giallo95, rosso166, rosso144, nero7). Contiene E223. Vedere il foglio illustrativo per ulteriori informazioni.

Uso transdermico. Leggere il foglio illustrativo prima dell'uso.
Tenere fuori dalla vista e dalla portata dei bambini.
Medicinale soggetto a prescrizione medica.
Non conservare a temperatura superiore ai 30°C.

ITALIA
Rappresentante locale: UCB Pharma S.p.A.
Tel: +39 / 02 300 791

001421852

Può alterare la capacità di guidare veicoli e di usare macchinari.
Da vendersi dietro presentazione di ricetta medica.
A.I.C.: 037152055/E Prezzo: € 105,64

← Original

UCB Pharma S.A.
Allée de la Recherche 60
B-1070 Bruxelles
Belgio

EU/1/05/331/005

CIB72148A 6513255 7692

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← Fälschung Unterschiedliche Nummern Fehler

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