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: Vimpat 100 mg	5. Marketing Authorisation Number: EU/1/08/470/005 For use in humans
6. Brand/Trade Name:	7. INN or Generic Name:
8. Dosage Form: Film-coated-tablet	9. Strength: 100mg
10. Batch number (and bulk, if different): 271854	11. Expiry Date: 08/2022
12. Pack size and Presentation: 56 film-coated-tablets, 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__RAS 291_2020**	
18. Details: During control of incoming goods at the parallel distributor ACA Mueller ADAG Pharma AG (ACA) in 78244, Gottmadingen, Germany, differences between purchased packages were noticed: 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.	

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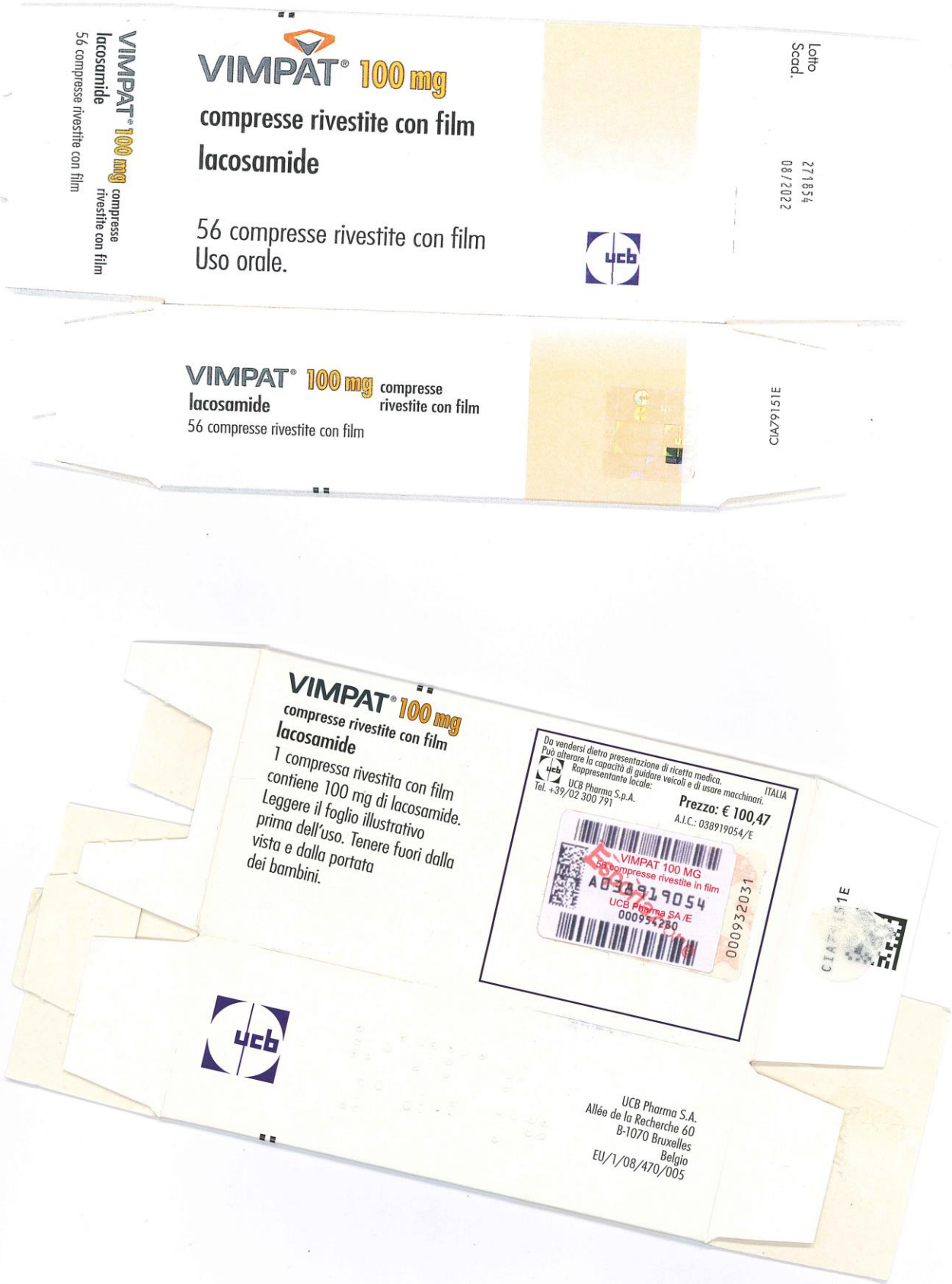
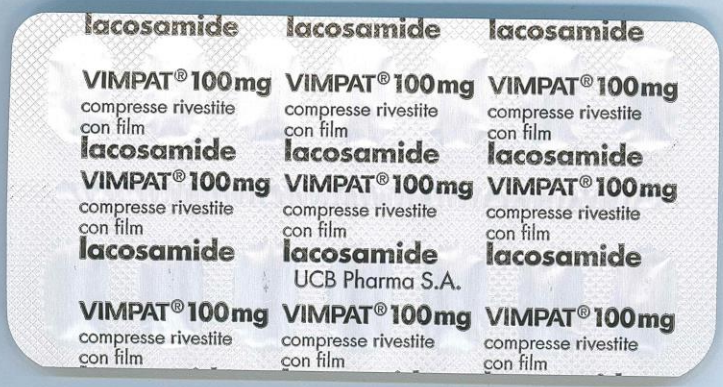
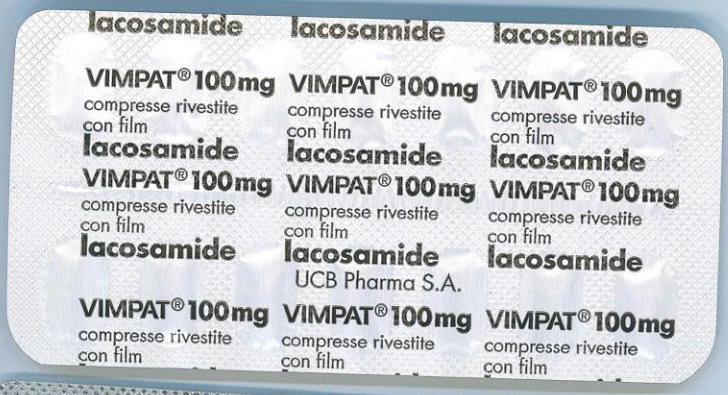
20. Action taken by Issuing Authority: RA-Notification		
21. Proposed Action: This is the first purchase of this batch by ACA. Therefore no falsified packages were marketed by ACA. UCB Pharma (40789, Monheim, Germany) was contacted by ACA whether they could check if it is a counterfeit.		
22. From (Issuing Authority): Regierungspräsidium Tübingen Leitstelle Arzneimittelüberwachung mail to: miriam.schnitzler@rpt.bwl.de	23. Contact Person: Dr. Miriam Schnitzler Telephone: +49 7071 757 3239	
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.*


VIMPAT® 100 mg
compresse rivestite con film
lacosamide
56 compresse rivestite con film
Uso orale.
Lotto
Scad.
271854
08/2022
VIMPAT® 100 mg compresse rivestite con film
lacosamide
56 compresse rivestite con film
VIMPAT® 100 mg compresse rivestite con film
lacosamide
56 compresse rivestite con film
CIA79151E
VIMPAT® 100 mg
compresse rivestite con film
lacosamide
1 compressa rivestita con film contiene 100 mg di lacosamide.
Leggere il foglio illustrativo prima dell'uso. Tenere fuori dalla vista e dalla portata dei bambini.
Da vendersi dietro presentazione di ricetta medica.
Può alterare la capacità di guidare veicoli e di usare macchinari.
ITALIA
Rappresentante locale:
UCB Pharma S.p.A.
Tel. +39/02 300 791
Prezzo: € 100,47
A.I.C.: 038919054/E
VIMPAT 100 MG
56 compresse rivestite in film
A038919054
UCB Pharma SA /E
000954280
000932031
Esemplare
CIA79151E
UCB Pharma S.A.
Allée de la Recherche 60
B-1070 Bruxelles
Belgio
EU/1/08/470/005


lacosamide
VIMPAT® 100 mg
compresse rivestite con film
lacosamide
UCB Pharma S.A.


lacosamide
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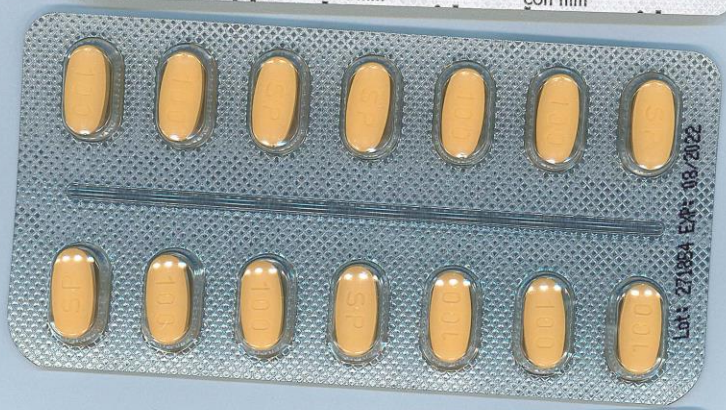
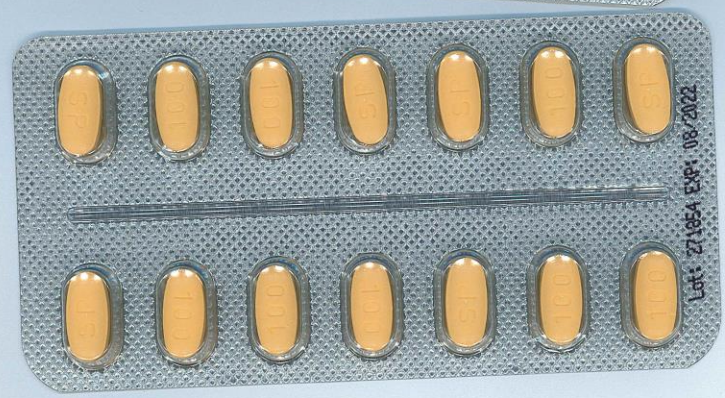

Lot: 27184 EXP: 08/2022


Lot: 27184 EXP: 08/2022