## DRINGEND - BITTE SOFORT AUSLIEFERN! IMPORTANT - DELIVER IMMEDIATELY

| Rapid Alert Notification of a Medicinal Product Falsification |  |  |
| :---: | :---: | :---: |
| Bezirksregierung Düsseldorf |  |  |
| 1. To/Empfänger: |  | FAX |
| $\square$ Bundesinstitut für Arzneimittel und Me | nprodukte (BfArM) | 0228-207-4636 |
| $\square$ Bundesamt für Verbraucherschutz und | ebensmittelsicherheit (BVL) | 030-18444-30409 |
| $\square$ Paul-Ehrlich-Institut/Bundesamt für Ser | und Impfstoffe (PEI) | 06103-77-1263 |
| 区 MAGS NRW |  |  |
| 2. Classification (not mandatory) | 3. Falsification |  |
| 4. Product: Tadalafil-neuraxpharm 5 mg Filmtabletten | 5. Marketing Authorisation 97267.00.00 For use in humans | Number: * |
| 6. Brand/Trade Name: Tadalafil-neuraxpharm | 7. INN or Generic Name Tadalafil |  |
| 8. Dosage Form: film coated tablets | 9. Strength: 5 mg |  |
| 10. Batch number (and bulk, if different): 0464004A | 11. Expiry Date: 02/2022 |  |
| 12. Pack size and Presentation: 28 film coated tablets, German presentation | 13. Date Manufactured:* |  |
| 14. Marketing Authorisation Holder: Neuraxpharm Arzneimittel GmbH Elisabeth-Selbert-Str. 23 40764 Langenfeld Germany |  |  |
| 15. Manufacturert: <br> Pharmactive llac San. ve Tic. A.S. Cerkezköy Organize Sanayi Bölgesi, Kapakli/Tekirdag, Turkey <br> Contact Person: <br> Anika Staack (QPPV Neuraxpharm) Telephone: +4915906751603 | 16. Recalling Firm |  |
| 17. Rapid Alert Notification Reference Number: DE_ |  |  |
| 18. Details: Neuraxpharm imported the batch from the manufacturer in Turkey. When the goods arrived at Neuraxpharm, the lack of 160 packages was found. Investigation revealed that damage was found during loading at Frankfurt Airport. However, the loss of packages was only discovered upon arrival at Neuraxpharm. A theft must be assumed. The serial numbers were not uploaded to the verification system so far. |  |  |

19. Information on distribution including exports (e. g. type of customer, e.g. hospitals):* The batch has not yet been put into circulation. Serial numbers of concerned packages will not be uploaded to the verification system.

## 20. Action taken by Issuing Authority: FOR YOUR INFORMATION

21. Proposed Action: information of wholesalers and pharmacies
22. From (Issuing Authority): Bezirksregierung Düsseldorf mail to: ute.neuberger@brd.nrw.de
23. Contact Person: Ute Neuberger Telephone: +49 211/475-5112
24. Signed: Ute Neuberger
25. Date: 08.10.2020
26. Time:

* Information not required, when notified from outside EU.
t 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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