T.C. Sağlık Bakanlığı
Türkiye İlaç ve Tıbbi Cihaz Kurumu

IMPORTANT – DELIVER IMMEDIATELY
Rapid Alert Notification of a Quality Defect / Recall

<table>
<tr><td colspan="3">From: Turkish Medicines And Medical Devices Agency (TMMDA)</td></tr>
<tr><td colspan="3">1. To:</td></tr>
<tr><td colspan="2">2. Product Recall Class of Defect: II</td><td>3. Falsification/Fraud
(Yes) No</td></tr>
<tr><td colspan="2">4. Product:
Dysport 500 U Powder for Solution for Injection</td><td>5. Marketing Authorisation Number:
112/92 (Genuine Product, Türkiye)
For use in Humans</td></tr>
<tr><td colspan="2">6. Brand/Trade Name:
Dysport 500 U Powder for Solution for Injection</td><td>7. INN or Generic Name:
Botulinum toxin type A</td></tr>
<tr><td colspan="2">8. Dosage Form:
Powder for Solution for Injection</td><td>9. Strength: 500 U</td></tr>
<tr><td colspan="2">10. Batch number (and bulk, if different):
U20520</td><td>11. Expiry Date:
31.08.2023</td></tr>
<tr><td colspan="2">12. Pack size and Presentation:
500 U Powder for Solution for Injection</td><td>13. Date Manufactured:
20.12.2021</td></tr>
<tr><td colspan="3">14. Marketing Authorisation Holder:
Gen İlaç ve Sağlik Ürünleri</td></tr>
<tr><td>15. Manufacturer:
Ipsen Biopharm Ltd</td><td colspan="2">16. Recalling Firm:</td></tr>
<tr><td colspan="3">17. Recall Number Assigned:</td></tr>
<tr><td colspan="3">18. Details of Defect:
In Türkiye, medicines have unique identification numbers that can be found on secondary packaging of medicines.
It has been determined that the unique identification number of the product in the legal supply chain has been copied.
You may find the copied unique ID numbers below
Dysport 500 U Powder for Solution for Injection: 08699783790110 GTIN and 00000169427599 SN
We have initiated the necessary investigations and actions against the possibility of falsified samples of the products whose lot numbers and expiration dates are specified above.</td></tr>
<tr><td colspan="3">19. Information on distribution including exports (type of customer, e.g. hospitals): -</td></tr>
<tr><td colspan="3">20. Action taken by Issuing Authority: Urgent actions have been initiated for the examination and evaluation of products with the risk of falsification.</td></tr>
<tr><td colspan="3">21. Proposed Action: -</td></tr>
<tr><td colspan="2">22. From (Issuing Authority):</td><td>23. Contact Person:</td></tr>
<tr><td>24. Signed:</td><td>25. Date: 19.01.2023</td><td>26. Time:</td></tr>
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