Medicines & Healthcare products Regulatory Agency

MEDICINES RECALL

CLASS 2 MEDICINES RECALL

Action Within 48 Hours
Pharmacy/Wholesaler Level Recall

Date: 22 August 2022 EL (22)A/36 Our Ref: MDR 004-08/22

Dear Healthcare Professional,

Ipsen Limited

Dysport 500 Units Powder for Solution for Injection PL 34926/0001

Batch Number	Expiry Date	Pack Size	First Distributed
U14534	11/2023	1 x 500U vial	unknown

Active Pharmaceutical Ingredient: clostridium botulinum type A toxin-haemagglutinin complex

Brief description of the problem
The Medicines and Healthcare products Regulatory Agency (MHRA) has been investigating a report of a falsification of the above product in the UK.

The UK Marketing Authorisation Holder has confirmed that the batch above is falsified and has been supplied by unauthorised distributors to the UK.

See below for further details on identifying the falsified packs. This is also referenced in a Medical Product Alert issued by the World Health Organization (RPQ/REG/ISF/Alert N°4/2022):

- The falsified carton in the UK includes an incorrect serialisation number (DYN7PCXH84UNBF) and an incorrect GTIN number (03582186006207)

This recall is to remove falsified products from the supply chain. The MHRA has not received any reports indicating patient harm related to this issue but will monitor the situation closely.

Advice for healthcare professionals
Stop supplying the above falsified batch immediately. Quarantine all remaining stock and return it to your supplier for onward investigation by Ipsen Limited.

If patients felt unwell after the administration of the affected batch above, please report this to the Marketing Authorisation Holder and complete a Yellow Card report via the MHRA Yellow Card scheme.

Advice for patients
Patients are not required to take any action at this time. This product is administered by healthcare professionals only.

If you are concerned about this notification, please contact your healthcare professional. If you have an adverse reaction after administration of Dysport, please seek medical attention. Side effects should also be reported via the MHRA's Yellow Card scheme.

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Further Information
For medical information enquiries, please contact Ipsen Limited at medinfo.uk-ie@ipsen.com

Recipients of this Medicines Recall should bring it to the attention of relevant contacts by copy of this notice. NHS regional teams are asked to forward this to community pharmacists and dispensing general practitioners for information.

Falsified Medicines Directive
This notification covers regulation as defined in the Falsified Medicines Directive where it applies. Falsified Medicines Directive (FMD) 2011/62/EU introduced new requirements to enhance the security of the European supply chain. Where the MHRA has identified risks to the security of the supply chain, FMD Alerts will be issued.

Following the UK's departure from the EU, the 'safety features' Delegated Regulation (EU) 2016/161 no longer applies in Great Britain (England, Scotland and Wales) but still applies in Northern Ireland.

For further information about FMD and safety features, please see this link on GOV.UK.

Yours faithfully

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