

21 Sep 2025

Subject: Clarification Regarding Dysport® (abobotulinumtoxinA) Packaging and Labelling Materials

Dear Healthcare Professional,

Ipsen the Marketing authorization Holder of Dysport® (abobotulinumtoxinA) in agreement with the Saudi Food and Drug Authority (SFDA), would like to inform you of the following:

Summary :

- **This is to provide further clarity on the approved packaging and labelling materials for Dysport® (abobotulinumtoxinA).**

Further information on the safety concern and the recommendations:

Dysport® (abobotulinumtoxinA) is a Clostridium botulinum type A toxin-haemagglutinin complex (500 units) that is **indicated for use in adults** for:

- Treatment of muscle spasms affecting the eyes, face, neck, arms/shoulders, and legs.
- Temporary improvement of moderate to severe glabellar lines (frown lines) and crow's feet in patients under 65.
- Management of primary axillary hyperhidrosis (excessive underarm sweating interfering with daily life).

We would like to alert you that **a counterfeit version of Ipsen's Dysport® (abobotulinumtoxinA) has been detected in the Saudi market.** To protect patient safety and ensure the correct product is used, **please remain vigilant** and confirm that only authentic Ipsen Dysport® is used.





As a **precautionary measure**, we are sharing this communication to raise awareness of the counterfeit product.

The counterfeit details are as follows:

- **Batch No.:** U14534
- **Expiry Date:** December 2025

To verify authenticity, please check that the packaging includes the Marketing Authorization Holder (MAH) details clearly stating “Ipsen Ltd” as the MAH. For your reference, the approved packaging is provided in **Annex I**.

To ensure patient safety and maintain product quality, we strongly recommend directing all inquiries and requests regarding Dysport® through Ipsen’s official channels:

- **Product quality complaints:** product.complaints@ipsen.com
- **Adverse events:** pharmacovigilance.ksa@ipsen.com
- **Medical information inquiries:** medinfo.mea@ipsen.com

Should you require any further information or clarification, please do not hesitate to contact us through Ipsen’s official channels.

Call for reporting:

The National Pharmacovigilance Centre (NPC)

Saudi Food and Drug Authority (SFDA):

SFDA call center: 19999

E-mail: npc.drug@sfda.gov.sa

Website: <http://ade.sfda.gov.sa>

Ipsen Pharma:

Product quality complaints: product.complaints@ipsen.com

Adverse events: pharmacovigilance.ksa@ipsen.com

Medical information inquiries: medinfo.mea@ipsen.com

Sincerely,

Norah AlSuwaidan

Pharmacovigilance & Quality Manager

Annexes:

- Annex I

