

Republic of the Philippines Department of Health FOOD AND DRUG ADMINISTRATION



0 1 SEP 2022

FDA ADVISORY No. - 2022-1534

TO:

ALL HEALTHCARE PROFESSIONALS AND THE

GENERAL PUBLIC

SUBJECT:

Public Health Warning on Falsified Drug Product "Dysport"

Confirmed by the World Health Organization (WHO)

The Food and Drug Administration (FDA) notifies the public on the WHO Medical Product Alert on five (5) falsified Clostridium Botulinum Toxin Type A with brand name "Dysport" which were detected in Europe and Eastern Mediterranean regions from May to July 2022:

PRODUCT NAME	Dysport 500 IU	Dysport 500 IU
STATED MANUFACTURER	IPSEN Biopharm Ltd.	IPSEN Biopharm Ltd.
BATCH	U14534	U14534
EXP. DATE	11/2023	03/2023
PACKAGING LANGUAGE	English	Turkish
IDENTIFIED IN	Jordan, Poland, United Kingdom	Turkiye, Kuwait
AVAILABLE PHOTO	GTIN:03582186006207 SN:DYN7PCXH84UNBF EXP 11/2023 LOT U14534	Part No: U14534 Son Kull. To:: 03/2023 Part No: U14534 SonKulta: 68.2023

Figure 1. Clostridium Botulinum Toxin Type A [Dysport] detected in Jordan, Poland, United Kingdom, Turkiye, and Kuwait

Civic Drive, Filinvest City, Alabang, Muntinlupa City, Philippines
Trunk Line +63 2 857 1900
Fax +63 2 807 0751
Website: www.fda.gov.ph
Email: info@fda.gov.ph



Management System ISO 9001:2015



PRODUCT NAME	Dysport 500 IU	Dysport 500 IU
STATED MANUFACTURER	IPSEN Biopharm Ltd.	IPSEN Biopharm Ltd.
BATCH	U05804	U01975
EXP. DATE	12/2022	07/2024
PACKAGING LANGUAGE	Turkish	English
IDENTIFIED IN	Jordan, Poland	Kuwait
AVAILABLE PHOTO	Enjeksiyonluk Çözelti İçin Toz İçeren Flakon Ciberidinin bobalınım tip A steril sosun-magutinin kompleksi sosun-magutinin kompleksi sosun-magutinin kompleksi sosun-magutinin kompleksi sosun-magutinin kompleksi sosun-magutinin kompleksi sosun-magutinin kompleksi sosun-magutinin kompleksi sosun-magutinin kompleksi sosun-magutinin kompleksi sosun-magutinin kompleksi sosun-magutinin kompleksi sosun-magutinin kompleksi sosun-magutinin kompleksi sosun-magutin komp	Mfg: 07/2021 Exp: 07/2024 Country of origin: UK
		Specifications: Manufacturer

Figure 2. Clostridium Botulinum Toxin Type A [Dysport] detected in Jordan, Poland, and Kuwait

PRODUCT NAME	Dysport 500 IU	
STATED MANUFACTURER	IPSEN Biopharm Ltd.	
ВАТСН	U12523	
EXP. DATE	04/2023	
PACKAGING LANGUAGE	English	
IDENTIFIED IN	Poland	
AVAILABLE PHOTO	Cleateristum botulinum type-A Ison hammagguint complex 500 units viail 700 20 60 60 60 60 60 60 60 60 60 60 60 60 60	

Figure 3. Clostridium Botulinum Toxin Type A [Dysport] detected in Poland

The FDA strongly advises the public to be vigilant on the circulation of this falsified drug product since this poses a particular risk to patients as they are administered subcutaneously or intramuscularly, and their sterility, quality, and safety are unknown. A falsified drug product deliberately or fraudulently misrepresents its identity, composition, or source and its safety and quality are unknown. The genuine manufacturer, IPSEN Biopharm Ltd., confirmed that all the products and their variable data (batch numbers, manufacturing, and expiry dates) referenced are falsified, including discrepancies in the packaging languages, type of vial, and, printing errors on the cartons.

This is to emphasize that the authentic Botulinum Toxin Type A 500 Units Lyophilized Powder for Injection (IM/SC) [Dysport] is registered with FDA with Registration No. BR-540 and used to treat symptoms of cervical dystonia, glabellar lines (wrinkles), and spasticity.

Therefore, all Local Government Units (LGU) and Law Enforcement Agencies (LEAs), after the issuance of this advisory, are requested to ensure that this falsified drug product is not sold or not administered to patients in their localities or areas of jurisdiction.

For more information and inquiries, please e-mail us at cdrr_postmarketsurveillance@fda.gov.ph. To report unauthorized sale or distribution of the abovementioned, kindly e-mail us via cdrr.od@fda.gov.ph. You may also call the Center for Drug Regulation and Research at telephone number (02) 8809-5596.

Dissemination of the information to all concerned is highly requested.

DR. SAMUEL A. ZACATE

Page 3 of 3