



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



02 MAY 2022

FDA ADVISORY
No. **2022-1013**

TO : ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC

SUBJECT : Public Health Warning Against the Purchase and Use of the Following Unregistered Drug Products:

1. Botox® 100 U. Enjeksiyonluk Cozelti Icin Liyofilize Toz 1 Flakon Liyofilize Toz 100 Unite
2. S10970037 [Label in Foreign Language]
3. Glutax® 1800000GS Pico Cell Absorption [secondary packaging]

The Food and Drug Administration (FDA) advises the public against the purchase and use of the following unregistered drug products:

Botox® 100 U. ENJEKSİYONLUK ÇÖZELTİ İÇİN LİYOFİLİZE TOZ
1 Flakon
Liyofilize Toz
100 ÜNİTE
Allergan
Steril

Formülü: Bir BOTOX® flakon, sterili liyofilize formda 100 ünite OnabotulinumtoksinA - nörotoksik kompleks, yardımcı madde olarak insan albumini ve sodyum klorür içerir. İlave bilgi için kullanım talimatına bakınız. **"Dikkat Toksikdir", "Dağıtım, Kullanım ve Kullanım Sonrası Talimatlarına Uyulmalıdır".** "BOTOX® ile ilgili daha fazla bilgi için lütfen 0212 365 50 00 no'lu telefonla arayınız. **Ruhsat Sahibi:** Allergan İlaçları Tic. A.Ş. Bilim Sokak, No: 5 Sun Plaza, Kat: 21-22-23 Maslak/Sarıyer/İstanbul **Üretim Yeri:** Allergan Pharmaceuticals Ireland Castlebar Road, Westport/Co. Mayo/İrlanda (BOTOX® Facility) **Ruhsat No:** 06.10.2010 - 130/20

Reçete ile satılır. Kullanmadan önce kullanma talimatını okuyunuz. Beklenmeyen bir etki görüldüğünde doktorunuza başvurunuz. Çocukları göremeyeceği, erişemeyeceği yerlerde ve ambalajında saklayınız. Kesilmiş veya açılmış ambalajları satın almayınız. Açılmamış flakonlar buzdolabında 2°C ile 8°C arasındaki sıcaklıkta veya dondurucuda -5°C'de veya daha altında saklanmalıdır. BOTOX® sulandırıldıktan sonra 2°C ile 8°C arasında buzdolabında saklanmak koşuluyla 24 saat içerisinde kullanılmalıdır. **Kullanma talimatını okumadan uygulamayınız.**

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Botox® 100 U. Enjeksiyonluk Cozelti Icin Liyofelize Toz 1 Flakon Liyofilize Toz 100 Unite
Manufactured by: Allergan Pharmaceutical Ireland - Castlebar Road, Westport/Co. Mayo/İrlanda (Botox(R) Facility) [as translated]
License Owner: Allergan İlaçları Tic. A.S. Bilim Sokak, No: 5 Sun Plaza, Kat: 21-22-23 Maslak/Sarıyer/İstanbul [as translated]

Figure 1. Unregistered drug product





Figure 2. Unregistered drug product



Figure 3. Unregistered drug product

FDA Post-Marketing Surveillance (PMS) activities have verified that the abovementioned drug products have not gone through the registration process of the Agency and have not been issued with proper authorization in the form of Certificate of Product Registration. Thus, the Agency cannot guarantee their quality, safety and efficacy. Therefore, consumption of such violative products may pose potential danger or injury to health.


Pursuant to Republic Act No. 9711, otherwise known as the "Food and Drug Administration Act of 2009", the manufacture, importation, exportation, sale, offering for sale, distribution, transfer, promotion, advertising or sponsorship of health products without proper authorization from FDA is prohibited.

All concerned establishments and/or entities are warned not to distribute the above-identified violative drug products until they have already been covered by the appropriate authorization, otherwise, regulatory actions and sanctions shall be strictly pursued. Always check if the products are registered with the FDA by using the **FDA Verification Portal feature** accessible at <https://verification.fda.gov.ph>.

All Local Government Units (LGUs) and Law Enforcement Agencies (LEAs) are requested to ensure that these products are not sold or made available in their localities or areas of jurisdiction.

For more information and inquiries, please e-mail us at info@fda.gov.ph. To report continuous sale or distribution of unregistered health products, kindly e-mail us via ereport@fda.gov.ph. You may also call the Center for Drug Regulation and Research at telephone number (02) 8809-5596. For any suspected adverse drug reaction (ADR), report immediately to FDA through this link: <https://primaryreporting.who-umc.org/Reporting/Reporter?OrganizationID=PH> and fill out all the required fields.

Dissemination of the information to all concerned is requested.


DR. OSCAR G. GUTIERREZ, JR.
Officer-in-Charge Director General

DTN: 

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