12-Aug-2025

DAEWOONG PHARMACEUTICAL CO.LTD

Direct Healthcare Professional Communication

Nabota® (Botulinum Toxin Type A)

Guidance on Identifying Genuine Nabota® Product and Proper Procurement Channel in Saudi Arabia

Dear Healthcare Professionals,

Daewoong Pharmaceutical in agreement with SFDA would like to provide important information regarding the identification of authentic Nabota® (Botulinum Toxin Type A) products and proper procurement channels in Saudi Arabia, to ensure patient safety and product efficacy.

Summary

Botulinum Toxin Type A is indicated to be used in Glabellar lines, Focal upper limb spasticity, Crow's feet lines, Blepharospasm, and Dysphagia in cervical dystonia and chronic migraine patients.

The purpose of this DHPC is to guide HCP on how to verify the product authenticity and to provide the proper channels for ADR reporting.

Further information on the safety concern and the recommendations

1. Product Information

Trade Name	**Nabota®**
Register Number	2509222631
Scientific Name	CLOSTRIDIUM BOTULINUM TYPE A TOXIN-HAEMAGGLUTININ COMPLEX
Strength	100
Strength Unit	IU
Dosage Form	Powder for solution for injection
Route of Administration	Intramuscular use
Package Type	Vial
Package Size	1
Legal Status	Prescription
Product Control	Restricted
Distribution Site	Hospital
Shelf Life	36
Storage Conditions	Store in a refrigerator (2°C – 8°C)
Manufacturer Name	DAEWOONG PHARMACEUTICAL CO., LTD
Manufacturer Country	South Korea
Agent	AME Company for Medical Supplies
ATC Code	M03AX01
Description Code	7000000312-100-100000073866

This letter approved by SFDA

DAEWOONG PHARMACEUTICAL CO.LTD

2. Label

Please refer to the images below which depict the label design of the genuine product.

▲

Hologram Silver Foil

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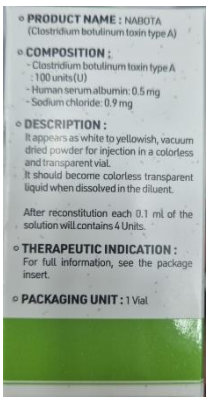
<td> 
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Recommended Action:

Verification of Product Authenticity

Healthcare professionals can verify the authenticity of NABOTA by checking the packaging elements described above. Additionally, the batch number format provides further validation.

Batch Number Example:

" X25001A "

- **Always begins with the letter 'X'.**
- **Followed by a five-digit number.**
- **The second and third characters represent the last two digits of the manufacturing year (e.g., '25' refers to a batch manufactured in 2025).**
- **If applicable, a single alphabet letter at the end denotes a sub-batch.**

Procurement Guidance

To ensure product authenticity, NABOTA must be purchased exclusively from AME Company for Medical Supplies, the sole and authorized distributor of NABOTA in Saudi Arabia. NABOTA supplied through any other channel cannot be guaranteed to be genuine. NABOTA requires strict cold chain management (2–8°C) during storage and transportation to maintain product efficacy and quality. Products offered at a significantly reduced price may have been stored or transported under uncontrolled temperature conditions, which could severely compromise safety and therapeutic effects. Therefore, we strongly recommend using NABOTA only through official import and distribution channels.

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Call for Reporting

Suspected adverse reactions is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions to:

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

AME

Local Representative: AME Company for Medical Supplies

Email: regulatory@ame.med.sa

Mobile: +966509895314

Daewoong

Daewoong Pharmaceutical Co., Ltd

Email: scmoon@daewoong.co.kr

Mobile: +82 10 3170 0944

DAEWOONG PHARMACEUTICAL CO., LTD.
Seongsoo Park
PRESIDENT

This letter approved by SFDA