



Direct Healthcare Professional Communication
Penicillin G Infectopharm (Benzylpenicillin Sodium) Important Safety Information
Regarding Distribution of certain Batches without English Package Leaflet

Dear Healthcare Professional,

Dhah Taiba Pharmaceutical Company, in agreement with the Saudi Food and Drug Authority (SFDA), would like to notify you of an important safety concern regarding Penicillin G Infectopharm 1 Mega IU Powder for Solution for Injection.

Summary of the Safety Concern

- Certain batches were distributed without an English package leaflet.
- Missing leaflet may limit access to essential prescribing and safety information
- Healthcare professionals should consult the attached English product information
- Patients should be provided with appropriate counselling
- Future batches will contain the English package leaflet

Recommendations for Healthcare Professionals

- Ensure patients receive the necessary medical guidance and counseling in the absence of the English leaflet.
- Refer to the approved English product information provided by the company for full details on indications, dosing, contraindications, warnings, and safety profile.
- Report any suspected adverse reactions related to Penicillin G Infectopharm promptly to the National Pharmacovigilance Center.

Background on the Safety Concern

- Penicillin G Infectopharm (Benzylpenicillin Sodium) is indicated for the treatment of susceptible bacterial infections as described in the approved Saudi SPC.
- The package leaflet is a key reference for healthcare professionals and patients.
- Its absence may increase the risk of inappropriate use, lack of awareness of contraindications, and under-reporting of adverse events.
- Corrective actions are currently being implemented to ensure all future batches distributed in Saudi Arabia will contain the English package leaflet.

Call for Reporting

Healthcare professionals are strongly encouraged to report any suspected adverse reactions associated with Penicillin G Infectopharm

To the National Pharmacovigilance Center NPC – Saudi Food and Drug Authority

- SFDA Call Center : 19999
- Email: npc.drug@sfda.gov.sa
- Website: <https://ade.sfda.gov.sa>



Contact Information

For any inquiries regarding this communication, please contact:

Email: pharmacovigilance@dhaitaiba.com

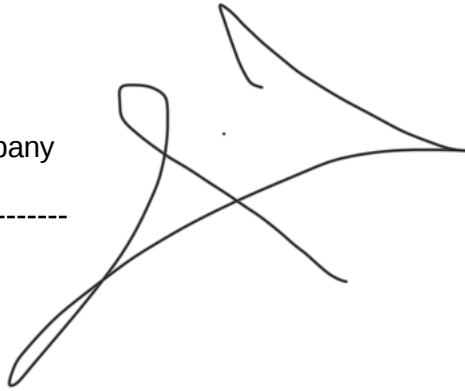
Phone: 0504815709

Sincerely,

Dr. Norah Fahd El Saqr

Pharmacovigilance Director

On behalf of Dhaitaiba Pharmaceutical Company

A handwritten signature in black ink, consisting of several fluid, overlapping loops and strokes, positioned to the right of the printed name and title.