

## Direct Healthcare Professional Communication (DHPC)

15 February 2026

### Empagliflozin SPC 10 mg and 25 mg - Film-Coated Tablets - Important Information Regarding Packaging.

Dear Healthcare professional,

Sudair Pharma Company, in agreement with the Saudi Food and Drug Authority (SFDA), would like to inform you of the following:

#### Summary

- Multiple complaints have been received regarding difficulty in tablet extraction from the currently marketed alu-paper blister packaging.
- Investigation confirmed that there is no defect in product quality, stability, or efficacy.
- The issue is related to handling and extraction technique.
- A card for tablet extraction instructions has been created to be distributed to all health care facilities for previously distributed products.
- Updated tablet extraction instructions have been added to the Patient Information Leaflet (PIL) for ongoing products supply.
- To permanently mitigate this usability issue, Sudair Pharma will initiate a variation to replace the alu-paper blister packaging with standard alu-alu blister packaging for future batches.
- No recall is required.

#### Further information on the concern and the recommendations

- Following distribution of Empagliflozin SPC 10 mg and 25 mg in alu-paper blister packaging, Sudair Pharma Company and SFDA received multiple product complaints from patients and healthcare professionals concerning difficulty in extracting tablets from the blister cavity.
- The issue was determined to be related to usability and insufficient clarity of extraction instructions.
- No causal relationship with adverse drug reactions has been established.
- The DHPC is being disseminated to proactively mitigate potential medication-use errors and ensure optimal patient use during the transition period.

### Advice for Healthcare Professionals

- Counsel patients on the appropriate method of tablet extraction from the current blister packaging.
- Continue prescribing and dispensing the product as usual, as no recall or suspension is required.

### Placing the risk in the context of the benefit

- Empagliflozin SPC 10 mg and 25 mg remains an effective and authorized treatment for Type 2 diabetes mellitus, heart failure & chronic kidney disease.
- The identified issue relates solely to packaging usability and does not affect product quality, safety, or efficacy.

### Call for reporting

Healthcare professionals are reminded of the importance of reporting suspected adverse drug reactions and product complaints through the following contact details:

- To Saudi Food and Drug Authority (SFDA):
  - Website: <https://ade.sfda.gov.sa>
  - SFDA Call Center: 19999
  - E-mail: [npc.drug@sfda.gov.sa](mailto:npc.drug@sfda.gov.sa)
- To Sudair Pharma Company:
  - Website: <https://sudairpharma.com/>
  - Phone: +966-920001432 Ext. 107
  - Email: [Pharmacovigilance@SudairPharma.com](mailto:Pharmacovigilance@SudairPharma.com)

**Sincerely,**  
Soliman Alzahrani  
Pharmacovigilance Manager

### Annexes

- Patient instruction cards.
- Patient Information Leaflet (PIL).