Kingdom of Saudi Arabia
Saudi Food & Drug Authority

Saudi Drug Updates (SDU)

Nov 2024 A monthly electronic bulletin published by the drug sector

Drug Safety Updates

Most Commonly Reported Medication Errors

Products	Report and Corrective action
DIAOPTIM MR vs ESCITAM 10 mg	Report: The packaging of the products is similar in appearance Corrective action: The Marketing Authorization Holder (MAH) has submitted a variation to redesign the packaging of the products to feature a distinctly different background, thereby reducing the risk of potential medication errors.
Potassium chloride plastic ampoule 10 mL (High Alert Medication) vs water for injection plastic ampoule 10 mL Diluent	Report: The packaging of the products is similar in appearance Analysis: these two products were registered at SFDA before the establishment of medication errors department (MED) Both have lookalike plastic ampoules, inner labels and outer packages with unified company design. Corrective action:- 1. (MED) requested from the MAH to submit a variation no. 46 on both products to redesign the outer packages and inner labels on the plastic ampoules to feature a distinctly different design and colors according to the Guidance of Graphic Design of medication packaging. (see 2.3 plastic ampoules page no. 50)., thereby reducing the risk of serious potential medication errors due to lookalike similarity. The variation requests have been approved by the SFDA to prevent future errors. 2. Urgent prevention of Medication errors we requested a Direct Healthcare Professional Communication (DHPC) for review and approval to inform healthcare professionals (HCPs) along with permanent labels to differentiate between the ampoules. However, the MAH surveyed and collected customers feedback, the stock of the products was low and they were satisfied with the SFDA approved DHCP.