SFDA
Safety communication

[26 /06/2024]

Risk of Cross-Compatibility Issues with The Use of Optional Autoinjector Devices with Glatiramer Injection.

The Saudi Food and Drug Authority (SFDA) would like to notify healthcare professionals about reported issues regarding the Cross-compatibility of Glatiramer injection with certain autoinjector devices.

The SFDA observed reports from global health authorities indicating that the use of incompatible autoinjectors with the patient's specific glatiramer acetate injection product can result in medication errors, such as a missed dose or administration of a partial dose.

Glatiramer acetate injection is used in the treatment of relapsing forms of multiple sclerosis. for the current approved Glatiramer products in Saudi Arabia: GLATIJECT and GALTIPEX.

Glatiramer injection is used with optional autoinjector devices designed to ensure safe administration. while other glatiramer acetate injection products must only be injected using the prefilled syringe. Healthcare providers must review the device compatibility as listed in the approved product labeling to avoid the risks associated with the use of incompatible devices.

In addition, the SFDA advises healthcare professionals to ensure that patients are using autoinjectors that are explicitly compatible with Glatiramer injection as specified in the product labeling. Educate patients on the proper use of autoinjectors, including demonstrations on correct techniques and handling. Monitor patients to confirm the autoinjector is compatible during routine visits.

Call for reporting:
The SFDA urges both healthcare professionals and patients to report ADRs related to use of any medication to the SFDA using the following contact information:
The National Pharmacovigilance Centre (NPC):
Call Center: 19999
Website: https://ade.sfda.gov.sa
SFDA RMM Webpage: