SFDA
Safety communication

[18/07/2024]

Risk of Drug Interaction between Warfarin and Tramadol.

The Saudi Food and Drug Authority (SFDA) would like to notify healthcare professionals regarding the risk of drug interactions between warfarin and tramadol, which may increase the International Normalized Ratio (INR), and result in severe ecchymoses (bruising) and bleeding, which could be life-threatening in some patients.

Warfarin is a coumarin-derived vitamin K antagonist used for prevention and treatment of blood clots. Warfarin has a low therapeutic index, which means that co-prescribed medicines should be taken with caution due to the possibility of interactions that could increase risk of bleeding.

Tramadol is a non-selective opioid analgesic. The local Summary of Product Characteristics (SPC) for tramadol and warfarin state that caution should be exercised during concomitant treatment of tramadol with warfarin due to reports of increased INR with major bleeding and ecchymoses in some patients.

Globally, there is a case of brain hemorrhage reported fatal outcome due to concurrent treatment with warfarin and tramadol. The risk of major bleeding with warfarin treatment is rare, however the concomitant use of warfarin with tramadol may increase the risk of bleeding.

As result, SFDA advises healthcare professionals to take the following precautions:

- Before prescribing any concomitant medication with warfarin, take a complete patient's medical history, including all the concurrent medications
- Exercise caution when co-prescribing warfarin with other medications, as warfarin has a low therapeutic index

- Monitor the INR more closely in case of prescribing warfarin (or other coumarin derivatives) with tramadol.
- Inform your patients that warfarin may interact with some medications, leading to an increased risk of bleeding.
- Educate the patient to seek immediate medical attention if they experience any of the following symptoms: prolonged nosebleeds, blood in the vomit, sputum, stool, or urine, unusual headaches, severe bleeding gums, or severe or unexplained bruising.

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: