SFDA
Safety communication

[14/06/2021]

The SFDA cancels the registration of products containing Cefoperazone

In accordance with the continuous monitoring of the safety of pharmaceutical products registered in the Kingdom of Saudi Arabia, the Saudi Food & Drug Authority (SFDA) would like to notify healthcare professionals about cancelling registration of products containing cefoperazone (marketing as trade name CEFOBID®).

Cefoperazone is a third generation cephalosporin antibiotic. It has a wide spectrum activity against many types of bacteria. It is indicated for the treatment of wide ranges of infections including respiratory tract infections, peritonitis and other intra-abdominal infections, bacterial septicemia, urinary tract infections and infections of the skin and skin structures.

Several published studies suggested that N-methylthiotetrazole chain in the structure of some cephalosporin antibiotic including cefoperazone is associated with the risk of bleeding via inhibiting vitamin K metabolism, which can lead to hypoprothrombinemia.

We reviewed published literature and post-marketing databases on the potential risk of hypoprothrombinemia and bleeding with cefoperazone use. We found that the current evidence indicates an increased risk of hypoprothrombinemia and bleeding with the use of cefoperazone compared to other safer therapeutic alternatives that available in Saudi Arabia for the same indications. Serious bleeding cases, including fatalities, have been reported with the use of cefoperazone worldwide.

The evaluation of the benefit-risk profile of products containing cefoperazone showed that the potential risks outweigh the benefits. Therefore, the SFDA have informed the healthcare institutions as to stop using these products by official MEMO.

The SFDA advises healthcare professionals to stop prescribing products containing cefoperazone to patients and use safer alternative antibiotics.

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):
Fax: +966-11-205-7662
SFDA Call Center: 19999
E-mail: npc.drug@sfda.gov.sa
Website: https://ade.sfda.gov.sa