Saudi Food & Drug Authority (SFDA)

SAFETY COMMUNICATION

22 December 2019

Ceftriaxone: a reminder for the risk of hypersensitivity

The Saudi Food and Drug Authority (SFDA) would like to inform healthcare professionals about the occurrence of several hypersensitivity and allergic reactions cases in patients using ceftriaxone. Hypersensitivity is a known risk with ceftriaxone use.

Since 2015, the National Pharmacovigilance Center has received 153 serious reports of ceftriaxone hypersensitivity, including two reports of fatal outcomes in 2019. After evaluation of these cases, we did not conclude that there is a specific ceftriaxone-containing product or a cluster of cases that would warrant special investigation.

Ceftriaxone has a similar R-group to the following antibiotics: cefotaxime, cefpodoxime, cefditoren, ceftizoxime and cefmenoxime. Cephalosporin with similar R-group are at high risk for cross-sensitivity. Cross-sensitivity between penicillins and ceftriaxone is not common due to the differences in their chemical structure. Patient's penicillin allergy may be associated with increased risk of allergy to first-generation cephalosporin but not second- or third-generation cephalosporins like ceftriaxone.

The SFDA would like to advise healthcare professionals to be aware about the potential risk of hypersensitivity with the use of ceftriaxone. To minimize the risk of allergic reactions, healthcare professionals should consider the following:

- Before starting ceftriaxone therapy, obtain patient's medication history, including known drug allergies for previous and current medications, including other cephalosprorins or beta-lactam antibiotics. If the patient had an allergic reaction in the past, information about the medication used, route of administration should be obtained and documented in patient's medical history in order to take the appropriate action.
- Skin testing for cephalosporin allergy is not a standard practice because the positive and negative predictive value of skin testing have not been precisely defined or established
- Practitioners should be aware that an anaphylactic reaction is a part of continuum. Life-threatening symptoms might not immediately occur. Therefore, monitor patients upon first exposure to ceftriaxone, as early intervention is essential to prevent serious complications or fatality. Discontinuation of ceftriaxone in patients

developing early signs of anaphylactic reactions might be required to avoid serious manifestation.

- Patients should be informed to seek medical attention immediately if they develop early signs of allergic reactions after administration of ceftriaxone.

The SFDA urges healthcare professionals to report ADEs via any of the following contact information:

National Pharmacovigilance Center (NPC)
Saudi Food and Drug Authority-Drug sector
4904 Northern ring branch re-
Hitteen District
Riyadh 13513 - 7148
Kingdom of Saudi Arabia
Reporting hotline: 19999
Fax: +966112057662
Email: npc.drug@sfda.gov.sa
Webpage: http://ade.sfda.gov.sa