SFDA
Safety communication

[09/05/2022]

The Potential Risk of Major Congenital Malformations with the Use of Pregabalin in Pregnant Women

The Saudi Food and Drug authority (SFDA) would like to notify healthcare professionals about the potential risk of major congenital malformations associated with the use of pregabalin. Pregabalin indicated in adults for peripheral and central neuropathic pain, as adjunctive therapy in patients with partial seizures with or without secondary generalization, and for generalized anxiety disorder.

The concern for increased risk of major congenital malformations in the unborn child emerged from the Nordic observational study, which included more than 2,700 pregnancies exposed to pregabalin in the first trimester. The study showed that the adjusted prevalence ratio was slightly higher with pregabalin monotherapy in comparison to those not exposed pregabalin or to any antiepileptic medicines but not statistically significant (adjusted prevalence ratio (aPR) 1.14 (95% confidence interval (95% CI) 0.96 to 1.35)).However the exposure to pregabalin in the first trimester had statistically significant increase in the risk of major congenital malformations in comparison to lamotrigine (aPR 1.29 (95% CI 1.01 to 1.65)) or duloxetine (aPR 1.39 (95% CI 1.07 to 1.82)

Infants exposed to pregabalin had slightly greater risks of specific malformations of the neurological system, eye, face (orofacial clefts), urinary system, and genitals when compared to those exposed to lamotrigine, duloxetine or unexposed to any antiepileptic drugs.

Healthcare providers should advise patients to use effective contraception methods while receiving treatment and to avoid using pregabalin throughout pregnancy unless it is clearly necessary, taking into consideration the patient's unique circumstances. When the benefit clearly exceeds the risk and pregabalin is definitely necessary during pregnancy, it is suggested to:

- Use the lowest effective dose.
- Report any suspected adverse drug reactions, including those on infants.

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
E-mail: npc.drug@sfda.gov.sa
Website: https://ade.sfda.gov.sa