SFDA
Safety communication

[26/Apr/2021]

Potential Risk of Hyperglycemia with Use of Vemurafenib

The Saudi Food & Drug Authority (SFDA) would like to notify health care professionals about occurrence of Hyperglycemia with the use of Vemurafenib. The risk of developing hyperglycemia with use of vemurafenib increases in patients with preexisting diabetes or had a history of exposure to the other treatments known to cause hyperglycemia such as everolimus, decitabine, or ipilimumab.

Vemurafenib received approval by the SFDA for treatment of adult patients with BRAF V600 mutation-positive unresectable or metastatic melanoma. Hyperglycemia can lead to many serious life-threatening complications that include damage to the eye, kidneys, nerves, heart, and the peripheral vascular system, if left untreated.

We reviewed published literature and post marketing databases on the potential risk of hyperglycemia with vemurafenib use. Our review found nine published clinical trials and a single observational study, suggesting a temporal association between the hyperglycemia and vemurafenib use.

In addition, we identified 131 spontaneous case reports of hyperglycemia reported with the use of vemurafenib in the World Health Organization (WHO) database.

The SFDA evaluated thirteen cases with the highest completeness score, based on the WHO causality assessment system, three cases showed a probable association and eight cases showed possible association between hyperglycemia and vemurafenib. Most of the cases were serious and caused prolonged hospitalization with time to onset within 3 to 60 days after initiation of vemurafenib. The rest of cases were evaluated as un-assessable due to insufficient information.

Therefore, the SFDA request to update the products information of vemurafenib by adding hyperglycemia as a rare adverse event. In addition, the SFDA advises health care professional to inform their patients at increased risk of hyperglycemia about signs and symptoms of hyperglycemia and monitor the blood sugar levels closely.

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