SFDA SAFETY COMMUNICATION

18-04-2016

Saudi Food and Drug Authority (SFDA) – Risk of potentiation of radiation toxicity with Vemurafenib when given before, during, or after radiotherapy

The Saudi Food & Drug Authority (SFDA) would like to inform the healthcare professionals about the recent safety issue regarding the risk of potentiation of radiation toxicity with Vemurafenib when given prior to, during, or following radiotherapy.

Vemurafenib is a kinase inhibitor indicated for the treatment of patients with BRAF V600 mutation-positive unresectable or metastatic melanoma.

Recently, there has been 20 reports that associate radiation toxicity, in form of radiation recall or radiation sensitization, with the use of Vemurafenib, three of which had fatal outcomes. The majority of the cases were cutaneous in nature. However, some cases involved visceral organs (e.g. esophagitis, cystitis, brain and liver necrosis).

The SFDA concluded that Vemurafenib could potentiate radiation toxicity when given before, during, or after radiotherapy. As a result, the summary of product characteristics (SPC) and patient information leaflet (PIL) will be updated.

The SFDA advises healthcare professionals to use Vemurafenib with caution when given prior to, during, or following radiotherapy. Patients should be monitored closely when Vemurafenib is administered concomitantly or sequentially with radiation treatment.

Report Adverse Drug Events (ADRs) to the SFDA

The SFDA urges both healthcare professionals and patients to report ADRs resulted from using any medications to the SFDA either online, by regular mail or by fax, using the following contact information:

National Pharmacovigilance and Drug Safety Center (NPC)
Saudi Food and Drug Authority-Drug sector
3292 Northern Ring Road
Al Nafal District
Riyadh 13312 – 6288
Kingdom of Saudi Arabia
Toll free number: 8002490000
Tel: 01 2038222 ext. 2317, 2356, 2340, 5769
Fax: 01 2057662
Email: NPC.Drug@sfda.gov.sa