SFDA

Safety Communication

[10/05/2022]

Potential Risk of Rhabdomyolysis Associated with Alectinib use

The Saudi Food and Drug authority (SFDA) would like to notify healthcare professionals about the potential risk of rhabdomyolysis associated with the alectinib use.

The SFDA approved alectinib for the treatment of adult patients with ALK-positive advanced non-small cell lung cancer. Rhabdomyolysis is a potential life-threatening disorder, which involves the breakdown of damaged skeletal muscle, and leakage of large quantities of potentially toxic intracellular contents into plasma. The risk seems be increased with trauma, extreme physical activity, immobility, illicit drug use, some medications that may cause rhabdomyolysis.

We reviewed published literature and post marketing databases on the potential risk of rhabdomyolysis associated with alectinib use. Our review found sixteen spontaneously reported cases in the World Health Organization (WHO) database reported between 2014 and September 2021. The cases involved 10 male patients, and 6 female patients. The reported age range was between 36-75 years. All the reported cases were serious. Upon evaluation of WHO cases, two cases were found to be certainly associated with the use of alectinib. They were both male, 49 years-old and 53 years-old. The time to onset was about 14 days.

Therefore, the SFDA requests to update the product information of alectinib containing products by adding rhabdomyolysis as post marketing adverse event.

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