Saudi Food & Drug Authority (SFDA)
SAFETY COMMUNICATION

26/03/2018

Risk of Progressive Multifocal Encephalopathy (PML) Following Ofatumumab Use

The Saudi Food and Drug Authority (SFDA) would like to inform Healthcare Professionals (HCPs) about the risk of progressive multifocal encephalopathy (PML) following the ofatumumab use. The SFDA received considerable number of internationally reported cases of PML, including death cases, in patients treated with ofatumumab.

Ofatumumab is a prescription monoclonal antibody drug, which appears to treat chronic lymphocytic leukemia (CLL). A possible link between ofatumumab use and PML could be explained by the influence of ofatumumab on the immune system. Ofatumumab is known to suppress the immune system and PML occurs frequently in immunocompromised patients.

Based on the available information, the SFDA requested from the marketing authorization holder (the licensed agent by SFDA) to update ofatumumab's labelling by adding a black box warning concerning the risk of PML. The SFDA advises HCPs to seek out any signs or symptoms of PML in patients using ofatumumab, including those who develop new or worsening onset of neurological disorders. Ofatumumab therapy should be discontinued when PML was obviously figured out by a concerned HCP.

Report Adverse Drug Events (ADEs) to the SFDA

The SFDA urges healthcare professionals to report ADEs resulted from using Clarithromycin containing products to the SFDA 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
Reporting hotline: 19999
Fax: 01 2057662
Email: NPC.Drug@sfda.gov.sa
Webpage: www.sfda.gov.sa/npc