SFDA

Safety communication

[20/06/2021]

Potential Risk of Sleepwalking Associated with the Use of Olanzapine

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

The SFDA approved olanzapine for treatment of schizophrenia and bipolar disorder including mixed or manic episodes. Somnambulism or sleepwalking is an arousal parasomnia consisting of a series of complex behaviors initiated during slow-wave sleep that result in large movements in bed or walking during sleep. Sleepwalking can be caused by sleep deprivation, physical or emotional stress, certiain medcications, alcohol use and abuse, infection with a fever (especially in children), and other sleep disorders such as obstructive sleep apnoea and restless legs syndrome.

We reviewed published literature and post marketing databases on the potential risk of sleepwalking associated with olanzapine use. Our review found one case series for two patients and seven published case reports suggesting a possible association between the sleepwalking and olanzapine use. In addition, we identified 64 spontaneous case reports of somnambulism with olanzapine use in the World Health Organization (WHO) database, reported between 1999 and May 2021. Most reported cases was from the United States. The cases involved 32 males and 29 females, the rest of cases were unknown. Age ranges in most cases were between 45 to 64 years old. Among these cases, 32 cases reported as serious cases. Time to onset in most cases ranged from one day up to 8 years following olanzapine use. However, 16 cases reported concomitant confounding medications such as valproic acid, sertraline, haloperidol, and mirtazapine. The proposed mechanism of olanzapine induced sleepwalking is due to increase slow wave sleep via blockade of o 5-hydroxytryptamine (5-HT) 2C receptors.

Therefore, the SFDA requests to update the product information of olanzapine containing products by adding sleepwalking 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