

## SFDA

### Safety Communication

[1/11/2023]

#### **The Potential Risk of Inappropriate Antidiuretic Hormone Secretion with the Use of Products Containing Olanzapine.**

The Saudi Food and Drug authority (SFDA) would like to notify healthcare professionals about the potential risk of the syndrome of inappropriate antidiuretic hormone secretion (SIADH) associated with the use of olanzapine containing products.

Olanzapine is an atypical antipsychotic drug which works by modulating serotonin (5-hydroxytryptamine), norepinephrine and/or histamine neurotransmission as well. It's approved in Saudi Arabia for the treatment of schizophrenia, moderate to severe manic episode, and for the prevention of recurrence of manic episode in patients with bipolar disorder.

The SFDA reviewed the current evidence including published literature and post-marketing data on the potential risk of SIADH with the use of olanzapine containing products. The review identified several published cases suggesting a possible association between olanzapine containing products and SIADH. Additionally, the SFDA identified 448 spontaneous case reports of SIADH reported with olanzapine use in the World Health Organization (WHO) database.

Therefore, the SFDA requests to update the product information of olanzapine containing products as following:

Section 4.8: Undesirable Effects:

*Endocrine disorders: syndrome of inappropriate antidiuretic hormone secretion (frequency unknown)*

It is noteworthy to mention that SIADH adverse event is already included in the product information of other atypical antipsychotics such as paliperidone, amisulpride, risperidone and quetiapine.

For further information on registered olanzapine containing products, please visit the SFDA [Drug List](#)

**Call for reporting:**

The SFDA urges both healthcare professionals and patients to report ADRs related to use of any drug/vaccine to the SFDA using the following contact information:

The National Pharmacovigilance Centre (NPC):

Call Center: 19999

E-mail: [npc.drug@sfd.gov.sa](mailto:npc.drug@sfd.gov.sa)

Website: <https://ade.sfd.gov.sa>

Risk Minimization Measures:

