



24/05/2016

SFDA SAFETY COMMUNICATION

Saudi Food and Drug Authority (SFDA) –Anticholinergic Drugs and Cognitive Problems in Elderly

The Saudi Food and Drug Authority (SFDA) would like to notify Health Care Professionals (HCPs) that certain anticholinergic drugs might be associated with cognitive impairment and an increased risk of memory loss, known as dementia, in elderly patients. The risk appears to increase with high doses and with longer use of anticholinergic drugs.

The anticholinergic drugs are widely used for various conditions including vomiting, gastrointestinal spasms, bladder problems, Parkinson treatment, and depression. In addition, some of these drugs are available as over the counter (OTC) products such as antihistamines for allergy relief or sleep disorders.

On 2015, the SFDA reviewed all available evidence on the association of anticholinergic drugs with cognitive impairment and dementia in older adults. The SFDA concluded that there is a potential risk of cognitive impairment and dementia with long-term use of anticholinergic drugs and the general awareness about this risk is low.

A recent study followed 402 older adults with normal cognition (mean age, 73), 52 of whom were taking at least one medication with medium or high anticholinergic activity, for around 32 months. The study found that patients who regularly took at least one anticholinergic drug developed poor cognition, brain structure changes and less glucose metabolism in the brain, which may reinforce the concerns regarding this risk.

The SFDA emphasizes that anticholinergic drugs should be used with caution in elderly patients. The SFDA advises HCPs to consider the lowest effective dose of anticholinergic drugs with regular monitoring for the signs of confusion or dementia in elderly patients particularly when prescribing any of these drugs for a long-term use.

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