SFDA SAFETY SIGNAL

"A signal is defined by the SFDA as reported information on a possible causal relationship between an adverse event and a drug, the relationship being unknown or incompletely documented previously. Usually more than a single report is required to generate a signal, depending upon the seriousness of the event and the quality of the information. A signal is a hypothesis together with data and arguments and it is important to note that a signal is not only uncertain but also preliminary in nature".

23/11/2016

Saudi Food and Drug Authority (SFDA) – Reports of Potential Signal of Hypotension Associated with the Use of Etanercept

Etanercept is a human tumor necrosis factor (TNF) inhibitor used to treat rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, plaque psoriasis and Paediatric plaque psoriasis.

Low blood pressure (hypotension) occurs when blood pressure is much lower than normal. This means the heart, brain, and other parts of the body do not get enough blood.

The SFDA has investigated a potential signal of association of etanercept and hypotension raised from local serious adverse drug reaction (ADR) report. The World Health Organization (WHO) global database of ADRs has been searched using MedDRA preferred terms Hypotension and Etanercept Five hundred and thirty-three international ADR reports has been found, 474 cases were not sufficiently documented for proper medical assessment. Out of the remaining 59 cases, one case has reported a positive dechallenge* and rechallenge** reaction.

The currant available evidence does not support a causal relationship between etanercept and hypotension. However, the high number of internationally reported cases may indicate potential association and warrants further investigation. Therefore, the SFDA encourages healthcare provider and patient on etanercept to monitor the BP regularly and report any adverse drug events that might occurs.

The SFDA will continue closely monitoring this event and will update healthcare provider if new information has raised.

* Dechallenge: This refers to the stopping of the drug, usually after an adverse event (AE) or at the end of a planned treatment.

** Rechallenge: his refers to the restarting of the same drug after having stopped it, usually for an AE.

Report Adverse Drug Events (ADRs) to the SFDA

The SFDA urges both healthcare professionals and patients to continue reporting adverse drug reactions (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: 011 2038222 ext. 2317, 2356, 2340,
Fax: 011 2057662
Email: NPC.Drug@sfda.gov.sa