



## **SFDA SAFTEY COMMUNICATION**

September 9<sup>th</sup>, 2013

### **Saudi Food and Drug Authority (SFDA) PRESS RELEASE- skin reactions associated with paracetamol**

The Saudi Food and Drug Authority would like to share recent information regarding the use of paracetamol containing products. It has been recently found that paracetamol could be associated with serious skin reactions Such as; Stevens-Johnson Syndrome (SJS), Toxic Epidermal Necrolysis (TEN) and Acute Generalized Exanthematous Pustulosis (AGEP). These reactions could be considered as rare, serious and fatal in some cases. It is difficult to determine how frequent these reactions can occur with paracetamol because of the widespread use of the drug. However, in the United States, 170 cases were reported having skin reactions associated with paracetamol between 1969 and 2012, of which 67 resulted in hospitalizations and 12 in death. Healthcare Providers should be aware about any skin reactions develop in patients using paracetamol even for those who used paracetamol previously.

### **Report Adverse Drug Reactions (ADRs) to the Saudi FDA**

The SFDA urges both healthcare professionals and patients to report ADRs resulted from using such a medication and other 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: 8002490000  
Tel: 011-2038222 ext. 2354, 2317,2340  
Fax: 011-2057662  
Email: [NPC.Drug@sfda.gov.sa](mailto:NPC.Drug@sfda.gov.sa)  
Online: : <http://ade.sfda.gov.sa/>