



SFDA SAFTEY COMMUNICATION

19 February 2012

Saudi Food and Drug Authority (SFDA) PRESS RELEASE – Benzyl Alcohol Containing Parentral Products and The Risk of Gaspig Syndrome

The Saudi Food and Drug Authority (SFDA) would like to advise healthcare professionals (HCP) about the potential risk of developing a life threatening condition called “Gaspig Syndrome” in neonates and infant after administering parentral products that contain benzyl alcohol as a preservative.

Benzyl alcohol is metabolized to benzoic acid, which is further conjugated in the liver and excreted as hippuric acid. Nonetheless, the conjugation process may not be well developed in premature infants. Therefore, benzoic acid, may accumulate resulting in metabolic acidosis.

Several case reports of Gaspig syndrome were reported after administering flushing solution containing benzyl alcohol in pre-term neonates. Observational studies also suggest a decrease in the rate of Gaspig syndrome after abstaining from the use of products containing benzyl alcohol in the practice. It should be noted that the toxic quantity cannot be estimated. Therefore, the safety of use of medicines containing benzyl alcohol in neonates has not been established.

Consideration for Healthcare Professionals

1. The use of benzyl alcohol containing diluents in preparing injectable medicines for pediatric patients is not recommended
2. When applicable, use acceptable alternative medicines that do not contain benzyl alcohol
3. Healthcare professionals should be aware about the potential risk of Gaspig syndrome and to weight the benefits compared to potential risks when using benzyl alcohol-containing parentral products

A call for reporting

SFDA will continue to monitor the safety of medicines in Saudi Arabia. For more information, please visit the Saudi Food and Drug Authority website: www.sfda.gov.sa SFDA encourages healthcare professionals to report adverse drug events through the following methods:

Regular mail:

The National Pharmacovigilance and Drug Safety Centre
Saudi Food and Drug Authority-Drug sector
3292 Northern Ring Road- Alnafal District
Riyadh 13312-6288

Telephone: 800249000 or 012759222 Ext 2353, 2317, 2356, or 2340

Fax: 012057662

Email: npc.drug@sfda.gov.sa