

May 7th, 2013

Title: The use of codeine containing products for children after tonsillectomy and /or adenoidectomy surgery

Dear Healthcare Professional;

Summary

GlaxoSmithKline Consumer Healthcare would like to inform you about important recent safety information concerning the need to avoid use of codeine in children after tonsillectomy and /or adenoidectomy surgery. There is an increased risk of serious adverse effects in children who receive codeine for pain relief following tonsillectomy and/or adenoidectomy; therefore codeine and codeine containing products should be contraindicated in children for post surgery pain relief. The Saudi Food and Drug Authority (SFDA) has reviewed the safety profile of Codeine and it was observed that deaths have occurred in children with obstructive sleep apnea who took codeine for pain relief after tonsillectomy and/or adenoidectomy. These children had evidence of being ultra-rapid metabolizers of codeine, the result of a genetic variation whereby codeine is metabolized to morphine at a greater rate and extent versus the general population. Ultra-rapid metabolizers are more likely to have higher-than-normal levels of morphine in their blood after taking codeine.

Further information for Health care providers

- You are requested to prescribe an alternate analgesic for post-operative pain control in children who are undergoing tonsillectomy and/or adenoidectomy. Codeine containing products should not be used for pain relief in children following these procedures.
- GlaxoSmithKline marketed Solpadeine Capsule and Solpadeine Soluble tablet, contain a combination of paracetamol, caffeine and codeine. Solpadeine is indicated for relief of mild to moderate pain and fever. When used as per recommended doses within the licensed indication, healthcare professionals should be vigilant for any unusual symptoms such as sleepiness, confusion, or difficult or noisy breathing which could be indicative of

higher-than-normal levels of morphine which may be suggestive signs of ultra-metabolism of codeine.

- The Solpadeine product labeling will be updated to include the following contraindication **'The use of codeine should be avoided for children after tonsillectomy and /or adenoidectomy surgery'**.

The information in this letter has been agreed with the Saudi Food and Drug Authority (SFDA).

Call for reporting:

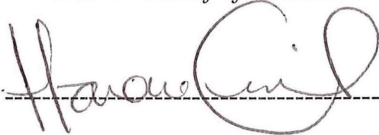
For reporting adverse reactions, please contact Dr. Faisal Shujrah on fax: +96626536660 or by email: faisal.m.shujrah@gsk.com or to:

National Pharmacovigilance and Drug Safety Centre

Fax: +966-1-2057662

Email: npc.drug@sFDA.gov.sa.

Thanks & Regards
Yours respectfully,
For and On behalf of GlaxoSmithKline,



Dr. Hanan Emil,
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