July 8th t, 2013

Re: Cilest® recall all batches

Dear Healthcare Provider:

Janssen would like to inform you that all batches of Cilest® an oral contraceptive will be recalled from the Saudi Arabian market.

Summary

The reason for the recall is that dissolution testing of norgestimate yielded an out of specification test result after 30 minutes in two batches, one at 24 months interval and the other at 18 months interval. The average dissolution at 30 minutes for norgestimate was 67% versus the specification limit of ≥ 70%. Sixty minute results met specifications with an average of 81% (specification limit ≥80%). Dissolution test results for ethinyl estradiol at both 30 and 60 minutes met specifications.

Based on the review of the norgestimate dissolution data and review of the available post-marketing safety data, the likelihood of women experiencing an adverse event related to the slower than expected dissolution of norgestimate appears to be very low.

Theoretically, a slower release of norgestimate could result in a decreased contraceptive efficacy. However, this possibility is unlikely as Cilest® is an oral tablet that is only taken once daily. Achieving adequate norgestimate drug levels in 60 minutes rather than 30 minutes would not be expected to impact the 24 hour drug exposure.

A trend analysis in our internal safety database on indicative of lack of effect and pregnancy data for Cilest® conducted for the period between 01 January 2009 and 31 December 2012, the time during which the affected batches were on the market, showed a decline in the number of reports received on lack of efficacy and pregnancy.

The Company is evaluating options to resupply the markets in shortest possible timeframe.

Information for Health Care Providers

Please do not put new patients on to Cilest® as there will be an out of stock situation for a couple of weeks. Patients already on Cilest® should be switched to another oral contraceptive if they run out of stock.

As always, if you receive reports of lack of efficacy or any other adverse event in a patient using Cilest®, please report the adverse event and include the batch number in the report whenever possible.

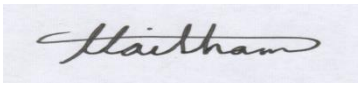
The information in this letter has been agreed with the Saudi Food and Drug Authority (SFDA).

Call for reporting:

- Janssen Scientific Office
    - E-mail to: GCC-PV@its.jnj.com or amohamed1@its.jnj.com
    - Fax : +966-11-2153190 ext.4609 /4711
    - Mobile : +966540015811

- SFDA (National Pharmacovigilance and Drug Safety Center)
- E-mail to: npc.drug@sfda.sa.
- Fax: +966 -11- 2057662.

Yours sincerely,



Haitham Al-Zuhair

Regulatory Affairs Director, GCC