JANSSEN
SIN EL-FIL
GENERAL CHEHAB AVENUE
(Near Clinique du Levant)
Beirut-LEBANON

Malta June 3, 2013

Re: Direct Healthcare Professional Communication, Cilest® recall all batches

Dear Healthcare Provider,

Janssen-Cilag International would like to inform you that all batches of Cilest® an oral contraceptive will be recalled on a wholesaler and pharmacy level.

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 a woman 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.

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 according to the local regulations and include the batch number in the report whenever possible.

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

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.

Call for reporting
We remind you that any suspected adverse reaction should be reported according to the national spontaneous reporting system. **Any suspected adverse drug reactions can be reported to:**

Medicines Authority Post-licensing Directorate, 203, Level 3, Rue D'Argens, Gżira GŻR 1368,
MALTA, or at: http://www.medicinesauthority.gov.mt/adrportal
Telephone Number: +356 2343 9000

Or to

AM Mangion Ltd, N/S off Valletta Road, Luqa LQA 6000, Telephone Number + 356 2397 6333 or on pv@ammangion.com.mt

Alternatively, adverse events may be reported to the address representing the Marketing Authorization Holder below:

Janssen-Cilag International, Turnhoutseweg 30, 2340 Beerse, Belgium

Communication information

Should you have any questions please contact:

Janssen Regional office:

Mr. Hassan Bibi, Regional Regulatory Affairs Director
Dr. Tony Bou Khalil, Medical Affairs Manager
Ms. Marie Jose Sabbagh, Regional Quality Executive
Tel: (+961.1)518700
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Or

The responsible contact persons in Malta
Mr. Alan Mulligan, Regulatory Affairs Coordinator
Tel: + 356 2397 6000

Yours faithfully,

Hassan Bibi

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