



Medicines Authority
Inspectorate and Enforcement Division
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Drug Alert
CLASS 2 MEDICINES RECALL
ACTION WITHIN 48 HOURS

Date: **28th May 2013**

Our Ref: **MDR 14-05/13**

Dear Responsible person for Wholesale Dealer/Managing Pharmacist/General Public

Cilest[®] 250/35 tablets
(250mcg norgestimate 35mcg ethinyl estradiol)

- MA 018/00501
- PI908/03401A
- PI521/05601A

Batch Number	Expiry date	Pack size	First distributed
All Batches	All	One pack size	All

The Inspectorate and Enforcement Directorate within the Medicines Authority were informed that Janssen-Cilag International N.V. are initiating a voluntary preventative product recall of Cilest[®] 250/35 Oral Contraceptive Tablets (250µg norgestimate 35µg ethinyl estradiol).

The company reports a failure of the norgestimate dissolution test at the 24 and 18 months stability time points. Slowed dissolution can potentially lead to decreased contraceptive efficacy. The likelihood of a patient experiencing an adverse event related to the slower than expected dissolution of norgestimate appears to be very low.

A recall of Cilest[®] is being affected from wholesaler dealers and pharmacies.

A press release is being issued advising patients to contact their prescribing doctor for advice on continuation of their treatment.

Regards

Christopher Attard
Medicines Inspector