Drug Alert

CLASS 2 MEDICINES RECALL

Action Within 48 Hours

Date: 13th May 2016

Our Ref: MDR 010-05/2016

Dear Healthcare Professional,

GlaxoSmithKline (Malta) Limited

1 (first floor) Floor, De la Cruz Avenue
Qormi QRM 2458
Malta

Actifed tablets **MA167/00104**

(Pseudoephedrine hydrochloride /

Triprolidine hydrochloride)

Batch Number	Expiry Date	Pack Size	First Distributed
B9944A	31th January 2018	x24	29th May 2014

Under the supervision of the Medicines Authority, GSK Malta Ltd. in collaboration with Alfred Gera & Sons Ltd. (the local agent/distributor) is recalling Actifed tablets (pseudoephedrine hydrochloride/triprolidine hydrochloride), batch number **B9944A** up to pharmacy level.

The Medicines Authority has been notified by GSK Malta that a recent Out of Specification (OOS) investigation at the Aspen Bad Oldesloe site has identified an error in the calculations of the assay method to determine triprolidine content.

As a consequence of the incorrect calculation, all the batches in shelf life have been released reporting an incorrect amount of triprolidine (approximately 5% above the actual content) in the assay test. The recalculation of the triprolidine assay results has revealed that 1 bulk batch was released with triprolidine content below the lower limit of the release specification for this test. This affects 1 packed batch: **B9944A**

With respect to the rest of Actifed tablets batches within shelf life distributed in Malta, despite the calculation error, once corrected it is confirmed all of them complied with the triprolidine content specification at the time of release.

No other Actifed products are impacted by this issue.

Wholesale dealers and pharmacies are asked to quarantine all stock of the above product with batch number **B9944A** and follow the recall instructions of GSK Malta Ltd.

Yours faithfully,

Judit FEHÉR
Medicines Inspector

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