

Drug Alert

CLASS 2 MEDICINES RECALL

Action Within 48 Hours

Date: 17th December 2013

Our Ref: MDR 5-12/13

Dear Healthcare Professional,
George Borg Barthet Ltd

Product	Batch	Expiry
Tixylix Chesty Cough 100ml	2RR	01.08.2015
	1RR	01.08.2015
Tixylix Baby Cough 100ml	10RR	01.11.2015
	2SS	01.12.2015
Tixylix Toddler Cough 100ml	5RR	01.09.2015
	7RR2	01.09.2015
	2VV	01.06.2016

The above batches of medicinal are being recalled up to patient level as a precautionary measure by George Borg Barthet Ltd (local distributor) representing Alston Garrard & Co. Ltd. (Marketing Authorisation Holder) under the supervision of the Malta Medicines Authority.

The Medicines Authority was alerted to a potential manufacturing fault with the tamper seal on some Tixylix® liquid medicines which might result in small pieces of plastic being found in the medicine. This potential defect only affects specific batches of Tixylix manufactured from October 2012 onwards.

No evidence of defective products has been identified in the market, and there have been no reports of adverse events.

Pharmacists and wholesale dealers are asked to quarantine all unexpired stock of the product and return it to their original supplier.

Patients are asked to contact George Borg Barthet Ltd on 21244205 for details on how to return the product.

Yours faithfully

Karl De Marco
Medicines Inspector

Medicines Authority Distribution (if applicable): Not Applicable