

DRUG ALERT

CLASS 2 MEDICINES RECALL

**Action Within 48 Hours
Patient Level Recall**

Date: 13 December 2013

EL (13)A/30

Our Ref: MDR 47-11/13

Dear Healthcare Professional,

Novartis Consumer Health UK Ltd

Tixylix Toddler Syrup 100ml (Glycerol)	PL 00030/0150
Tixylix Toddler Syrup 150ml (Glycerol)	PL 00030/0150
Tixylix Baby Syrup 100ml (Glycerol)	PL 00030/0150
Tixylix Blackcurrant Flavour Syrup 100ml (Glycerol)	PL 00030/0150
Tixylix Chesty Cough 100ml (Guaifenesin)	PL 00030/0082

Novartis Consumer Health UK Ltd have been 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 Oct 2012 onwards and as a precautionary measure these batches are being recalled to patient level. The specific batches subject to recall are listed on pages 2 and 3.

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

Pharmacists and retailers are asked to quarantine all unexpired stock of the product and return it to their original supplier for credit

Consumers are asked to contact Novartis Consumer Health on 0800 854 100 or tixylix.co.uk for details on how to return product.

For medical information queries and questions relating to the recall, please contact Novartis Consumer Health on 0800 854 100.

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As the majority of these products are GSL medicines, this notification will be supported by press notifications by the marketing authorisation holder and the MHRA.

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this letter. Local area teams are asked to forward this to relevant clinics, general practitioners and community pharmacists for information.

Yours faithfully

Adam Burgess

Defective Medicines Report Centre
151 Buckingham Palace Road
London
SW1W 9SZ
Telephone +44 (0)20 3080 6574

Affected batches

Tixylix Chesty Cough 100ml

Batch Number	Expiry Date	Pack Size	First Distributed
1RR	01/08/15	1 x 100ml	26/02/2013
1TT	01/05/16	1 x 100ml	25/11/2013
2RR	01/08/15	1 x 100ml	26/02/2013

Tixylix Toddler Syrup 100ml

Batch Number	Expiry Date	Pack Size	First Distributed
10SS2	01/02/16	1 x 100ml	14/06/2013
11SS	01/02/16	1 x 100ml	17/06/2013
12RR	01/11/15	1 x 100ml	13/02/2013
13RR	01/11/15	1 x 100ml	08/03/2013
13RR2	01/11/15	1 x 100ml	16/04/2013
1RR	01/09/15	1 x 100ml	27/11/2012
1TT	01/02/16	1 x 100ml	27/08/2013
2RR	01/09/15	1 x 100ml	29/11/2012
2VV	01/06/16	1 x 100ml	15/10/2013
3RR	01/09/15	1 x 100ml	26/11/2012
4RR	01/09/15	1 x 100ml	03/12/2012
4VV	01/06/16	1 x 100ml	05/11/2013
5RR	01/09/15	1 x 100ml	19/12/2012
5VV	01/06/16	1 x 100ml	21/11/2013
6RR	01/09/15	1 x 100ml	18/12/2012
6VV	01/06/16	1 x 100ml	23/09/2013
7RR	01/09/15	1 x 100ml	11/01/2013
7RR2	01/09/15	1 x 100ml	10/01/2013
7VV	01/06/16	1 x 100ml	26/11/2013
8RR	01/10/15	1 x 100ml	14/02/2013
9RR	01/10/15	1 x 100ml	29/01/2013
9SS	01/02/16	1 x 100ml	30/09/2013

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Tixylix Toddler Syrup 150ml

Batch Number	Expiry Date	Pack Size	First Distributed
12SS	01/02/16	1 x 150ml	19/09/2013
14RR	01/11/15	1 x 150ml	01/03/2013

Tixylix Baby Syrup 100ml

Batch Number	Expiry Date	Pack Size	First Distributed
10RR	01/11/15	1 x 100ml	31/01/2013
11RR	01/11/15	1 x 100ml	04/02/2013
1SS	01/11/15	1 x 100ml	05/03/2013
2SS	01/12/15	1 x 100ml	29/05/2013
2TT	01/02/16	1 x 100ml	17/10/2013
8SS2	01/01/16	1 x 100ml	01/10/2013
8VV	01/06/16	1 x 100ml	22/11/2013

Tixylix Blackcurrant Flavour Syrup 100ml

Batch Number	Expiry Date	Pack Size	First Distributed
1VV	01/06/16	1 x 100ml	15/10/2013
3VV	01/07/16	1 x 100ml	12/09/2013
3VV2	01/06/16	1 x 100ml	07/08/2013