

DRUG ALERT

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Distribute to Hospital Pharmacy Level

Date: 15 October 2014

EL (14)A/15

Our Ref: MDR 50-09/14

Dear Healthcare Professional,

Beecham Group PLC and Beecham Group Ltd trading as GlaxoSmithKline UK

Amoxil Vials for Injection 500mg	PL 00038/0222
Amoxil Vials for Injection 1g	PL 00038/0225
Augmentin Intravenous 600mg	PL 00038/0320
Augmentin Intravenous 1.2g	PL 00038/0320

Product	Batch Number	Expiry Date	Pack Size	First Distributed
Amoxil 500mg	637179	18 Apr 2015	1 x 10	01/08/2013
Amoxil 500mg	644732	18 Apr 2015	1 x 10	08/11/2013
Amoxil 1g	637276	18 Apr 2015	1 x 10	04/08/2013
Augmentin 600mg	619927	28 Dec 2014	1 x 10	18/04/2013
Augmentin 600mg	629800	01 Jan 2015	1 x 10	31/05/2013
Augmentin 600mg	638735	10 Apr 2015	1 x 10	23/09/2013
Augmentin 600mg	648688	11 Apr 2015	1 x 10	15/11/2013
Augmentin 600mg	671149	17 Jul 2015	1 x 10	07/05/2014
Augmentin 600mg	671150	13 Nov 2015	1 x 10	25/04/2014
Augmentin 600mg	676171	02 Jan 2016	1 x 10	08/07/2014
Augmentin 1.2g	622808	21 Nov 2014	1 x 10	19/04/2013
Augmentin 1.2g	629852	29 Jan 2015	1 x 10	10/06/2014
Augmentin 1.2g	633467	30 Jan 2015	1 x 10	03/07/2013
Augmentin 1.2g	640863	08 Nov 2014	1 x 10	19/09/2013
Augmentin 1.2g	647734	28 May 2015	1 x 10	07/02/2014
Augmentin 1.2g	663747	26 Jul 2015	1 x 10	10/04/2014

GlaxoSmithKline has informed us of a very low incidence of cracks being found in vials used for packaging of the above products. The cracks are positioned where the base of the vial meets the side wall and there are concerns that sterility may be breached in affected vials. Although the defect has to date been identified in a limited number of batches, all the above batches use the same type of vial and may potentially be affected.

Cont/.....

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In order to avoid product shortages, the above batches are not being recalled. Recipients of these batches are asked to check each vial for cracks prior to use by turning upside down and looking for chips, cracks or damage where the base meets the side wall. The contents of the vials should only be used if the solution is a colourless or pale straw coloured liquid upon reconstitution. If any cracked or discoloured vial is identified, please retain and contact GlaxoSmithKline Medical Information on 0800 221 441 to return product.

Please note: For Augmentin a transient pink colouration may or may not develop during reconstitution. For Amoxiil, a transient pink colouration or slight opalescence may appear during reconstitution.

If you have any enquiries concerning this incident, please contact GlaxoSmithKline Medical Information, tel 0800 221 441 email customercontactuk@gsk.com

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this letter.

Yours faithfully

Alison Bunce

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