DRUG ALERT

CLASS 2 MEDICINES RECALL

Action Within 48 Hours
Pharmacy, Dispensing Clinic and Wholesale Level Recall

Date: 28 July 2014 EL (14)A/12 Our Ref: MDR 40-03/14

Dear Healthcare Professional,

ViroPharma SPRL

Buccolam 2.5mg Oromucosal Solution	**EU/1/11/709/001**
Buccolam 5mg Oromucosal Solution	**EU/1/11/709/002**
Buccolam 7.5mg Oromucosal Solution	**EU/1/11/709/003**
Buccolam 10mg Oromucosal Solution	**EU/1/11/709/004**

(Midazolam Hydrochloride)

ViroPharma SPRL is recalling specific batches of Buccolam Oromucosal Solution, listed in the attached appendix, following a routine inspection of the company's contract manufacturing site in the UK. The inspection identified the possibility for chemical contamination. No evidence of contamination has been identified within Buccolam Oromucosal Solution on the market.

Replacement stocks of Buccolam are available. Pharmacists are asked to quarantine any remaining stocks of the batches listed in the Appendix and return them to the original wholesaler for credit. For stock enquiries please contact Michelle Barber at UDG on 01773 515124 or by email to UDGCREDITCLAIMS@UDG.CO.UK.

For medical information enquires please contact Christopher Rains, ViroPharma SPRL Medical Information on 0800 7312801 or by email to uk.medinfo@viropharma.com.

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

Alison Bunce
Defective Medicines Report Centre
151 Buckingham Palace Road
London
SW1W 9SZ
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Appendix

Buccolam 2.5mg Oromucosal Solution EU/1/11/709/001

Batch Number	Expiry Date	Pack Size	First Distributed
1304029	30/09/2014		13/6/2013
1304071	30/11/2014		13/8/2013
1308017	31/12/2014		8/11/2013
1309008	28/02/2015		4/2/2014
1310011	28/02/2015		19/2/2014
1311027	30/04/2015		11/4/2014
1401040	30/04/2015		13/5/2014
1405019	30/06/2015		17/6/2014

Buccolam 5mg Oromucosal Solution EU/1/11/709/002

Batch Number	Expiry Date	Pack Size	First Distributed
1301060	31/08/2014		2/5/2013
1303014	30/09/2014		19/6/2013
1303016	31/10/2014		8/7/2013
1304028	30/11/2014		2/9/2013
1307034	31/10/2014		23/8/2013
1309024	31/01/2015		19/12/2013
1310001	31/12/2014		21/11/2013
1310012	31/03/2015		11/2/2014
1310056	30/04/2015		17/4/2014
1311054	30/04/2015		11/4/2014
1401002	30/06/2015		25/6/2014

Buccolam 7.5mg Oromucosal Solution EU/1/11/709/003

Batch Number	Expiry Date	Pack Size	First Distributed
1302032	31/08/2014		21/5/2013
1303017	30/09/2014		26/6/2013
1304067	30/09/2014		10/9/2013
1306021	30/11/2014		16/9/2013
1307002	30/11/2014		20/9/2013
1307052	31/12/2014		1/10/2013
1309006	31/03/2015		1/11/2013
1310013	31/03/2015		31/1/2014
1311028	30/04/2015		12/3/2014
1311053	28/02/2015		7/1/2014
1311055	30/04/2015		10/4/2014
1312001	31/05/2015		22/5/2014
1405018	31/07/2015		24/6/2014

Buccolam 10mg Oromucosal Solution **EU/1/11/709/004**

Batch Number	Expiry Date	Pack Size	First Distributed
1301043	31/07/2014		25/3/2013
1301057	31/08/2014		29/4/2013
1301058	31/08/2014		21/5/2013
1301079	31/08/2014		11/6/2013
1303015	30/09/2014		18/7/2013
1303020	30/11/2014		29/8/2013
1303021	31/12/2014		17/9/2013
1303022	31/08/2014		8/7/2013
1304026	31/12/2014		15/10/2013
1304027	30/09/2014		19/8/2013
1307032	31/01/2015		8/11/2013
1307033	31/01/2015		3/12/2013
1308015	31/01/2015		30/12/2013
1308016	31/01/2015		28/1/2014
1310014	31/03/2015		25/2/2014
1310040	31/03/2015		19/3/2014
1310053	28/02/2015		21/2/2014
1311025	30/04/2015		9/4/2014
1311052	30/04/2015		8/5/2014
1312007	31/05/2015		26/5/2014
1401034	30/06/2015		17/6/2014
1401069	31/07/2015		22/07/14