

BATCH RECALL – see page 2 for listed batches**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 (Midazolam Hydrochloride)	EU/1/11/709/004

28 July 2014,

Dear Pharmacist,

We wish to advise you that the batches of Buccolam Oromucosal Solution listed in the attached Appendix are being recalled with immediate effect. This recall is going to pharmacy level. Replacement batches are immediately available in Ireland.

This action has been agreed with the Health Products Regulatory Authority (formally known as the IMB).

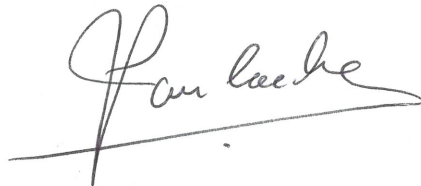
The reason for the recall is that insufficient manufacturing and equipment cleaning controls were found to be in place during an inspection at the manufacturing site which produces the Buccolam product. As a consequence of this finding, there is a theoretical risk of cross-contamination with Amsacrine at the manufacturing site. This risk has been assessed as being very low. There is no evidence of any actual cross-contamination having occurred, and no Amsacrine has been detected in any batch of Buccolam during product testing. Nevertheless, these batches of Buccolam are being recalled to pharmacy level as a precautionary measure.

Please immediately quarantine any units of the Buccolam batches listed in the attachment which you have in your pharmacy and return them to the wholesaler who supplied them to you. The last date by which returned stock will be received back for credit is August 30th, 2014. For Hospital Pharmacies: Please ensure that the above quarantine and return request extends to packs that may be at ward level in your hospital, or at any other location within your hospital.

We apologise for any inconvenience this action may cause. Should you have any queries, please contact Christopher Rains, ViroPharma SPRL Medical Information, on 0044800 7312801 or by email to uk.medinfo@viropharma.com.

Yours sincerely,

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Appendix to the Buccolam Oromucosal Solution Recall Letter dated July 28th, 2014
Buccolam 2.5mg Oromucosal Solution
EU/1/11/709/001

Batch	Expiry date	1st date of distribution
1304029	30/09/2014	01/07/2013
1304071	30/11/2014	26/08/2013
1309008	28/02/2015	18/12/2013
1311027	30/04/2015	12/02/2014
1401040	30/04/2015	25/06/2014
1405019	30/06/2015	04/07/2014

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

Batch	Expiry date	1st date of distribution
1301060	31/08/2014	07/05/2013
1303014	30/09/2014	27/06/2013
1304028	30/11/2014	04/10/2013
1306020	31/10/2014	05/09/2013
1309024	31/01/2015	14/01/2014
1401002	30/06/2015	12/05/2014

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

Batch	Expiry date	1st date of distribution
1303017	30/09/2014	15/08/2013
1306021	30/11/2014	04/10/2013
1309006	31/03/2015	07/02/2014
1312001	31/05/2015	11/06/2014

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

Batch	Expiry date	1st date of distribution
1301043	31/07/2014	02/04/2013
1303018	30/09/2014	26/06/2013
1303020	30/11/2014	16/10/2013
1309022	28/02/2015	19/11/2013
1311026	30/04/2015	25/02/2014
1311052	30/04/2015	02/04/2014
1401001	30/06/2015	25/04/2014
1401034	30/06/2015	21/05/2014
1401069	31/07/2015	08/07/2014