VIROPHARMA

## 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** | **EU/1/11/709/004** |

**(Midazolam Hydrochloride)**

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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Company Registry Brussels 0898.258.897 | VAT BE 0898.258.897
EUR a/c : IBAN BE29 5490 0372 0164 | BIC : CHASBEBX
GBP a/c : IBAN GB21 CHAS 6092 4240 6385 04 | BIC : CHASGB2L
USD a/c : IBAN GB75 CHAS 6092 4240 6385 02 | BIC : CHASGB2L

## 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 |



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USD a/c : IBAN GB75 CHAS 6092 4240 6385 02 | BIC : CHASGB2L