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Shire

Batch Recall

See Appendix 1 for Batch Listing

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**

28 August 2018

Dear Pharmacist,

We wish to advise you that the batches of Buccolam listed in Appendix 1, attached, are being recalled with immediate effect.

This recall has been agreed with the Health Products Regulatory Authority (HPRA).

This is a pharmacy-level recall only. However, you are requested to take certain actions with respect to packs currently at patient level. These actions are listed on page 2 of this letter.

The reason for the recall is that there is the potential for a quality defect to be present in the syringe cap components. This cap is composed of two different plastic parts – a red part and an inner translucent part which should come off the syringe together when the cap is removed. The nature of the defect is that, when removing the cap from the syringe, the inner translucent part of the cap may stay on the syringe tip and it may not be removed with the red part. This presents a risk that the translucent part could get transferred into the patient's mouth when administering the medicine and it could be inhaled or ingested, leading to a risk of choking.

In response to this defect issue and, due to the fact that a recall would have caused a stock shortage at the time, Shire sent a Direct Healthcare Professional Communication to all pharmacists in November 2017. This was followed in January 2018 by a Dear Caregiver Letter for carers of Buccolam patients (this is shown in appendix 2). The Dear Caregiver Letter has been attached to all packs released for distribution to Ireland since 19/01/2018, in order to make carers aware of the defect, so that they could check the syringe tip before administering the medicine.

Please immediately quarantine any units of any of the batches listed in Appendix 1 which you have in your possession and return them to your wholesaler for credit or replacement, by 14th September. For hospital pharmacists, this includes all units at ward or clinic level in hospitals, as well as units for paramedic use, residing in ambulances or other emergency services, and any other area within the hospital. Replacement, unaffected syringes are currently available to order.

If you have supplied units from the below-listed batches to another pharmacy, wholesaler or other entity, please contact them and request that any remaining units are returned to you.

In addition to the recall action above, we request that you please perform the following important actions with respect to packs that are currently at patient level, regardless of their batch number:

- The affected packs of Buccolam entered the medicine supply chain on **14/08/2017.** Please check your dispensing records to identify patients who were dispensed Buccolam (any batch, any strength) since **14/08/2017.** There is no need to go back further than this date.
- For each dispensing activity on or after 14/08/2017, please contact the carer of the patient by telephone, to ascertain if they currently have a copy of the Dear Caregiver Letter. This needs to be a colour copy. If they do not have a copy of the letter, please advise them how they can access it, either online (https://www.hpra.ie/docs/default-source/Safety-Notices/important-safety-information---buccolam-(midazolam).pdf?sfvrsn=0) or ask them to come to your pharmacy to receive a hard copy of the letter from you. If you require further colour copies of the Dear Caregiver Letter, please contact your wholesaler so that arrangements can be made to provide them with your pharmacy delivery.
- It is important that a copy of the Dear Caregiver letter is available at all locations where the syringes are stored. Please ask the carer if there are any syringes for the patient currently stored in other locations, apart from in the home, such as at the child's school or at a relative's home. If there are, arrangements should be made with your wholesaler to provide you with sufficient colour copies of the Dear Caregiver Letter so that copies of the letter can be given by you to the carer for each location where the syringes are stored.

Your assistance in the execution of this recall and with the other actions above is greatly appreciated.

Replacement batches are available to order.

For medical enquiries, please contact Shire Medical Information on Ph: 1800 818016 or medinfoEMEA@shire.com .

For returns enquiries, please contact the wholesaler from which you purchased the stock.

We apologise for any inconvenience that the above actions may cause.

Yours sincerely,

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Rob Smyth
Product Quality Surveillance Lead
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Appendix 1: List of Buccolam Batches to be Recalled

Product Strength	Batch Number	Expiry date
BUCCOLAM 2.5MG x 4 syringes Ireland	1704033	30/09/2018
BUCCOLAM 2.5MG x 4 syringes Ireland	1706021	31/12/2018
BUCCOLAM 2.5MG x 4 syringes Ireland	5708012	31/12/2018
BUCCOLAM 2.5MG x 4 syringes Ireland	5709022	31/01/2019
BUCCOLAM 5MG x 4 syringes Ireland	1704032	30/09/2018
BUCCOLAM 5MG x 4 syringes Ireland	1705033	31/10/2018
BUCCOLAM 5MG x 4 syringes Ireland	5707014	30/11/2018
BUCCOLAM 5MG x 4 syringes Ireland	5709017	31/01/2019
BUCCOLAM 7.5MG x 4 syringes Ireland	1704028	30/09/2018
BUCCOLAM 7.5MG x 4 syringes Ireland	1706019	30/11/2018
BUCCOLAM 7.5MG x 4 syringes Ireland	5708010	31/12/2018
BUCCOLAM 10MG x 4 syringes Ireland	1704034	30/09/2018
BUCCOLAM 10MG x 4 syringes Ireland	1706017	31/10/2018
BUCCOLAM 10MG x 4 syringes Ireland	1706022	30/11/2018

Appendix 2: Dear Care Giver Letter

Instructions for patients and caregivers

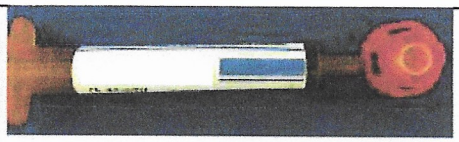
Instructions for correct administration of BUCCOLAM Prefilled Plastic Syringes

The clear tip-cap of BUCCOLAM syringes can sometimes remain attached to the syringe after the red cap has been taken off. If this happens, the tip-cap can detach in the patient's mouth and they might breathe it in or swallow it. If this happens, this could be a choking hazard.

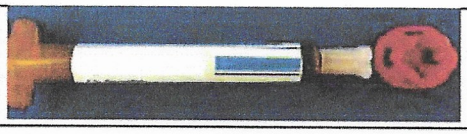
Continue to give BUCCOLAM as your doctor, nurse or pharmacist has told you to, **BUCCOLAM remains safe to use.**

Before you use of Buccolam you must follow the instructions below:

Correct

1. Before giving BUCCOLAM, pull the red cap off the end. Check the clear tip-cap is attached to the red cap, as shown.	

Incorrect

2. Make sure the clear tip-cap is not still attached to the syringe, as shown.	

3. If the clear tip-cap is still attached to the syringe, you should **pull it off before** giving BUCCOLAM to prevent it from going into the patient's mouth.

! If you think the tip-cap is in the patient's mouth, **do not** insert a finger into the mouth to look for it or remove it. Instead, turn the patient onto their side (recovery position) and make sure they spit it out when they stop fitting.

Call for reporting

If you get any side effects, talk to your doctor, pharmacist or nurse. You should also tell them about any occasions in which the clear tip-cap remained attached to the syringe.
You can also report side effects to the HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2, Tel: +353 1 6764971, Fax: +353 1 6762517, Website: www.hpra.ie e-mail: medsafety@hpra.ie

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