Medicines Safety Alert

No. 10

Health and Social Care Board

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To: All GPs, Dentists and Community Pharmacists for onward cascade to relevant staff

Dear Colleague

Action to Minimise the Risks with Buccal Midazolam Preparations

Buccal midazolam may be considered as an alternative to rectal diazepam for the treatment of prolonged seizures and is available from several different manufacturers. The two most commonly-used products are:

- Buccolam® 5mg/mL oral liquid.
  This product has recently received a licence for paediatric use and is available in a range of prefilled oral syringes.
- Epistatus® 10mg/mL oral liquid (unlicensed).
  This is available from a 'specials' manufacturer in a multi-dose bottle and as prefilled oral syringes.

It should be noted that another generic buccal midazolam 10mg/ml product (unlicensed) is available from 'specials' manufacturer, UL Medicines. Some patients may be receiving this product.

Historically Epistatus® has been the main buccal midazolam product prescribed and is included in the treatment plan for many patients with epilepsy in Northern Ireland. The manufacturers of Epistatus® have submitted an application for a product licence to the MHRA and the outcome of this is expected later this year. Following this, consideration can be given to a regional recommendation for a preferred buccal midazolam solution for use across Northern Ireland.

Important differences between Buccolam® and Epistatus®

Buccal midazolam solution				
	Licensed Product?	Salt	Strength	Products available
Buccolam®	Yes - for 3 months- 18 years*	Midazolam hydrochloride	5mg/1ml	Prefilled syringes: 2.5mg/0.5ml 7.5mg/1.5ml, 5mg/1ml 10mg/2ml
Epistatus®	No	Midazolam maleate	10mg/1ml	Prefilled syringes: 2.5mg/0.25ml 7.5mg/0.75ml 5mg/0.5ml 10mg/1ml 5ml bottle – 10mg/ml

*Infants aged 3–6 months: treatment should only be in hospital where monitoring is possible and resuscitation equipment is available

Action by Prescribers and Pharmacists

Although licensed medicines should always be used where possible, due to the potential risks associated with switching buccal midazolam preparations, it would seem sensible to maintain patients on their current preparation until a regional approach is agreed after the MHRA decision regarding the Epistatus® licence. Transfer of patients from one product to another requires careful planning and consideration. The following points should be noted:

1. If any changes are made to a patient's current buccal midazolam product, prescribers should consult with:
   - the patient's secondary care specialist and Epilepsy Specialist Nurse to ensure the patient's Care Management Plan is updated and necessary education and training is provided for the patient and/or carer
   - the patient's usual community pharmacy to enable stock arrangements to be put in place and to allow additional counselling as required.

2. Prescribers and pharmacists should be familiar with the differences between Buccolam® and unlicensed buccal midazolam solutions e.g. Epistatus®. In particular, it should be noted that Buccolam® (5mg/ml) is half the strength of some other unlicensed preparations. Dose changes should be calculated carefully and computer records updated.
3. Additional care should be taken when prescribing and dispensing buccal midazolam to ensure the correct preparation is selected. Buccal midazolam should be prescribed by brand name; if this is not prescribed by brand name, pharmacists should check the intended product with prescribers. Doses of buccal midazolam should be prescribed in 'mg'.

It should be noted that Epistatus® prefilled syringes (PFS) are not currently listed in some primary care clinical system drug dictionaries. Clinical system suppliers are working to resolve this issue. In the meanwhile it may be necessary to manually prescribe Epistatus® PFS.

4. Patients and/or carers must be counselled on any medication change.

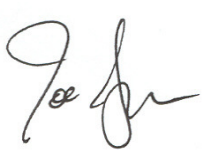
It is recommended that all patients currently receiving buccal midazolam preparations are reviewed to ensure the preparation prescribed corresponds with the patient's Epilepsy Care Plan and that an incorrect preparation has not been inadvertently prescribed or dispensed.

Further information is available at:
http://www.nelm.nhs.uk/en/NeLM-Area/News/2012---February/29/NPSA-Signal-Prevention-of-harm-with-buccal-midazolam/

http://www.mhra.gov.uk/Safetyinformation/DrugSafetyUpdate/CON131931

If you have any queries please contact your Medicines Management Adviser.

Yours Sincerely



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