Central and North West London NHS
NHS Foundation Trust

Milton Keynes Community Health Services

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Dear Doctor

BUCCAL MIDAZOLAM – Change of formulation used in Milton Keynes

NICE Clinical Guideline – Epilepsy CG137 recommends only prescribing buccal midazolam (first line) or rectal diazepam for use in the community for children, young people and adults who have had a previous episode of prolonged or serial convulsive seizures. http://guidance.nice.org.uk/CG137/NICEGuidance/pdf/English

You will be aware that there is now a licensed buccal midazolam product available, ***Buccolam®***, which contains the hydrochloride salt (10mg in **2**ml). ***Buccolam®*** is licensed for use in children only, not adults, and is available in pre-filled syringes in several doses (2.5mg, 5mg, 7.5mg and 10mg).

There is also **another** buccal midazolam product, ***Epistatus®***, which is **unlicensed** and contains the maleate salt (10mg in **1**ml). This unlicensed product has been available for many years and Milton Keynes has been using this product until now.

The products are not interchangeable and there is high risk of harm if patients receive the incorrect brand and strength of buccal midazolam.

MHRA Guidance
The MHRA issued a warning (Drug Safety Update in October 2011) that care was needed if transferring from unlicensed ***Epistatus®*** to licensed ***Buccolam®*** due to the differences in strengths between products.
http://www.mhra.gov.uk/Safetyinformation/DrugSafetyUpdate/CON131931

There have also been other errors reported to the National and Reporting Learning System (NRLS) involving confusion between the mg and mL e.g. 2.5mL (25mg) was prescribed when 0.25mL (2.5mg) was intended.
http://www.nrls.npsa.nhs.uk/resources/type/signals/?entryid45=132975

The MHRA recommend that a licensed product used 'off-label' is preferable to an unlicensed preparation, unless there is a good clinical reason for prescribing the unlicensed product.

Local recommendation on choice of buccal midazolam product

Buccolam® is now the product of choice in Milton Keynes. ***Buccolam®*** should be prescribed **by brand** for all new patients. Existing patients on unlicensed products should be assessed by a specialist on an individual basis and, in discussion with the patient and their family or carer, switched to ***Buccolam®*** whenever appropriate.

Always prescribe by brand to ensure that the correct product is supplied.
Buccolam® (midazolam HCL 10mg/**2mL** or 5mg/1mL) pre-filled syringe
Epistatus® (midazolam maleate 10mg/**1mL**) bottle or pre-filled syringe

When switching to or initiating ***Buccolam®*** make sure that carers and family are fully aware that:

- ***Buccolam®*** is twice the volume per mg dose compared to ***Epistatus®***
- Half the ***Buccolam®*** dose should be placed in one side of the mouth and then half in the other.
- For adult patients the product is used off-label. The packaging and information leaflets for ***Buccolam®*** could cause confusion for service users and carers due to the clear and bold markings emphasising that the product is ONLY licensed for children.
- Make sure patients and carers are aware of the requirement to stay with the same brand.

If you have any queries regarding this, please contact your patient's specialist for further advice.

Medicines Management Team, CNWL-MK