Buccolam® (buccal midazolam): a review of its use for the treatment of prolonged acute convulsive seizures in the dental practice

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IN BRIEF

- Reports the use of buccal midazolam in the treatment of prolonged acute convulsive seizures.
- Provides an update on the stocking and administration of Buccolam® in the dental practice.
- Highlights the reclassification of midazolam as a Schedule 3 controlled drug.

This article is published in response to a query from reader Sarah Clements, based at Golding House Dental Practice Ltd in Kent, regarding the *BDJ* paper entitled 'Updated guidance on medical emergencies and resuscitation in the dental practice' (*BDJ* 2012; 212: 41–43). Sarah wished to be provided with further clarification on the ordering, prescribing and administration of midazolam.

INTRODUCTION

Prolonged or repeated acute convulsive seizures are regarded as medical emergencies in both children and adults. Uncontrolled, such seizures may progress to status epilepticus carrying an increased risk of morbidity (for example, severe cerebral damage) and mortality;^{1–2} their early treatment may prevent such consequences. Prolonged acute seizures may occur in the dental practice³ and dental practitioners should be able to manage and treat them appropriately.

The National Institute for Health and Clinical Excellence (NICE) has recently published updated guidance on the management of prolonged convulsive seizures, recommending the administration of buccal midazolam as first-line treatment in children and adults with prolonged (>5 minutes) or repeated (more than three in a hour) seizures in the community.⁴ The Resuscitation Council (UK) has also recently updated their guidance on the use of buccal midazolam for seizure treatment in the dental practice.⁵

BUCCOLAM® (MIDAZOLAM OROMUCOSAL SOLUTION)

The British National Formulary, advanced paediatric life support course, national epilepsy organisations and Royal College of Paediatrics and Child Health have, for a number of years, recommended buccal midazolam for the emergency treatment of prolonged convulsive seizures.⁵ Until recently no licensed formulation was available and unlicensed 'specials' were used.

Buccolam® (midazolam oromucosal solution) has recently acquired a paediatric use marketing authorisation (PUMA) from the European Commission⁶ to become the first and only licensed oromucosal midazolam for the treatment of prolonged, acute, convulsive seizures in infants, children and adolescents (from 3 months to <18 years of age). Following buccal administration, it is rapidly absorbed across the mucous membranes directly into the bloodstream. Clinical studies show that cessation of visible signs of seizures within ten minutes was achieved in 65–78% of children receiving oromucosal midazolam.

Buccolam® is available in age-specific, pre-filled, plastic, oral syringes (Fig. 1) and

has a shelf life of 18 months. It is available as a 5 mg/ml solution for use in children up to 18 years. Its use in adults remains 'off-label' but the Resuscitation Council (UK) recommends a 10 mg (2 ml) dose for adults (as for the older child) and considers that such 'off-label' use of a licensed product is justified in the emergency situation.⁵

In both 'licensed' and 'off-label' settings, the drug does not need to have been prescribed to the patient when used in an emergency. In the dental practice, it should, however, be administered by (or under the supervision of) a dental practitioner.⁵

PROCEDURE FOR ADMINISTERING BUCCOLAM®

- Select appropriate age-specific dose for the patient (Table 1)

Fig.1 Buccolam® pre-filled doses

Label colour	Age range	Midazolam dose	Volume
Yellow	3 months to <1 year	2.5 mg	0.5 ml
Blue	1 to <5 years	5 mg	1.0 ml
Purple	5 to <10 years	7.5 mg	1.5 ml
Orange	10 to <18 years	10 mg	2.0 ml

Table 1 Recommended doses of midazolam according to the age of the patient

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Accepted 8 June 2012
DOI: 10.1038/sj.bdj.2012.617
©British Dental Journal 2012; 213: 81–82

- Remove the syringe cap (do not attach a needle to the syringe: Buccolam® must not be injected)
- Carefully and slowly advance the syringe into the space between the gum and the cheek and insert the Buccolam® liquid (for larger volumes of Buccolam® and/or smaller patients, it is recommended to slowly insert half into one side of the mouth and the other half into the other side)
- Show the empty syringe to the paramedics once they arrive so they know what dose has been administered.

Only administer a single dose of Buccolam® (if the seizure has not stopped within ten minutes after its administration, if not done already, call 999 for an ambulance).⁷

RECLASSIFICATION OF MIDAZOLAM AS A SCHEDULE 3 CONTROLLED DRUG

Concerns have been raised regarding the recent reclassification of midazolam as a

'Schedule 3' controlled drug. Although this reclassification does require certain legal processes, there is no legal requirement for midazolam to be stored in a locked cupboard nor to maintain a midazolam controlled drug register.⁵

ORDERING STOCKS OF MIDAZOLAM

Concerns have also been raised regarding the ordering of stocks of midazolam for use in the emergency treatment of seizures. A dentist can issue a requisition for any licensed product for use within their practice, as appropriate, using the standardised requisition form: FP10CDF.⁵

Dentists who do not use midazolam on a regular basis can still requisition this Schedule 3 drug under the conditions laid out by the Royal Pharmaceutical Society of Great Britain in their guidance *Medicines, ethics and practice: the professional guide for pharmacists*.⁸

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