

Prevention of Harm with Buccal Midazolam | Signal

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1329

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This Signal addresses the risks involved with buccal midazolam preparations.

A sample incident reads:

"Buccal midazolam administered for prolonged epileptic seizure. Resulted in severe respiratory distress, patient required oxygen and suctioning and ambulance transfer to the resus department at the hospital."

Buccal midazolam can be used in varying doses to treat status epilepticus in adults and children. It is administered to the buccal mucosa (between the gum and cheek). It is available in two strengths; a 5mg/mL oral liquid product, recently licensed for paediatric use (Buccolam®) in a range of prefilled oral syringes, and an unlicensed 10mg/mL oral liquid product available from various 'specials' manufacturers in a multidose bottle and / or prefilled oral syringes.

A search of the National Reporting and Learning System (NRLS) showed that between 1st April 2008 and 22nd August 2011; 132 relevant medication incidents were reported; three were associated with severe harm, five with moderate harm and the remainder with no or low harm.

Identified wrong dose errors include incidents where:

- 2.5mL (25mg) was prescribed when 0.25mL (2.5mg) was intended;
- 2.5mg to 5mg was prescribed however, 2.5mL of 10mg/mL strength (25mg) was administered; and,
- 0.5mL was prescribed, however, the pharmacy label stated "give one 5mL spoonful".

Other potential errors include:

- Where a product with a 'Luer' connector could be inadvertently administered via the IV route; and,
- a dosing error caused by transfer from unlicensed buccal midazolam 10mg/mL to licensed buccal midazolam 5mg/mL (Buccolam®). [The MHRA has previously issued guidance on this risk.](#)

Healthcare organisations can minimise these risks by:

- using licensed medicines where possible;
- developing a Trust policy to cover the use of unlicensed medicines, including midazolam;
- developing a written protocol for the use of buccal midazolam, which includes essential information on clinical indication, dose and administration method, and ensuring that this is available in all clinical areas using this medicine;
- ensuring that the dose is always prescribed in mg and mL; and,
- ensuring that buccal midazolam is only administered using oral syringes that are not compatible with intravenous or other parenteral devices.

We would like to hear from you - please [contact us](#) with your initiatives to reduce risks in this area.

Signals are notifications of key risks emerging from review of serious incidents reported to the NRLS and shared by the NPSA.