NHS England
South (South West)

Local Incident reported regarding prescribing and dispensing of midazolam prefilled syringes

Confusion between a GP and a Community Pharmacist over the intended dose of buccal midazolam for a child under the care of a hospice could potentially have caused a large overdose if it had been administered as directed. The GP prescribed prefilled syringes of the licensed product Buccolam® as an alternative to the unlicensed product that the parents were familiar with, but the intended dose was not clear on the prescription. The pharmacist supplied syringes containing double the dose suitable for the child's age, telling the mother to administer half a syringe if needed. The child was small for their age, and so should have been prescribed a lower dose anyway. Also, the syringes are not designed for partial administration and it is likely that the child would have received a considerable overdose if they had been used.

Buccolam® is licensed for use in children for the treatment of prolonged, acute, convulsive seizures in infants, toddlers, children and adolescents (from 3 months to < 18 years). It is available in pre-filled syringes, in several doses (2.5mg, 5mg, 7.5mg and 10mg).

Buccolam® 2.5mg, 5mg, 7.5mg and 10 mg oromucosal solution

Age range	Dose	Label colour
3 to 6 months (hospital setting)	2.5 mg	Yellow
> 6 months to < 1 year	2.5 mg	Yellow
1 year to < 5 years	5 mg	Blue
5 years to < 10 years	7.5 mg	Purple
10 years to < 18 years	10 mg	Orange

The appropriate dose of Buccolam® should be tailored to each patient by a specialist clinician, but in general, doses between 0.3-0.5 mg/kg up to a maximum single dose of 10 mg are used in children. The dosing in the SPC is done by age rather than weight, and this can make a significant difference if a child is disabled and a low weight for their age.

Because formulations of midazolam are available as 5 mg/ml or 10mg/ml, great care is also required to maintain consistency and educate parents and carers so that under or overdosing is avoided. Prescribing should be by brand to avoid inadvertent changing of concentrations for patients, and parents should receive appropriate training by a health professional with expertise in epilepsy, and written advice that supports the chosen product.

The National Reporting and Learning System (NRLS) recorded 132 medication incidents between 1/4/2008 and 22/8/2011 involving buccal midazolam; three were associated with severe harm, five with moderate harm and the remainder with no or low harm. Identified wrong dose errors include;

• 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

• 0.5mL was prescribed, however, the pharmacy label stated ''give one 5mL spoonful''

GPs and Pharmacists are asked to be extra vigilant around the prescribing and dispensing of buccal midazolam to avoid any confusion in the dose, and the advice given on administration.

Sue Mulvenna NHS England CDAO 21.10.15