

NCGC National Clinical Guideline Centre

Sedation in children and young people

Sedation for diagnostic and therapeutic procedures
in children and young people

Appendix J

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10 Appendix J – Licensing indications

The table that follows provides a summary reference guide to pharmacological treatment. It was prepared from data available in September 2010. Prescribers should refer to the British National Formulary for Children (BNFc) and summary of product characteristics for each drug for full and up-to-date details of licensing. Informed consent should be obtained and documented for the use of any drug outside the licensed indications.

Drug	Indication	Licensed status and advice for use (taken from the 'British national formulary for children' [BNFc] 2010/11, correct at the time of publication)
Chloral hydrate	Sedation	Not licensed for sedation in painless procedures. However, dosing for painless procedures in children from neonates to 18 years is given in the BNFc; by mouth or by rectum.
Fentanyl	Analgesia and enhancement of anaesthesia and for deep sedation	Licensed for use in children older than 1 month with spontaneous respiration for analgesia, and during operations for enhancement of anaesthesia by intravenous injection over at least 30 seconds. If deep sedation is needed fentanyl may be used. It should be used only under the supervision of a specialist experienced in its use.
Ketamine	Anaesthesia (lower doses are used for sedation than for anaesthesia for surgery)	Licensed for use in anaesthesia for all ages; intravenous and intramuscular. If deep sedation is needed ketamine may be used. It should be used only under the supervision of a specialist experienced in its use.
Midazolam	Sedation	Not licensed for use in children younger than 6 months for premedication and conscious sedation. Not licensed for use by mouth or by buccal administration. Intravenous midazolam is not licensed for use in children younger than 6 months for conscious sedation. No UK marketing authorisation for oral or intranasal midazolam for sedation. However, dosing for children from age 1 month is given in the BNFc.
Nitrous oxide	Sedation	50% nitrous oxide licensed for use in sedation for all ages; inhalation. Nitrous oxide in concentrations greater than 50% is not licensed for analgesia without loss of consciousness.

Opioids	Sedation	The BNFC stipulates that if deep sedation is needed a general anaesthetic (for example, propofol or ketamine), or a potent opioid (for example, fentanyl) may be used. However, they should be used only under the supervision of a specialist experienced in the use of these drugs.
Propofol	Anaesthesia	Licensed for use in children older than 1 month in doses of 0.5% or 1%; intravenous.
	Sedation	Licensed for use in people older than 17 years. The GDG decided to recommend off-label use of propofol for sedation in children of all ages. This was because propofol is widely used in the UK for sedation in children of all ages and the doses used for sedation are much lower than those used for anaesthesia. If deep sedation is needed, propofol may be used. It should be used only under the supervision of a specialist experienced in its use.
Sevoflurane	Anaesthesia	Licensed for use in anaesthesia for all ages; inhalation.
	Sedation	Not licensed for sedation.