

BRIEF SUMMARY OF THE TRANSPARENCY COMMITTEE OPINION**PROPOFOL LIPURO (propofol emulsion with medium and long chain triglycerides), anaesthetic**

No clinical benefit demonstrated for sedation during short diagnostic or surgical procedures in children

Main points

- ▶ PROPOFOL LIPURO is a rapid-acting anaesthetic that now has Marketing Authorisation for sedation during diagnostic and therapeutic procedures, alone or in combination with local or regional anaesthesia in children. It should not be administered by the person performing the surgical or diagnostic procedure.
- ▶ The dosage of 5 mg/mL is suitable for induction of sedation in children over 1 month of age. The dosage of 10 mg/mL is suitable for the sedation of children over 1 month of age and that of 20 mg/mL is suitable for children over 3 years of age.
- ▶ No study has compared PROPOFOL LIPURO with HYPNOVEL, another anaesthetic with Marketing Authorisation in this indication in children.

Pre-existing indications

- PROPOFOL LIPURO 5 mg/ml already has Marketing Authorisation in the induction of general anaesthesia in adults and children over 1 month of age, in adults only the induction of sedation during diagnostic or surgical procedures and, depending on the doses, in the induction and maintenance of general anaesthesia in adults and children over the age of 1 month (10 mg/ml) and children over the age of 3 years (20 mg/ml), sedation during diagnostic or surgical procedures, alone or in combination with local or regional anaesthesia in adults and children over the age of 16 years and during the sedation of ventilated patients over the age of 16 in the intensive care unit.
- This summary does not cover these indications.

Therapeutic use

- The pain caused during surgical and/or diagnostic procedures in children justifies the use of sedation, even anaesthesia.
- Sedation may be obtained by oral sugar solutions in newborns, local anaesthetics, and EMONO (equimolar mixture of oxygen and nitrous oxide) in children. In children over the age of 1 month, among the injectable anaesthetics, only midazolam (HYPNOVEL) is also indicated.
- **Role of the medicinal product in the therapeutic strategy**
In children, when a hypnotic anaesthetic agent is planned, propofol is an alternative to midazolam.

Clinical data

An observational prospective, non-comparative study, assessed, in infants and children, the efficacy and safety of PROPOFOL sedation during cerebral and spinal MRI. The results of the primary endpoints are: the sedation induction duration was 2 minutes, the sedation time was 55 minutes and the recovery time was 8 minutes and additional sedation was necessary in 2.2% patients. None of the patients had heart problems, a paradoxical reaction or sedation failure.

Special prescribing conditions

PROPOFOL LIPURO should only be administered in a hospital establishment or in day centres that are properly equipped and only by anaesthetists and intensive care physicians.

Benefit of the medicinal product

- The actual benefit* of PROPOFOL LIPURO for sedation in diagnostic and therapeutic procedures in children above the age of 1 month is significant.
- PROPOFOL LIPURO does not provide clinical added value (CAV V) in the therapeutic strategy.
- Recommends inclusion on the list of reimbursable products for hospital use.



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ⁱ * The actual benefit (AB) of a proprietary medicinal product describes its benefit primarily in terms of its clinical efficacy and the seriousness of the condition being treated. The HAS Transparency Committee assesses the AB, which can be substantial, moderate, low or insufficient for reimbursement for hospital use.

** The clinical added value (CAV) describes the improvement in treatment provided by a medicinal product compared with existing treatments. The HAS Transparency Committee assesses the degree of CAV on a scale from I (major) to IV (minor). A level V CAV means "no improvement".