

TRANSPARENCY COMMITTEE

OPINION

20 NOVEMBER 2019

lidocaine
LIDOCAINE AGUETTANT 10 mg/ml WITHOUT PRESERVATIVES, solution for injection

New indications

► Key points

Approved for reimbursement by intravenous route in adults and in children over the age of 1 year in the prevention of pain related to the injection of propofol by intravenous route and in adults, in prevention of postoperative pain, in particular to accelerate the resumption of intestinal transit after abdominal surgery.

► What therapeutic improvement?

No progress in the therapeutic strategy.

► Role in the care pathway?

In the prevention of pain associated with the injection of propofol intravenously in children and adults:
Currently, the SPC for certain propofol-based proprietary medicinal products recommends minimising induction pain by using larger veins in the forearm and the antecubital fossa or also by co-administration of lidocaine with propofol 10 mg/ml.

European guidelines¹ also mention the minimising of pain associated with the injection of propofol by reducing the concentration of propofol (to 0.5%), or by administering lidocaine or opioids intravenously before administration.

AGUETTANT LIDOCAINE 10 mg/ml WITHOUT PRESERVATIVES, solution for injection is a first-line treatment for the indication concerned.

In the prevention of postoperative pain, particularly in order to accelerate the resumption of intestinal transit after abdominal surgery in adults:

The current management of postoperative pain treatment is based on the establishment of treatment protocols with multi-modal analgesia techniques comprising non-morphine analgesics and/or loco-regional analgesia in order to allow postoperative morphine sparing .

To prevent these pains, the SFAR national guidelines mention that it is “probably recommended to administer lidocaine intravenously and continuously at a dose of 1 to 2 mg/kg as an intravenous bolus followed by 1 to 2 mg/kg/h, in adult patients undergoing major surgery (abdominal-pelvic, spinal) and not benefiting from concomitant perinervous or epidural analgesia in order to reduce postoperative pain and improve rehabilitation”. It is also specified that "comparisons between intravenous lidocaine and locoregional analgesia techniques would make it possible to specify the role of each of the techniques".

AGUETTANT LIDOCAINE 10 mg/ml WITHOUT PRESERVATIVES, solution for injection is a first-line treatment for the indication concerned.

¹ European Society of Gastrointestinal Endoscopy (ESGE) / Gastroenterology (ESG) and European Society of Anaesthesiology

COMMITTEE'S CONCLUSIONS

Actual benefit

Prevention of pain associated with the intravenous injection of propofol in adults and children over 1 year of age.

- ▶ Pain associated with the intravenous injection of propofol as part of sedation or general anaesthesia is frequent and affects up to two thirds of patients.
- ▶ AGUETTANT LIDOCAINE 10 mg/ml WITHOUT PRESERVATIVES, solution for injection is a preventive treatment for pain associated with the injection of propofol.
- ▶ The efficacy/adverse effects ratio of AGUETTANT LIDOCAINE 10 mg/ml WITHOUT PRESERVATIVES, solution for injection is high in this indication.
- ▶ There are no medicinal alternatives.
- ▶ AGUETTANT LIDOCAINE 10 mg/ml WITHOUT PRESERVATIVES, solution for injection is a first-line treatment for the prevention of pain associated with the intravenous injection of propofol in adults and children over 1 year of age.

Public health benefit

Considering:

- the severity of the pain associated with the injection of propofol,
- their incidence,
- the unmet medical need,
- the lack of quality of life data,
- the lack of data on a possible impact on the organisation of care,
- the lack of response to the identified need (limited meta-analysis data suggesting moderate efficacy of IV lidocaine compared to placebo),

AGUETTANT LIDOCAINE 10 mg/ml WITHOUT PRESERVATIVES is unlikely to have an impact on public health.

Given all of these elements, the Committee considers that the actual benefit of AGUETTANT LIDOCAINE 10 mg/ml WITHOUT PRESERVATIVES, solution for injection, is high in preventing pain related to the intravenous injection of propofol in adults and in children over the age of 1 year.

The Committee issues a positive opinion for hospital formulary listing of reimbursed pharmaceutical products approved for use in the prevention of pain related to the intravenous injection of propofol in adults and children over the age of 1 year and at the MA dosages.

In the prevention of postoperative pain, particularly in order to accelerate the resumption of intestinal transit after abdominal surgery in adults

- ▶ Postoperative pain is frequent and its intensity depends on the surgical procedure and patient sensitivity. The interruption of postoperative intestinal transit in abdominal surgery is one of the main unfavourable factors slowing convalescence and therefore likely increase the length of hospital stay.
- ▶ AGUETTANT LIDOCAINE 10 mg/ml WITHOUT PRESERVATIVES solution for injection is a preventive treatment.
- ▶ The efficacy/adverse effects ratio of AGUETTANT LIDOCAINE 10 mg/ml WITHOUT PRESERVATIVES is high in this indication.
- ▶ There are no medicinal alternatives

► AGUETTANT LIDOCAINE 10 mg/ml WITHOUT PRESERVATIVES, solution for injection is a first-line treatment to prevent postoperative pain, in particular to accelerate the resumption of intestinal transit following abdominal surgery in adults

Public health benefit

Considering:

- the severity of postoperative pain and/or the slowing of intestinal transit,
- their incidence,
- the unmet medical need,
- the lack of quality of life data,
- the lack of robust data on a possible impact on the organisation of care, and in particular on the reduction in the duration of postoperative hospitalisation,
- the lack of response to the identified need (limited meta-analysis data suggesting moderate efficacy of IV lidocaine compared to placebo),

AGUETTANT LIDOCAINE 10 mg/ml WITHOUT PRESERVATIVES is unlikely to have an additional impact on public health.

Given all of these elements, the Committee considers that the actual benefit of AGUETTANT LIDOCAINE 10 mg/ml WITHOUT PRESERVATIVES, solution for injection is high in preventing postoperative pain, in particular in order to accelerate the resumption of intestinal transit after abdominal surgery in adults.

The Committee issues a positive opinion for hospital formulary listing of reimbursed pharmaceutical products approved for use in the prevention of postoperative pain, in particular in order to accelerate the resumption of intestinal transit after abdominal surgery in adults and at MA dosages.

Clinical Added Value

► Prevention of pain associated with the intravenous injection of propofol in adults and children over 1 year of age

Given the limited data from meta-analyses suggesting a moderate efficacy of IV lidocaine compared to placebo on the incidence of pain associated with propofol injection, the Committee considers that AGUETTANT LIDOCAINE 10 mg/ml WITHOUT PRESERVATIVES, solution for injection does not provide any clinical added value (CAV V) in the therapeutic strategy for preventing pain associated with the intravenous injection of propofol in adults and children over 1 year of age .

► Of intestinal transit after abdominal surgery in adults in the prevention of postoperative

Given the limited data from meta-analyses suggesting moderate efficacy of IV lidocaine compared to placebo on early postoperative pain scores, the incidence of postoperative ileus and the time to first onset of intestinal movements/first gas, with high heterogeneity reported between studies limiting these results, the Committee considers that AGUETTANT LIDOCAINE 10 mg/ml WITHOUT PRESERVATIVES, solution for injection does not provide any clinical added value (CAV V) in the therapeutic strategy for the prevention of postoperative pain, in particular in order to accelerate the resumption of intestinal transit after abdominal surgery in adults.