

Original French opinion adopted by the Transparency Committee

The legally binding text is the original French opinion version

SUMMARY

Lidocaine hydrochloride

LIDOCAINE AGUETTANT 10 and 20 mg/mL

solution for injection in pre-filled syringe

Indication extensions and listing of a range
supplement

Adopted by the Transparency Committee on 12 March 2025

Summary of opinion

Indication extensions:

Favourable opinion for reimbursement only for local anaesthesia in the event of intravenous use to prevent injection-related pain in children from 12 years of age (only for the 10 mg/mL strength) and adults.

Unfavourable opinion for reimbursement for intravenous regional anaesthesia (IVRA) of the upper limbs in adults.

Listing of a range supplement (5-mL syringe):

Favourable opinion for reimbursement in the indications and at the MA dosages for local anaesthesia and peripheral nerve block anaesthesia.

Unfavourable opinion for reimbursement for intravenous regional anaesthesia (IVRA) of the upper limbs in adults.

No clinical added value of the new 5-mL form compared to the forms already available.

Transparency Committee's Conclusions

Clinical Benefit

Local anaesthesia in the event of intravenous use to prevent injection-related pain

- ➔ Pain related to the injection of medicinal products (particularly propofol) in the context of sedation or general anaesthesia is common and affects up to two-thirds of patients.
- ➔ LIDOCAINE AGUETTANT 10 and 20 mg/mL solution for injection in pre-filled syringe is a treatment to prevent pain related to the injection of medicinal products (particularly propofol).

- ➔ The efficacy/adverse effects ratio of LIDOCAINE AGUETTANT 10 and 20 mg/mL solution for injection in pre-filled syringe is high in this indication.
- ➔ There is a therapeutic alternative: LIDOCAINE AGUETTANT 10 mg/mL PRESERVATIVE-FREE solution for injection.
- ➔ LIDOCAINE AGUETTANT 10 and 20 mg/mL solution for injection in pre-filled syringe is a first-line treatment to prevent pain related to the intravenous injection of medicinal products (particularly propofol).

➔ **Public health benefit**

Considering:

- the frequency and severity of pain related to the injection of irritant medicinal products (particularly propofol),
- the already met medical need,
- the lack of response to the identified need considering the absence of evidence of an additional impact on morbidity and mortality or quality of life, and the absence of evidence of an impact on the organisation of care,

LIDOCAINE AGUETTANT 10 and 20 mg/mL solution for injection in pre-filled syringe is unlikely to have an additional impact on public health.

Considering all of these elements, the Committee deems that the clinical benefit of LIDOCAINE AGUETTANT 10 and 20 mg/mL solution for injection in pre-filled syringe is substantial for local anaesthesia in the event of intravenous use to prevent injection-related pain in children from 12 years of age (only for the 10 mg/mL strength) and adults.

The Committee issues a favourable opinion for inclusion of LIDOCAINE AGUETTANT 10 and 20 mg/mL solution for injection in pre-filled syringe in the list of covered drugs for inpatients approved for use for local anaesthesia in the event of intravenous use to prevent injection-related pain in children from 12 years of age (only for the 10 mg/mL strength) and adults and at the MA dosages.

Intravenous regional anaesthesia (IVRA) of the upper limbs in adults

- ➔ Intravenous regional anaesthesia (IVRA or Bier block) is a technique applied for anaesthesia of the upper limb.
- ➔ LIDOCAINE AGUETTANT solution for injection in pre-filled syringe is a preventive treatment for pain related to surgical procedures.
- ➔ The efficacy/adverse effects ratio of LIDOCAINE AGUETTANT 10 and 20 mg/mL solution for injection in pre-filled syringe is currently not adequately established in this indication dedicated to the use of lidocaine for intravenous regional anaesthesia (IVRA) of the upper limbs in adults, in view of the practice of ultrasound-guided nerve blocks, which is more selective, more precise and more practical, and the duration of which can be determined based on the choice of local anaesthetic used and the quantity administered.
- ➔ There are alternatives with broader indications that can include this clinical situation (XYLOCAINE 5 mg/mL PRESERVATIVE FREE solution for injection (lidocaine) and LIDOCAINE ACCORD 10 mg/mL solution for injection (lidocaine)).

- ➔ LIDOCAINE AGUETTANT 10 and 20 mg/mL solution for injection in pre-filled syringe no longer has a role in intravenous regional anaesthesia (IVRA or Bier block).

➔ **Public health benefit**

Considering:

- the high incidence of patients requiring locoregional anaesthesia,
- the met medical need,
- the lack of response to the identified need considering the absence of evidence of an additional impact on morbidity and mortality or quality of life, and the absence of evidence of an impact on the organisation of care,

LIDOCAINE AGUETTANT 10 and 20 mg/mL solution for injection in pre-filled syringe is unlikely to have an additional impact on public health.

Considering all of these elements, the Committee deems that the clinical benefit of LIDOCAINE AGUETTANT 10 and 20 mg/mL solution for injection in pre-filled syringe is insufficient for intravenous regional anaesthesia (IVRA) of the upper limbs in adults to justify public funding in view of the available alternatives.

The Committee issues an unfavourable opinion for inclusion of LIDOCAINE AGUETTANT 10 and 20 mg/mL solution for injection in pre-filled syringe in the list of covered drugs for inpatients approved for use for intravenous regional anaesthesia (IVRA) of the upper limbs in adults.

Range supplement

- ➔ LIDOCAINE AGUETTANT 10 and 20 mg/mL solution for injection in 5-mL pre-filled syringe is a preventive treatment.
- ➔ The efficacy/adverse effects ratio of LIDOCAINE AGUETTANT 10 and 20 mg/mL solution for injection in 5-mL pre-filled syringe is the same as for the other forms.
- ➔ The alternatives are the same as for the other forms.

➔ **Public health benefit**

LIDOCAINE AGUETTANT 10 and 20 mg/mL solution for injection in 5-mL pre-filled syringe is unlikely to have an additional impact on public health.

Considering all of these elements, the Committee deems that the clinical benefit of LIDOCAINE AGUETTANT 10 and 20 mg/mL solution for injection in 5-mL pre-filled syringe is:

- substantial for local anaesthesia and peripheral nerve block anaesthesia,
- insufficient for intravenous regional anaesthesia (IVRA) of the upper limbs in adults.

The Committee issues a favourable opinion for inclusion of LIDOCAINE AGUETTANT 10 and 20 mg/mL solution for injection in 5-mL pre-filled syringe in the list of covered drugs for inpatients approved for use in the indications and at the MA dosages for local anaesthesia and for peripheral nerve block anaesthesia.

The Committee issues an unfavourable opinion for inclusion of LIDOCAINE AGUETTANT 10 and 20 mg/mL solution for injection in 5-mL pre-filled syringe in the list of covered drugs

for inpatients approved for use for intravenous regional anaesthesia (IVRA) of the upper limbs in adults.

Clinical Added Value

Local anaesthesia in the event of intravenous use to prevent injection-related pain

Considering:

- limited data from meta-analyses having suggested a moderate efficacy of lidocaine IV compared to placebo on the incidence of pain related to the injection of propofol, taken into account for LIDOCAINE AGUETTANT 10 mg/mL PRESERVATIVE-FREE solution for injection,
- the identified medical need to have access to lidocaine to prevent pain related to the intravenous injection of medicinal products, particularly propofol, in accordance with good clinical practice,

the Committee deems that LIDOCAINE AGUETTANT 10 and 20 mg/mL solution for injection in pre-filled syringe provides no clinical added value (CAV V) compared with LIDOCAINE AGUETTANT 10 mg/mL PRESERVATIVE-FREE solution for injection.

Range supplement

LIDOCAINE AGUETTANT 10 and 20 mg/mL solution for injection in pre-filled 5-mL syringe are range supplements that do not provide any clinical added value (CAV V) compared to the forms already listed.