HAUTE AUTORITÉ DE SANTÉ

TRANSPARENCY COMMITTEE
SUMMARY
23 JUNE 2021

The legally binding text is the original French opinion version

Ropivacaine hydrochloride
ROPIVACAINE B. BRAUN 2 mg/ml solution for injection/infusion
New indication

Key points

Favourable opinion for reimbursement in acute pain management in paediatric patients via single and continuous nerve block in infants (from 1 year) and children (≤12 years).

What therapeutic improvement?

No clinical added value in the therapeutic strategy.

Role in the care pathway?

The local anaesthetics generally used for paediatric locoregional anaesthesia are amine amide-type local anaesthetics. The long-acting local anaesthetics ropivacaine and levobupivacaine are less cardiotoxic than bupivacaine.

These local anaesthetics (ropivacaine, bupivacaine and levobupivacaine) have been available to clinicians for several decades, with well-established medical use. While their pharmacological effect is a little different, the possibility of varying the concentration depending on the effect sought (anaesthesia or analgesia) makes locoregional anaesthetic solutions comparable for postoperative analgesic use.

Role of ROPIVACAINE B. BRAUN 2 mg/ml (ropivacaine) in the care pathway:

The medical use of ropivacaine has been well established for several years, with a reported efficacy in terms of control of analgesia and improvement in postoperative care. The risk of toxicity, which exists for all local anaesthetics, makes close monitoring necessary, along with use in a paediatric anaesthesia setting.

Consequently, ROPIVACAINE B. BRAUN 2 mg/ml (ropivacaine) is a first-line treatment in acute pain management in paediatric patients: single and continuous nerve block in infants (from 1 year) and children (≤12 years).

The clinical data available does not enable a conclusion to be reached with respect to the contribution of ropivacaine compared to the other local anaesthetics available in terms of efficacy and safety.

COMMITTEE'S CONCLUSIONS

Considering all of this information and further to debate and voting, the Committee considers:

Clinical benefit

◗ Postoperative pain remains the most common complaint in the postoperative follow-up of children.

◗ ROPIVACAINE B. BRAUN 2 mg/ml (ropivacaine) is a symptomatic medicinal product.

◗ The efficacy/adverse effects ratio of ROPIVACAINE B. BRAUN 2 mg/ml (ropivacaine) is high in the indication concerned.

◗ There are therapeutic alternatives.

◗ ROPIVACAINE B. BRAUN 2 mg/ml (ropivacaine) is a first-line treatment in acute pain management in paediatric patients: single and continuous nerve block in infants (from 1 year) and children (≤12 years).

Public health impact

Considering:

- the seriousness of acute pain in paediatric patients and its incidence,
- the partially met medical need,
- the well-established use of ropivacaine in the improvement of postoperative care at the recommended doses in children, appropriate for clinical practice, but the lack of response to the identified need due to absence of demonstration of an additional impact on morbidity and mortality or quality of life:
    - in the absence of comparative efficacy studies conducted by the pharmaceutical company comparing the efficacy of ropivacaine to the other available alternatives,
    - in the absence of quality of life data,
- the lack of data on a potential impact on the organisation of care,

ROPIVACAINE B. BRAUN 2 mg/ml (ropivacaine) medicinal products are unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of ROPIVACAINE B. BRAUN 2 mg/ml (ropivacaine) is substantial in the indication extension for acute pain management in paediatric patients via single and continuous nerve block in infants (from 1 year) and children (≤12 years).

The Committee issues a favourable opinion for inclusion in the hospital formulary list of reimbursed proprietary medicinal products approved for use in the MA indication extension and dosages.

Clinical Added Value

Considering:

- **limited paediatric data from the literature having suggested an efficacy of ropivacaine in terms of analgesia for various peripheral nerve blocks,**
- **the lack of efficacy and safety data compared to the other local anaesthetics available,**
- **the well-established medical use of ropivacaine in the management of acute pain via nerve block,**

the Committee considers that ROPIVACAINE B. BRAUN (ropivacaine) 2 mg/ml solution for injection/infusion provides no clinical added value (CAV V) in the care pathway for acute pain management in paediatric patients via single and continuous nerve block in infants (from 1 year) and children (≤12 years).