HAUTE AUTORITÉ DE SANTÉ

TRANSPARENCY COMMITTEE
SUMMARY
14 SEPTEMBER 2022

The legally binding text is the original French opinion version

sufentanil
DZUVEO 30 µg, sublingual tablet

First assessment

Key points

Approval for reimbursement in multimodal management of acute pain insufficiently relieved by lower-step analgesics, for postoperative care or emergency medicine.

Therapeutic improvement?

No therapeutic improvement for moderate to severe acute pain.

Role in therapeutic strategy?

The current therapeutic strategy for moderate to severe acute pain is based on a multimodal analgesia approach, which consists of associating substances and technologies having different and complementary mechanisms of action, with a view to improving analgesia and reducing risks of adverse effects, particularly by reducing opioid use.

Role of the medicinal product

DZUVEO is to be administered by a healthcare professional in a medically monitored setting only. A medically monitored setting must have equipment and personnel trained to detect and manage morphine-induced respiratory depression. This medicinal product should not be used beyond 48 hours.

DZUVEO should be reserved for the management of acute pain insufficiently relieved by lower-step analgesics, for postoperative care or emergency medicine, in patients who can be closely monitored.

COMMITTEE'S CONCLUSIONS

Actual Clinical Benefit

- The quick and effective management of acute pain, particularly in postoperative care and emergency medicine, has a direct impact on patient comfort, and reduces perioperative and peritraumatic morbidities. This treatment is also a preventive factor for the onset of chronic pain.
- DZUVEO falls within the scope of symptomatic treatment.
- The efficacy/adverse effects ratio of the proprietary medicinal product assessed versus placebo in postoperative pain is significant. This ratio has yet to be specified versus active comparators in the management of acute pain insufficiently relieved by lower-step analgesics.
- There are many alternative medications in the indication.
- DZUVEO should be reserved for the management of acute pain insufficiently relieved by lower-step analgesics, for postoperative care or emergency medicine, in patients who can be closely monitored.

Public health benefit

Considering:

- the incidence of acute pain and its impact on morbidity,
- the medical need met by opioid and non-opioid analgesics and analgesia-pain relief procedures in the management of acute pain in adults,
- the lack of a demonstrated additional impact on morbidity or quality of life,
- the lack of data supporting a potential additional impact on the care and/or life pathway or on the healthcare organization,

DZUVEO 30 µg, sublingual tablet is not likely to have an additional impact on public health.

Considering all of these elements, the Committee deems that the actual clinical benefit of DZUVEO 30 µg, sublingual tablet is significant for the multimodal management of acute pain insufficiently relieved by lower-step analgesics, for postoperative care or emergency medicine.

The Committee approves inclusion in the list of proprietary medicinal products approved for community use for the multimodal management of acute pain insufficiently relieved by lower-step analgesics, for postoperative care or emergency medicine, at the marketing authorisation dosages.

Clinical Added Value

Considering:

- the evidence of the efficacy versus placebo of sufentanil 30 µg, sublingual tablet in moderate to severe acute pain, for postoperative care,

but in view of:

- the lack of controlled study versus active comparator(s),
- uncertainties as to the transposability to clinical practice of study findings,
- the medical need met by analgesic treatments available,
- the safety profile of strong opioids,
- and the wish to prioritise patient-controlled analgesia in many clinical contexts,

the Transparency Committee deems that DZUVEO 30 µg, sublingual tablet provides no clinical added value (CAV V) in the management of moderate to severe acute pain.