

BRIEF SUMMARY OF THE TRANSPARENCY COMMITTEE OPINION

PALEXIA LP (tapentadol), opioid analgesic

Insufficient clinical benefit in the treatment of severe, chronic non-cancer, non-neuropathic pain in adults that can only be adequately treated with opioid analgesics.

Main points

- ▶ PALEXIA LP has Marketing Authorisation in the treatment of severe, chronic pain in adults that can only be adequately treated with opioid analgesics.
- ▶ As a reminder, PALEXIA LP received a favorable opinion for reimbursement in the treatment of chronic severe **cancer pain**. Its clinical benefit is low in this indication.
- ▶ In chronic, severe **non-cancer, non-neuropathic pain**, given the clinically poorly-relevant efficacy demonstrated in studies with many methodological limitations, the potential for abuse and dependence, and the existence of alternatives for pain management, PALEXIA LP has no role in the treatment strategy.

Therapeutic use

- The choice of an analgesic depends on the intensity of the pain, on the source of the pain and on whether it is acute or chronic.
- Strong opioids can be considered as a last resort treatment, in the event of severe intractable pain:
 - in osteoarthritis of the knee or hip, at a stage where surgery is planned or in patients who are not candidates (due to refusal or contraindication) for prosthetic joint replacement surgery
 - in chronic low back pain,
- The role of this therapeutic category should be as limited as possible, after failure of other recommended medicinal and physical therapy measures and for the shortest duration possible, due to the risk of serious adverse reactions and the absence of long-term data. Use of an oral form is preferred.
- **Role of the medicinal products in the therapeutic strategy**
PALEXIA LP has no role in the treatment of severe, chronic non-cancer, non-neuropathic pain in adults that can only be adequately treated with opioid analgesics.

Clinical data

- In one phase III study that included 258 patients with chronic low back pain, a study of limited interpretation because of its open-label nature, the efficacy of tapentadol LP was compared to the combination of oxycodone/naloxone LP after 12 weeks of treatment, including 3 weeks of dose finding and was:
 - superior to the combination in terms of reduction of the mean pain intensity score with a mean variation of -1.0 on an 11 point scale (NRS 3).
 - not inferior to the combination in terms of the mean reduction in constipation symptoms score with a mean variation of -0.07 on an 48 point scale (PAC-SYM)
- The data from a metaanalysis including four clinical studies in treatment of moderate to severe chronic pain suggested at 12 weeks a mean pain reduction of 0.56 points for patients treated with tapentadol LP compared to placebo on an 11-point scale.
- The main adverse reactions with tapentadol LP are similar to those of other opioid analgesics, with a potentially lower frequency of gastrointestinal adverse reactions (constipation and vomiting) on tapentadol LP than on oxycodone/naloxone LP, in particular during the dose finding period.

Special prescribing conditions

- Narcotic
- Prescription limited to 28 days
- Controlled prescription in accordance with the specifications laid down by the Order of 31 March 1999

Benefit of the medicinal product

- The actual clinical benefit* of PALEXIA LP is insufficient to justify reimbursement by the National Health Insurance.
- Does not recommend reimbursement for supply by pharmacists and for hospital use in the treatment of severe, chronic non-cancer, non-neuropathic pain in adults that can only be adequately treated with opioid analgesics.



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This document was created on the basis of the Transparency Committee Opinion of 07 June 2017 (CT-15823) and is available at www.has-sante.fr

* The actual clinical benefit (ACB) of a 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 ACB, which can be substantial, moderate, low or insufficient for reimbursement for hospital use.