SUMMARY

Original French opinion adopted by the Transparency Committee

The legally binding text is the original French opinion version

nefopam

ACUPAN 30 mg

tablets

Inclusion on list: First listing

Range supplement

Adopted by the Transparency Committee on 12 February 2025

Summary of opinion

Favourable opinion for reimbursement in the “Symptomatic treatment of acute painful conditions, especially post-operative pains”.

No clinical added value of the new form compared to the forms already available (ACUPAN 20 mg/ 2 mL solution for injection and its generics, and NEFOPAM PANPHARMA 30 mg film-coated tablets).

Transparency Committee's Conclusions

Clinical Benefit

- The quick and effective treatment of acute pain (particularly postoperative and traumatic) has an immediate impact on patient comfort, and lowers perioperative and peritraumatic morbidities. This treatment is also a factor in preventing the onset of chronic pain.
- ACUPAN 30 mg is a symptomatic medicinal product.
- The efficacy/adverse effects ratio of this proprietary medicinal product is not adequately established and has yet to be defined versus active comparators in the management of acute pain.

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- ACUPAN 30 mg is a treatment option as part of the multimodal management of acute pain. It is a first- or second-line treatment.

→ **Public health benefit**

ACUPAN 30 mg is unlikely to have an additional impact on public health.

The Committee considers that the clinical benefit of ACUPAN 30 mg tablets (nefopam) is moderate in the MA indication.

The Committee issues a favourable opinion for inclusion in both the list of covered drugs for outpatients and the list of covered drugs for inpatients approved for use in the indication and at the MA dosages.

- **Recommended reimbursement rate for inclusion in the list of covered drugs for outpatients: 35%**

Clinical Added Value

This medicinal product is a range supplement that does not provide any clinical added value (CAV V) compared to the forms already listed (ACUPAN 20 mg/2 mL solution for injection and its generics, and NEFOPAM PANPHARMA 30 mg film-coated tablets).

The Committee highlights the fact that nefopam has no MA in chronic pain.