

Original French opinion adopted by the Transparency Committee.

The legally binding text is the original French opinion version.

SUMMARY

naldemidine

RIZMOIC 200 µg

film-coated tablets

Inclusion on list: First listing

Range supplement

Adopted by the Transparency Committee on 27 August 2025

Summary of opinion

Favourable opinion for reimbursement in the treatment of opioid-induced constipation (OIC) in adult patients who have previously been treated with a laxative.

No clinical added value of the new form of RIZMOIC film-coated tablets in packs containing 30 tablets in unit dose blisters, compared to the forms already available.

Transparency Committee's conclusions

Clinical Benefit

- Constipation is a common adverse effect of chronic opioid treatment. It impairs patients' quality of life and can lead to poor compliance with analgesic therapy.
- This is a symptomatic medicinal product.
- Its efficacy/adverse effects ratio is moderate, given a modest effect size and in the absence of evidence of an impact on quality of life.
- This is a first-line treatment in view of the therapies available.

→ Public health benefit

RIZMOIC (naldemedine) is unlikely to have an additional impact on public health.

The Committee considers that the clinical benefit of RIZMOIC 200 µg (naldemedine) film-coated tablets in packs containing 30 tablets in unit dose blisters is low in the treatment of opioid-induced constipation (OIC) in adult patients who have previously been treated with a laxative.

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: 15%

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.