

SUMMARY

tramadol/paracetamol

**IXPRIM 37.5 mg/325 mg,
ZALDIAR 37.5 mg/325 mg**

film-coated tablets

Inclusion on list: First listing

Range supplement

Adopted by the Transparency Committee on 20 November 2024

Summary of opinion

Favourable opinion for reimbursement in the symptomatic treatment of moderate to severe pain.

The use of IXPRIM and ZALDIAR should be restricted to patients whose moderate to severe pain is considered to require a combination of tramadol and paracetamol.

No clinical added value of the new forms *in non-pre-cut blister strips* compared to the forms already available *in individual pre-cut blister strips*.

Transparency Committee's conclusions

Clinical Benefit

- The quick and effective treatment of acute pain, particularly in postoperative care and emergency medicine, has an immediate impact on patient comfort, and lowers perioperative and peritraumatic morbidities. Chronic pain can cause a marked deterioration in patients' quality of life.
- The proprietary medicinal products IXPRIM and ZALDIAR (tramadol/paracetamol) are symptomatic medicinal products.
- The efficacy/adverse effects ratio of these medicinal products is moderate given the frequency and severity of their adverse effects.

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- They are a first- or second-line treatments depending on the origin and severity of the pain. The use of these medicinal products should be restricted to patients whose moderate to severe pain is considered to require a combination of tramadol and paracetamol.

→ **Public health benefit**

The proprietary medicinal products IXPRI^M and ZALDIAR (tramadol/paracetamol) packaged in non-pre-cut heat-formed blister strips are unlikely to have an additional impact on public health compared to the forms already listed; a negative impact on the patient's care pathway cannot be excluded.

The Committee considers that the clinical benefit of IXPRI^M 37.5 mg/325 mg film-coated tablets and ZALDIAR 37.5 mg/325 mg film-coated tablets (tramadol/paracetamol) is substantial 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: 65%**

Clinical Added Value

These medicinal products are range supplements that do not provide any clinical added value (CAV V) compared to the forms already listed.