

SUMMARY

esketamine

**ESKETAMINE RENAUDIN
5 and 25 mg/mL**

solution for injection

Indication extension

Original French opinion adopted by the Transparency Committee on
10 July 2024

The legally binding text is the original French opinion version

Summary of opinion

Favourable opinion for reimbursement for pain relief (analgesia) in emergency medicine and pain control in artificial respiration (intubation).

No clinical added value of ESKETAMINE RENAUDIN (esketamine) 5 and 25 mg/mL compared to the proprietary medicinal product ESKESIA (esketamine) 5 mg/mL and 25 mg/mL solution for injection/infusion.

Transparency Committee's conclusions**Clinical Benefit****Pain relief (analgesia) in emergency medicine**

- ➔ In emergency medicine, the rapid treatment of pain is a priority.
- ➔ This proprietary medicinal product is a symptomatic treatment.
- ➔ ESKETAMINE RENAUDIN (esketamine) has a high efficacy/adverse effects ratio.
- ➔ There are therapeutic alternatives.
- ➔ ESKETAMINE RENAUDIN (esketamine) is a first-line or second-line treatment.

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→ Public health benefit

ESKETAMINE RENAUDIN (esketamine) is unlikely to have an additional impact on public health.

The Committee considers that the clinical benefit of ESKETAMINE RENAUDIN (esketamine) is substantial in pain relief (analgesia) in emergency medicine.

The Committee issues a favourable opinion for inclusion in the list of covered drugs for in-patients approved for use in pain relief (analgesia) in emergency medicine and at the MA dosages.

Pain control in artificial ventilation (intubation)

- Pain control is necessary when initiating and maintaining artificial ventilation, but pain is not systematic in all conscious intubated and ventilated patients.
- This proprietary medicinal product is a symptomatic treatment.
- ESKETAMINE RENAUDIN (esketamine) has a high efficacy/adverse effects ratio.
- There are therapeutic alternatives.
- ESKETAMINE RENAUDIN (esketamine) is a second-line treatment.

→ Public health benefit

ESKETAMINE RENAUDIN (esketamine) is unlikely to have an additional impact on public health.

The Committee considers that the clinical benefit of ESKETAMINE RENAUDIN (esketamine) is substantial in pain control in artificial ventilation (intubation).

The Committee issues a favourable opinion for inclusion in the list of covered drugs for in-patients approved for use in pain control in artificial ventilation (intubation) and at the MA dosages.

Clinical Added Value

These proprietary medicinal products provide no clinical added value (CAV V) compared to ESKESIA (esketamine) 5 and 25 mg/mL solution for injection/infusion.