

**SUMMARY**

midazolam

**MIDAZOLAM AGUETTANT  
1 mg/ml and 5 mg/ml**

solution for injection

Inclusion on list: Indication extension

Original French opinion adopted by the Transparency Committee on  
26 June 2024

The legally binding text is the original French opinion version

**Summary of opinion**

Favourable opinion for reimbursement in the indication sedation in palliative care.

No clinical added value compared to the other generic medicinal products containing midazolam for injection already available in this indication (MIDAZOLAM ACCORD, solution for injection and MIDAZOLAM VIATRIS, solution for injection or rectal use).

**Transparency Committee's conclusions****Clinical Benefit**

- ➔ The end of life refers to the last moments of life of a person in the advanced or terminal phase of a serious and incurable disease/condition, inflicting physical or psychological suffering that cannot be alleviated or that the person considers to be intolerable.

Sedation proportionate to the severity of the symptoms can allow the patient to maintain a relational life; it may be transient, intermittent and potentially reversible. It must be accessible to advanced or terminal patients to respond to refractory suffering.

A patient can request a deep and continuous sedation, maintained until death, in the following two situations:

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Haute Autorité de Santé – Communication and Information Department

5 avenue du Stade de France – 93218 SAINT-DENIS LA PLAINE CEDEX – France. Tel.: +33 (0)1 55 93 70 00

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- if a patient presents suffering refractory to treatments, when he/she has a serious and incurable condition which is life-threatening in the short term;
  - if a patient with a serious and incurable condition decides to stop treatment, and this decision has life-threatening consequences in the short term and is likely to result in unbearable suffering.
- This is a symptomatic medicinal product.
- The efficacy/adverse effects ratio of midazolam in palliative care is high.
- In the sedation in palliative care indication, which includes proportionate sedation and continuous deep sedation, MIDAZOLAM AGUETTANT (midazolam) solution for injection is a first-line treatment according to the HAS guidelines, for use in both hospitals and the community setting, provided that the prerequisites of the recommended care pathway are met.

### → Public health benefit

MIDAZOLAM AGUETTANT (midazolam) solution for injection is unlikely to have an additional impact on public health compared to the other generic medicinal products containing midazolam for injection already available, MIDAZOLAM ACCORD (midazolam) solution for injection, and MIDAZOLAM MYLAN (midazolam) solution for injection or rectal use.

**The Committee considers that the clinical benefit of MIDAZOLAM AGUETTANT (midazolam) solution for injection is substantial in sedation in palliative care.**

**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 sedation in palliative care.**

- **Recommended reimbursement rate for inclusion in the list of covered drugs for outpatients: 65%**

## Clinical Added Value

**This medicinal product provides no clinical added value (CAV V) compared to the other generic medicinal products containing midazolam for injection already listed (MIDAZOLAM ACCORD solution for injection, and MIDAZOLAM VIATRIS solution for injection or rectal use) in the care pathway for sedation in palliative care.**