

SUMMARY

rocuronium bromide

**ROCURONIUM
AGUETTANT 10 mg/mL**

solution for injection in pre-filled syringe

Inclusion on list: First listing

Hybrid

Adopted by the Transparency Committee on 12 June 2024

Summary of opinion

Favourable opinion for reimbursement:

- in adult and paediatric patients from 2 years of age as an adjunct to general anaesthesia to facilitate tracheal intubation during routine sequence induction and to provide skeletal muscle relaxation during surgery.
- in adults to facilitate tracheal intubation during rapid sequence induction and as an adjunct in the intensive care unit (ICU) to facilitate intubation and mechanical ventilation for short term use.

No clinical added value of ROCURONIUM AGUETTANT 10 mg/ml solution for injection in pre-filled syringe compared to the other medicinal products already available.

Transparency Committee's conclusions**Clinical Benefit**

- ➔ Rocuronium bromide is used in the context of general anaesthesia, in critical and intensive care units, and in emergency medicine to facilitate tracheal intubation, mechanical ventilation and certain surgical procedures requiring complete muscle relaxation or total immobility.
- ➔ This is a symptomatic medicinal product.
- ➔ The efficacy/adverse effects ratio is high.
- ➔ It is a first-line treatment.

→ Public health benefit

ROCURONIUM AGUETTANT 10 mg/ml solution for injection in pre-filled syringe is unlikely to have an additional impact on public health compared to the reference medicinal product.

The Committee considers that the clinical benefit of ROCURONIUM AGUETTANT 10 mg/ml solution for injection in pre-filled syringe is substantial in the MA indications.

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 MA indications and at the MA dosages.

Clinical Added Value

This medicinal product is a hybrid that does not provide any clinical added value (CAV V) compared to the forms already listed.