

Original French opinion adopted by the Transparency Committee

The legally binding text is the original French opinion version

SUMMARY

nitric oxide

KINOX 800 ppm mol/mol

medicinal gas, compressed

Inclusion on list: First listing

Range supplement

Adopted by the Transparency Committee on 29 January 2025

Summary of opinion

Favourable opinion for reimbursement for the treatment of:

- newborn infants of ≥ 34 weeks' gestation with hypoxic respiratory failure associated with clinical or echocardiographic evidence of pulmonary hypertension, in order to improve oxygenation and to reduce the need for extracorporeal membrane oxygenation;
- episodes of peri- and post-operative pulmonary hypertension in adults and newborn infants, infants and toddlers, children and adolescents, aged 0-17 years in conjunction with heart surgery, in order to selectively decrease pulmonary arterial pressure and improve right ventricular function and oxygenation.

No clinical added value of the new forms compared to the forms already available.

Transparency Committee's Conclusions

Clinical Benefit

- ➔ Hypoxic respiratory failure associated with persistent pulmonary hypertension in the newborn (PPHN) is immediately life-threatening.
Heart surgery with extracorporeal membrane oxygenation can be complicated by episodes of pulmonary hypertension during the immediate perioperative period. Severe pulmonary hypertension with pulmonary artery pressure close to or equivalent to systemic blood pressure is a serious complication of heart surgery.
- ➔ This is a symptomatic medicinal product.
- ➔ KINOX is a first-line treatment.
- ➔ Efficacy/adverse effects ratio: high in the MA indications.

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→ Public health benefit

KINOX 800 ppm mol/mol medicinal gas, compressed is unlikely to have an additional impact on public health.

The Committee deems that the clinical benefit of KINOX 800 ppm mol/mol (nitric oxide) medicinal gas, compressed is substantial in the MA indications.

The Committee issues a favourable opinion for inclusion in the list of covered drugs for in-patients approved for use in the MA indications and at the MA dosages.

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.