

TRANSPARENCY COMMITTEE OPINION SUMMARY

PRENOXAD (naloxone), antidote



High clinical benefit in the emergency treatment of opioid overdose, pending management in a medical setting, but no demonstrated clinical added value in the therapeutic strategy.

Main points

- PRENOXAD has an MA for the emergency treatment of known or suspected opioid overdose, manifested by respiratory depression and/or central nervous system depression, pending management in a medical setting.
- It is essential that the prescription or supply of PRENOXAD be accompanied by training of the user in possession of the kit in its method of use (see SPC and documents supplied), this individual potentially being required to administer PRENOXAD as an intramuscular injection to a third party in the event of suspected opioid overdose. The emergency services must be contacted immediately, before the injection is administered, and the patient must be monitored following the injection until the emergency services arrive. Subsequent management in a medical setting must be systematic.
- The administration route of PRENOXAD and its packaging result in risks of acute withdrawal syndrome and accidental blood exposure (needle stick injury).

Therapeutic strategy

- The management of opioid overdose is based on reversal of the effects of opioids via the emergency administration of naloxone, a pure and specific antagonist of morphine-like drugs with no agonist effects, along with ventilation of the patient.
- At present, the naloxone-based medicinal products available in France are:
 - injectable naloxone-based medicinal products, for which a medical prescription is compulsory and which may only be dispensed in medical settings,
 - NALSCUE, nasal spray solution, for which medical prescription is optional, distributed in authorised structures and which can be administered by a third party pending medical management
- Role of the medicinal product in the therapeutic strategy**

PRENOXAD can be used in adults for the emergency treatment of known or suspected opioid overdose, manifested by respiratory depression and/or central nervous system depression, pending management in a medical setting.

Clinical data

- The efficacy and safety profile of naloxone used in a medical setting for the emergency management of opioid overdoses is known.
- No data concerning the pharmacokinetics of naloxone hydrochloride or its efficacy on the reversal of opioid-induced respiratory depression are available in accordance with the regimen and context of use of PRENOXAD (administration by a third party).
- No efficacy data documenting the benefit of early administration of PRENOXAD compared to current management based on emergency medical transfer and hospital treatment are available.

Special prescription requirements

- Medicinal product subject to optional prescription

Benefit of the medicinal product

- The actual clinical benefit* of PRENOXAD is high.
- PRENOXAD does not provide any clinical added value** (CAV V) in the emergency treatment, in adults, of known or suspected opioid overdose, manifested by respiratory depression and/or central nervous system depression, pending management in a medical setting.
- Approved for non-hospital pharmacy reimbursement and for hospital treatment.



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This document was drafted on the basis of the Transparency Committee opinion dated 05 December 2018 (CT-17390) available at www.has-sante.fr

* The actual clinical benefit (ACB) of a medicinal product describes its benefit primarily in terms of its clinical efficacy and the seriousness of the condition being treated. The HAS Transparency Committee assesses the ACB, which may be high, moderate, low, or insufficient for the medicinal product to be covered by public funding.

** The clinical added value (CAV) corresponds to the clinical improvement offered by a medicinal product compared to existing treatments. The HAS Transparency Committee assesses the CAV level from I, major, to IV, minor. A level V CAV (equivalent to "no clinical added value") denotes a "lack of clinical improvement".