Nyxoid (naloxone hydrochloride) 1.8 mg nasal spray Prescribing Information Republic of Ireland

Please read the Summary of Product Characteristics (SPC) before prescribing.

Presentation

Nasal spray solution in a single-dose container

Indications

Emergency therapy in adults and adolescents aged 14 years and over for known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression. ***Nyxoid*** is not a substitute for emergency medical care.

Dosage and administration

Recommended dose is one spray (1.8 mg) administered into one nostril. Further doses may be necessary. Administer a second dose after 2-3 minutes if the patient doesn't respond or immediately if the patient responds then relapses into respiratory depression. Further doses should be administered into alternate nostrils. Monitor patient whilst awaiting arrival of emergency services.

Nyxoid should be administered as soon as possible to avoid central nervous system damage or death.
Nyxoid contains only one dose so must not be primed or tested prior to administration.
See package leaflet for detailed instructions on use of ***Nyxoid***.
Not recommended in the paediatric population.

Contraindications

Hypersensitivity to active substance or excipients.

Precautions and warnings

Nyxoid should only be made available to suitable and competent individuals. Patients or anyone in a position to administer ***Nyxoid*** must be instructed on its indications and proper use, and the importance of seeking medical assistance. ***Nyxoid*** is not a substitute for emergency medical care.
Patients who respond to ***Nyxoid*** must be closely monitored, as respiratory depression may reoccur requiring further doses of naloxone.
Nyxoid can lead to a rapid reversal of the opioid effect, which can cause acute opioid withdrawal syndrome. Patients receiving opioids for chronic pain treatment may also experience pain when ***Nyxoid*** is administered. Opioid withdrawal may be life-threatening in neonates if not recognised and properly treated. Signs and symptoms may include: convulsions, excessive crying and hyperactive reflexes.
Reversal of buprenorphine-induced respiratory depression may be incomplete, and if this occurs respiration should be mechanically assisted.
Absorption and efficacy can be altered in patients with damaged nasal mucosa and septal defects.

Patients should be warned not to drive, operate machinery or engage in demanding physical and mental activities for at least 24 hours.

Interactions

Naloxone interacts with opioids and opioid agonists when administered to opioid dependent patients, may cause acute withdrawal symptoms including: hypertension, cardiac arrhythmias, pulmonary oedema and cardiac arrest.

May decrease analgesic effects of opioids used for pain relief.

Fertility, pregnancy and lactation

No clinical data on effects on fertility are available.

Nyxoid should not be used in pregnancy unless the condition of the woman requires treatment with naloxone. Monitor fetus for signs of distress. In opioid-dependant women, naloxone can cause withdrawal symptoms in newborn infants. Caution when administered to breast-feeding mothers; no need to discontinue breast-feeding.

Side effects

Very common (≥1/10) and common (≥1/100 to <1/10): dizziness, headache, tachycardia, hypotension, hypertension, nausea, vomiting.
Uncommon (<1/100) but potentially serious or fatal: hypersensitivity, anaphylactic shock, arrhythmia, bradycardia, cardiac fibrillation, cardiac arrest, hyperventilation, pulmonary oedema, erythema multiforme, drug withdrawal syndrome (in patients dependent on opioids).
Please refer to the SPC for further information and a full list of side effects.

Legal category

POM

Package quantities

Each pack contains two single-dose nasal sprays.

Marketing authorisation number(s)

EU/1/17/1238/001

Marketing authorisation holder

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