Alert | Naloxone should not be administered to babies whose mothers are known or suspected to be addicted to opioids. In such cases, an abrupt and complete reversal of opioid effects may precipitate an acute withdrawal syndrome and seizures.

Indication | 1. At birth – Reversal of respiratory depression secondary to maternal opioid administration.
2. Reversal of opioid effects (to facilitate extubation or avoid intubation, post-operative apnoea).

Action | Opioid antagonist. Little or no agonistic activity.

Drug Type | Semisynthetic opioid antagonist

Trade Name | DBL Naloxone Hydrochloride Injection; Naloxone Juno Solution for injection; Naloxone Min-I-jet Prefilled syringe; Narcan Solution for injection; Prenoxad Solution for injection.

Presentation | Ampoule and prefilled syringe contain 400 microgram/mL of naloxone hydrochloride. Also contains sodium chloride.
Contains 3.54 mg (0.15 mmol) of sodium. The solution is clear and colourless. pH 3.5

Dosage / Interval | 1. At birth – newborn infants with respiratory depression secondary to maternal opioid administration
100 microgram/kg. Repeat dose as required.
DO NOT USE IN INFANTS BORN TO MOTHERS SUSPECTED OR KNOWN TO BE ADDICTED TO OPIOIDS.

2. Reversal of opioid-induced respiratory depression
10–100 microgram/kg. Repeat dose as required.
CAUTION: Infants on prolonged opioid infusion may develop acute withdrawal following naloxone.

Maximum daily dose | 2 mg

Route | Intravenous (IV) injection preferred. IM suitable if the IV route is not available. Alternate routes: intraosseous and subcutaneous.

Preparation/Dilution | 400 microgram/mL

Administration | Use undiluted.
Intravenous (IV) bolus at proximal cannula site.
Intramuscular (IM).

Monitoring | Continuous cardiorespiratory monitoring is required.
Resuscitation facilities must be readily available.

Contraindications | Naloxone is contraindicated in persons known to be hypersensitive to it.

Precautions | Naloxone should not be administered to babies whose mothers are known or suspected to be addicted to opioids.
The duration of action of naloxone is short, particularly after intravenous administration, and subsequent observation of the infant should be instituted.

Drug Interactions | Naloxone reverses the analgesic and other effects of opioid agonists.

Adverse Reactions | Naloxone administered to babies whose mothers are known or suspected to be addicted to opioids may precipitate an acute withdrawal syndrome (tachycardia, tachypnoea, hypertension, tremors, vomiting and seizures). Cardiac arrest – there is a case report of a preterm neonate who developed cardiac arrest. [18]

Compatibility | Fluids: Glucose 5%, sodium chloride 0.9%
Y-site: Defibrotide, linezolid

Incompatibility | Do not mix in an alkaline solution.
Fluids: No information
Drugs: Solutions that contain bisulfites or sulfites, calcium folinate

Stability | Infusion solution: Use within 24 hours.

Storage | Ampoule and Min-I-Jet syringe: Store below 25°C. Protect from light. Do not freeze.

Special Comments | Always establish and maintain adequate respiration before administration of naloxone to a newborn infant.
The majority of infants born following intrapartum maternal opioid administration do not require administration of an opioid antagonist. Opioid antagonists should not be used as a substitute for provision of usual methods of clinical care and resuscitation of the newly born infant.

Evidence summary: Refer to full version.

References: Refer to full version.

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