This information was up to date at the time of release to the Heads of Midwifery.
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Updating arrangements for the formulary should be decided upon and implemented at a local level.

Naloxone (neonate)

Legal status (GSL, P or POM on exemption list, or PGD)	POM - midwife may administer as medicine is on midwives exemptions list
Patient group	Newborn babies with respiratory and other CNS depression resulting from the administration of opioid analgesic to the mother during labour.
Clinical indication	Reversal of respiratory depression and lethargy in neonates more than or equal to 34 weeks gestation at birth where the mother has received an opioid analgesic.Prior to the administration of naloxone it is essential that basic CPR measures are initiated if required; • Airway - ensure an adequate clear airway. • Breathing - initiate artificial ventilation. • Circulation - initiate cardiac massage.
Pharmacology (Onset and duration of action where appropriate)	Naloxone is a semi-synthetic morphine derivative that is a specific opioid antagonist. Naloxone acts within three to five minutes of intramuscular injection. The duration of the antagonistic effect depends on dose but in general is in the range of 1-4 hours. The need for repeated doses depends on the quantity, type and route of administration of the opioid to be antagonised.
Pharmaceutical form, strength, route of administration	Injection contains naloxone hydrochloride 400micrograms in 1ml ampoule. For intramuscular administration, use undiluted.
Dose, frequency and maximum number of doses or period of time for administration or supply	200 micrograms (0.5ml) by IM injection into the anterior thigh. Maximum of one dose.
Contra-indications/exclusion criteria	▪ known hypersensitivity to naloxone or any of the excipients ▪ infants of less than 34 weeks gestation at birth ▪ mother is a known substance misuser ▪ mother is on long term opiates for chronic painful conditions ▪ severe cardiovascular disease ▪ neonatal respiratory depression not caused by maternal opioid administration

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Cautions and action that will be taken if a caution applies	▪ cardiovascular disease ▪ babies who respond satisfactorily to naloxone hydrochloride must be closely monitored - the effect of opioids can be longer than the effect of naloxone hydrochloride and new injections may be necessary ▪ check for and document any allergies ▪ check and document past medical and drug history and current medication to ascertain potential for overdose ▪ if a caution applies consult with a doctor ▪ document consultation in maternity record
Drug interactions and action that will be taken if a patient is taking a medicine that may interact	▪ none known ▪ if there is a clinically significant drug interaction, consult with a doctor before administration or supply ▪ document consultation in neonatal record ▪ refer to current BNF for latest information on interactions
Potential adverse reactions and side effects including actions to be taken if adverse drug reaction is suspected	▪ naloxone can precipitate acute withdrawal symptoms in babies of substance misusing mothers - symptoms include hypertension, hypotension, arrhythmias, agitation, pulmonary oedema, cardiac arrest, sweating, nausea, vomiting, irritability, shrill cry, failure to feed and rarely seizures can occur. Additionally, allergic reactions, tremor, tachycardia, bradycardia, and arrhythmias. ▪ it may be associated with risk of intraventricular haemorrhage in babies less than 34 weeks gestation at birth ▪ local irritation and inflammation can occur after IM use ▪ a fast reversal of opioid effect can induce hyperventilation ▪ *if a serious adverse reaction is suspected please report to the MHRA Yellow Card Scheme* http://yellowcard.mhra.gov.uk/
Overdose	▪ in view of the indication and the broad therapeutic margin overdose is not to be expected ▪ immediate assessment/treatment is essential - refer to medical staff ▪ manage in accordance with established treatment guidelines or see BNF overdose section ▪ for further advice contact National Poisons Centre 0344 892 0111
Action if patient declines	▪ refer to authorised prescriber or doctor ▪ document in maternity record
Additional advice and information	▪ the reason for giving naloxone ▪ supply the manufacturer's patient information leaflet if requested

Naloxone (neonate)

Patient monitoring arrangements during and after treatment and follow-up required	Inform paediatric medical staff immediately after use of naloxone. Monitor for the return of respiratory depression or lethargy as the duration of action is shorter than the opioids**.**
Particular storage requirements	▪ Store at room temperature below 25ºC in original carton and protect from light.

References

1. Summary of Product Characteristics. Naloxone 400 micrograms/ml solution for injection (Hameln Pharmaceuticals ltd). Text revision 6.2.2019 . Accessed16.12.19 www.emc.medicines.org.uk

2. http://www.bnfc.org