NYXOID®

naloxone hydrochloride dihydrate



Needle-free opioid overdose reversal.[1]

NYXOID® nasal spray.[1]

No needles.

Ready-to-use.

Easy to administer.

A viable alternative to 0.4mg IM naloxone.[2]

NYXOID® nasal spray
1.8mg/0.1ml

mundipharma

NYXOID® (IN naloxone†) an easy-to-use alternative to 0.4mg IM naloxone injection[2,3]

NYXOID® is intended as part of the emergency treatment for known or suspected opioid overdose[1]

How to use:[1]

1. Call 000
2. Give one spray of NYXOID® into one nostril
3. Monitor and give CPR support
4. Give a second dose into the other nostril if there is no improvement within 2-3 minutes or if OD symptoms return

Based on its pharmacokinetics, a single dose of NYXOID® is expected to deliver:[1]

- A similar onset for reversing an opioid overdose, comparable to IM naloxone (0.4 mg)
- A lower risk of rebound OD

For optimal intranasal absorption, volume should be < 0.2 ml.[4,5]
NYXOID® comes in a concentrated 0.1 ml solution.[1]



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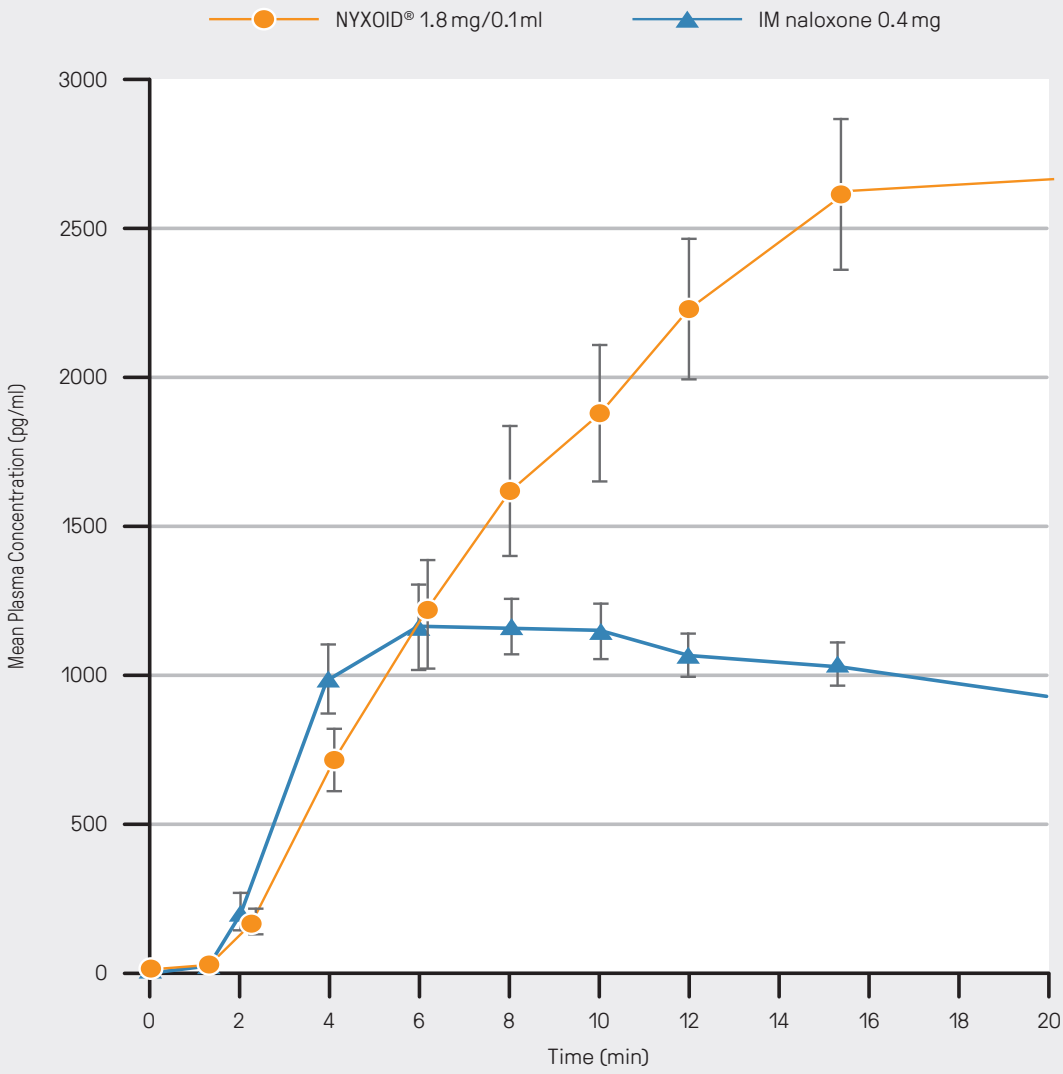
NYXOID®

Similar rapid rise in the first 10 minutes compared to IM naloxone (0.4 mg)[2]

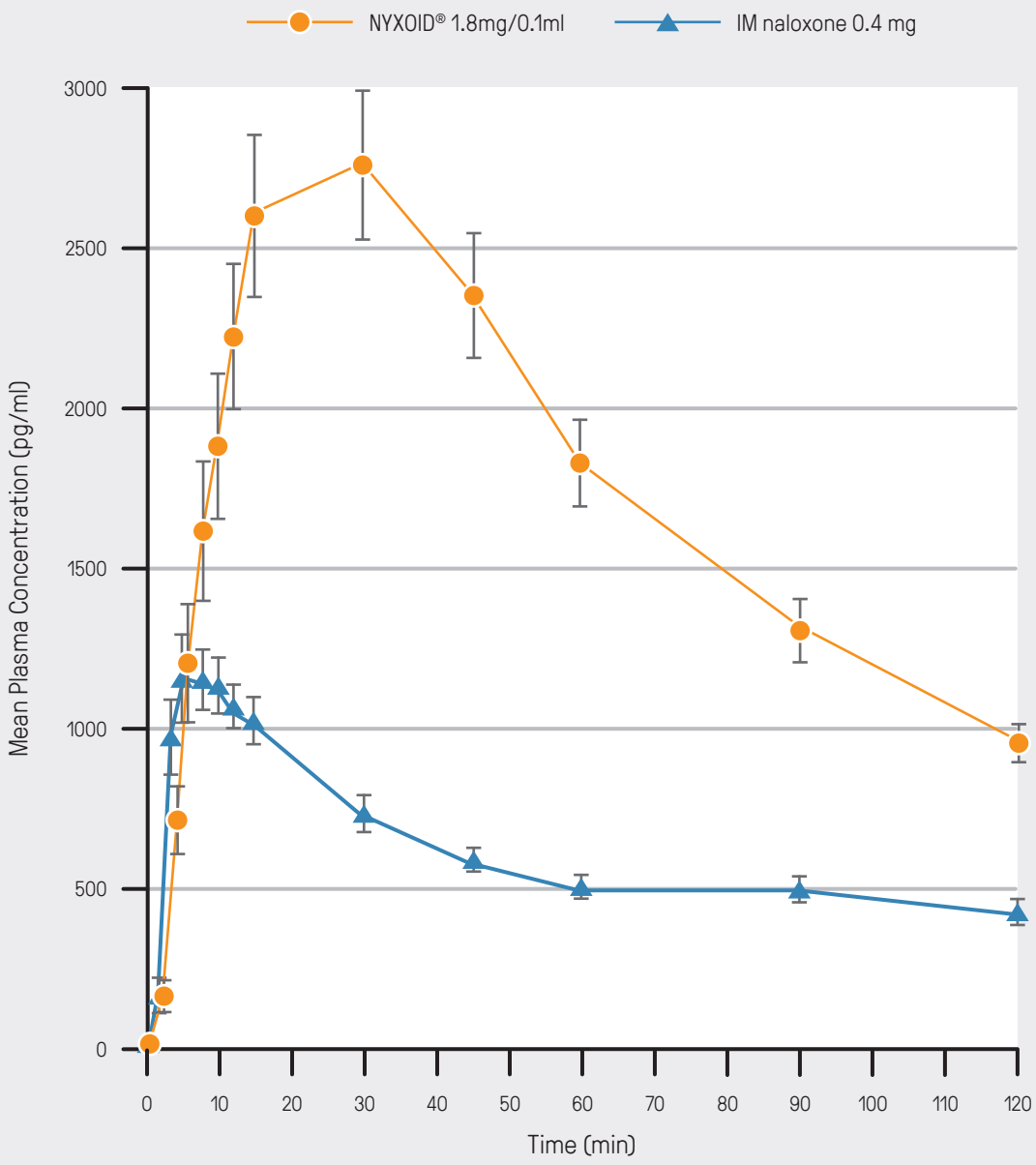


Study Design: A randomised, open-label, five-way cross-over study to determine naloxone pharmacokinetics in healthy volunteers (32 subjects completed all test doses). A total of 19 samples per test dose were analysed (pre-dose, at 1, 2, 4, 6, 8, 10, 12.5, 15, 30 and 45 minutes and 1, 1.5, 2, 4, 6, 8, 10 and 12 hours after dosing). The five test doses were: naloxone i.n. 1 mg/0.1ml one nostril; naloxone i.n. 2 mg/0.1ml one nostril; naloxone 2 mg/0.1 ml i.n. each nostril ; naloxone i.m. 0.4 mg/ml into the deltoid; and 0.4 mg naloxone i.v. The 2 mg i.n. dose followed the 0.4 mg i.m. reference most closely, and was chosen as comparator in exploratory analyses.[2]

† NYXOID® contains 1.8 mg naloxone (equivalent to 2 mg naloxone hydrochloride or 2.2 mg naloxone hydrochloride dihydrate) in a concentrated 0.1 ml solution.[1]

NYXOID®

Sustained higher levels from 15 minutes to 2 hours compared to IM naloxone (0.4 mg)[2]



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2 doses of NYXOID® are expected to perform similarly to 5 doses of IM naloxone (0.4 mg)[2†]

IN = 50% x 2 x 2mg
(= 2mg)



EXPECTED TO DELIVER
SIMILAR OUTCOMES



IM = 100% x 5 x 0.4mg
(= 2mg)

† The efficacy of NYXOID® has not been assessed in clinical trials. Efficacy has been inferred based on pharmacokinetic studies.[1] This expected result of multiple dosing is based on a pharmacokinetic simulation of repeat doses given at 3 minute intervals and the observed 50% relative bioavailability of NYXOID® compared to IM naloxone.[2]

NYXOID®
is well tolerated[1,3]



In the absence of opioids, naloxone has essentially no pharmacological activity[1]

Symptoms of opioid withdrawal are expected to occur following the use of NYXOID® in people physically dependent on opioids[4]

- These are generally transient, lasting approximately 30 minutes up to 2 hours[6,7]

Commonly reported adverse events reported with NYXOID® and other naloxone formulations include:[1,3]

- Very common (≥ 10%):
  Nausea
- Common (≥ 1%, < 10%):
  Dizziness, headache, tachycardia, hypotension, hypertension, vomiting.

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Needle-free opioid overdose reversal[1]

NYXOID® nasal spray overcomes some of the barriers to reversing an OD with injections, including:[8]

- Easier to use by laypersons
- The nose is typically readily accessible
- No fear or risk of needle stick injury
- Requires less training
- No preparation required

Effective even if the patient is unconscious[9]





Needle-free opioid overdose reversal.[1]

NYXOID® nasal spray.

NYXOID® nasal spray 1.8mg/0.1ml

www.nyxoid.com.au

NYXOID® nasal spray is listed on the PBS as an Unrestricted Benefit.

Please review the Product Information before recommending or prescribing. Approved Product Information can be accessed from https://www.mundipharma.com.au/products/

NYXOID® nasal spray MINIMUM PRODUCT INFORMATION.

NAME OF THE MEDICINE: NYXOID naloxone hydrochloride dihydrate 2.2 mg/actuation nasal spray vial.

INDICATIONS: NYXOID is intended as part of the emergency treatment for known or suspected opioid overdose as manifested by respiratory and/or central nervous system depression in:

- the home or other non-medical setting
- a health facility setting.

For this reason, NYXOID should be carried by persons at risk of, or likely to witness such events.

NYXOID is indicated in adults and children.

CONTRAINDICATIONS: Hypersensitivity to any of the active substances or to the excipients.

PRECAUTIONS: NYXOID is not a substitution for emergency medical care and cannot replace intravenous injection. Therefore, patients at risk or likely to witness an opioid overdose must be instructed in the proper use of NYXOID.

A return of respiratory and/or central nervous system depression after an initial improvement in symptoms.

INTERACTIONS: The effect of naloxone is based on the interaction with opioids and opioid agonists, reversing effects of opioids; rapid reversal may precipitate acute withdrawal syndrome in opioid dependence. At the usual naloxone dose there is no interaction with barbiturates and tranquillisers. In patients with multiple intoxication with opioids and sedatives or alcohol, the result of naloxone administration may be delayed, dependent on the cause of intoxication.

ADVERSE EFFECTS: Very common: nausea; common: dizziness, headache, tachycardia, hypotension, hypertension, vomiting, post-operative pain. Typical opioid withdrawal syndrome is expected with naloxone which may be caused by the abrupt withdrawal of opioid in persons physically dependent on them.

DOSAGE AND ADMINISTRATION: One spray of NYXOID into a nostril. Re-administer NYXOID, using a new NYXOID container, into the other nostril after 2 to 3 minutes if the patient does not respond or responds and then relapses into respiratory depression. Further doses may be given every 2 to 3 minutes if needed until further assistance is available.

DATE OF FIRST INCLUSION IN THE AUSTRALIAN REGISTER OF THERAPEUTIC GOODS (THE ARTG): 18 September 2018.

References: 1. NYXOID® nasal spray Product Information, September 2018. **2.** McDonald R *et al.* Addiction 2018;113:484-493. **3.** McKeage K, Lyseng-Williamson KA. Drugs Ther Perspect 2018;34:150-156. **4.** Castile J, *et al.* Drug Devel Ind Pharm 2013; 39(5):816–824. **5.** Dale O *et al.* Acta Anaesthesiol Scand 2002;46:759–770. **6.** Wermeling DP. Ther Adv Drug Saf 2015;6:20-31. **7.** EMCDDA. Preventing opioid overdose deaths with take-home naloxone. 2016 [Accessed 29 September 2018]. Available from: http://www.drugs.ie/resourcesfiles/ResearchDocs/Europe/Research/2016/Naloxone.pdf **8.** Kerensky T, Walley AY. Addict Sci Clin Pract. 2017;12:4. **9.** Barton ED. J Emerg Med 2005;29:265-271.

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