EMA/626193/2017
EMEA/H/C/004325

EPAR summary for the public

Nyxoid

naloxone

This is a summary of the European public assessment report (EPAR) for Nyxoid. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Nyxoid.

For practical information about using Nyxoid, patients should read the package leaflet or contact their doctor or pharmacist.

What is Nyxoid and what is it used for?

Nyxoid is a medicine used for emergency treatment in case of known or suspected overdose of opioid drugs (such as heroin or morphine).

Signs of overdose include pinpoint pupils, abnormally slow and irregular breathing, severe sleepiness and unresponsiveness to touch or loud noises. Nyxoid can be used in adults and adolescents from 14 years of age. It contains the active substance naloxone.

Nyxoid is a 'hybrid medicine'. This means that it is similar to a 'reference medicine' containing the same active substance, but is given in a different way. While the reference medicine Naloxon HCl B. Braun is given by injection, Nyxoid is given as a spray into the nose.

How is Nyxoid used?

Nyxoid is a nasal spray available in single-dose containers (1.8 mg). The recommended dose is one spray into one nostril given immediately on suspecting an opioid overdose and while awaiting emergency services; if the first dose does not have an effect, a second dose should be given after 2–3 minutes in the other nostril. If the first dose works well but the patient later worsens a second dose should be given immediately in the other nostril.

For further information, see the package leaflet.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

The medicine can only be obtained with a prescription.

How does Nyxoid work?

The active substance in Nyxoid, naloxone, counteracts the effects of opioid drugs. Opioids work by attaching to and activating opioid receptors (targets) in the body. Naloxone rapidly blocks these receptors, ending the opioid's effects such as slow breathing.

What benefits of Nyxoid have been shown in studies?

Naloxone, the active substance in Nyxoid, has been widely used in emergency medicine since the 1970s to treat opioid overdose. The company provided data from the published literature showing that naloxone is effective in treating opioid overdose when given by injection (the standard treatment for opioid overdose) as well as into the nose. In addition, a study involving 38 healthy volunteers showed that, when given by a healthcare professional, Nyxoid 2 mg given as a spray into the nose produced a similar level of naloxone in the body as naloxone given in the usual dose of 0.4 mg by injection into a muscle.

What are the risks associated with Nyxoid?

The most common side effect with Nyxoid (which may affect more than 1 in 10 people) is nausea (feeling sick). Typical opioid withdrawal syndrome is expected after Nyxoid is given to people addicted to opioids; symptoms include restlessness, agitation, feeling or being sick, a fast heart rate and sweating.

For the full list of all side effects and restrictions with Nyxoid, see the package leaflet.

Why is Nyxoid approved?

The safety and effectiveness of naloxone as an antidote for opioid overdose are well known. Compared with emergency treatments for opioid overdose given by injection, Nyxoid can be given by people with no medical training because it is sprayed into the nose. There is also no risk of needle injury with Nyxoid, and this could encourage members of the public to provide treatment promptly. Therefore, the European Medicines Agency decided that Nyxoid's benefits are greater than its risks and recommended that it be approved for use in the EU.

What measures are being taken to ensure the safe and effective use of Nyxoid?

The company that markets Nyxoid will issue educational materials, including a video, for healthcare professionals and for patients with detailed information on how to use the medicine. The company will also conduct a study on the effectiveness of Nyxoid when given by people with no medical training.

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Nyxoid have also been included in the summary of product characteristics and the package leaflet.

Other information about Nyxoid

The European Commission granted a marketing authorisation valid throughout the European Union for Nyxoid on 10 November 2017.

The full EPAR for Nyxoid can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Nyxoid, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 11-2017.