14 September 2017
EMA/CHMP/594248/2017
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Nyxoid

naloxone

On 14 September 2017, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Nyxoid, intended for the treatment of opioid overdose. The applicant for this medicinal product is Mundipharma Corporation Limited.

Nyxoid will be available as a nasal spray (1.8 mg). The active substance of Nyxoid is naloxone, an antidote that acts as opioid receptor antagonist (ATC code: V03AB15).

The benefits with Nyxoid are its ability to reverse symptoms of opioid overdose. The most common side effects are nausea and opioid withdrawal syndrome.

Nyxoid is a hybrid medicine[2] of Naloxon HCl (solution for injection) which has been authorised in the EU since 2006. Nyxoid contains the same active substance as Naloxon HCl, but it is given into the nostrils.

The full indication is:

"Nyxoid is intended for immediate administration as emergency therapy for known or suspected opioid overdose as manifested by respiratory and/or central nervous system depression in both non-medical and healthcare settings.

Nyxoid is indicated in adults and adolescents aged 14 years and over.

Nyxoid is not a substitute for emergency medical care."

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

[2] Hybrid applications rely in part on the results of pre-clinical tests and clinical trials for a reference product and in part on new data.

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