dne pharma

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Guidance document for Healthcare Professionals

Educational material for how to use

Naloxone 1.26 mg nasal spray, solution in single-dose container

The intention of this guidance document is to;

- Provide information to healthcare professionals about Naloxone 1.26 mg nasal spray, solution in single-dose container
- Support healthcare professionals in educating their patients at risk of an opioid overdose in the use of Naloxone 1.26 mg nasal spray.
- This education is also intended for their families, friends and caregivers.

Available educational material for Naloxone 1.26 mg nasal spray:

1. **Guidance document for Healthcare Professionals (this document):**
   An educational guidance for healthcare professionals with instructions for Naloxone 1.26 mg nasal spray that consists of:
   • Information for healthcare professionals
   • Patient Information Card to demonstrate the use of Naloxone 1.26 mg nasal spray for patients and caregivers.

2. **Patient Information Card:**
   • This Patient Information Card is for the patients or families, friends and caregivers to take home
   • This leaflet gives information to the patients, families, friends and caregivers about Naloxone 1.26 mg nasal spray and how you use it in an emergency situation caused by suspected overdose of opioids
   • This also has a QR-code for access to the video via a smartphone.

3. **Access online (web page) that shows:**
   • Video explaining what to do in the case of a suspected opioid overdose
   • Links to local access on where to get the educational material.

OTHER INFORMATION ABOUT NALOXONE 1.26 MG NASAL SPRAY AND USE

1 pack of Naloxone 1.26 mg nasal spray contains:
• One pebble containing 2 nasal sprays. The second spray is included to be able to give a second dose of naloxone if needed.
• A Quick Start Guide is included in the pebble with pictograms that show how Naloxone 1.26 mg nasal spray is used.
• A package leaflet with information about this medicinal product and stepwise instructions for use

INSTRUCTIONS FOR HEALTHCARE PROFESSIONALS:

Each nasal spray container delivers 1.26 mg of naloxone (as hydrochloride dihydrate) in a 0.1 ml solution. It 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.

Mechanism of action: Naloxone is a semi-synthetic morphine derivative (N-allyl-noroxymorphon) and a specific opioid antagonist that antagonises opioid effects by competing for the same receptor sites. The effect is due to antagonism of mu, kappa, delta opioid receptors. The antagonism of the mu receptor restores respiration. Naloxone has no agonistic effect and in the absence of opioids it exhibits no pharmacological activity.

Use of naloxone: Naloxone 1.26 mg nasal spray gives an alternative to intravenous, intramuscular or subcutaneous injections that are well-known by healthcare professionals. For many years and in several European countries naloxone has been used directly with people at risk of opioid overdoses including involved family and bystanders via «take-home» naloxone programs (THN)[2,3,4] based on targeted education.

Naloxone 1.26 mg nasal spray provides an alternative treatment that can be used within the local guidelines for the treatment of this group of patients.

Pharmacokinetic data have shown that naloxone is absorbed sufficiently through the nasal mucosa and exhibits a sufficient degree of antagonistic effect on opioids that have caused the symptoms of overdose. [5]

The patient is expected to respond within 2-3 minutes following administration.[1]

IMPORTANT INFORMATION ABOUT THE USE OF NALOXONE 1.26 MG NASAL SPRAY THAT MUST BE SHARED WITH THE PATIENT/CAREGIVER. THIS INFORMATION IS ALSO INCLUDED IN THE PATIENT INFORMATION LEAFLET.

To recognize a suspected overdose: If an overdose is suspected in a comatose patient, maybe with injection equipment close by, the bystander should approach the user carefully, check for response, airways and breathing as well as signs of overdose.

Call for help: Call emergency medical services immediately before administering Naloxone 1.26 mg nasal spray, even if the patient wakes up.

• As naloxone is a short-acting antagonist the effect can decrease, especially if the patient has taken long acting opioids that lasts longer than the effect of naloxone.

• Alternatively, the patient may need medical help if use of opioids is not the cause of the symptoms.

Correct use of Naloxone 1.26 mg nasal spray: Naloxone 1.26 mg nasal spray comes in ready-made sprays for delivery in the nostril.

• The spray is activated by pressing the plunger until you hear a “click”.

• The nasal spray must not be primed or tested before use, as the dose will be wasted. Each spray only contains one dose. Correct use of the first spray, and then the second spray if needed, provide a better chance of getting a response from the patient before the emergency medical services have arrived on site.

Stay with the patient until the emergency services arrive: Naloxone 1.26 mg nasal spray is not a substitute for emergency medical care (such as CPR).

• If the bystander is waiting with the patient, they can place the patient into the recovery position. Give the second dose if the patient is not responding to the first one or has experienced a relapse of respiratory depression. Give CPR and watch for relapsing respiratory depression or withdrawal symptoms. Tell the emergency medical services what has happened.

Possibility of reoccurring respiratory depression: This is a potential life-threatening situation. Two sprays are included in the pack to prolong the effect of naloxone until the emergency medical services arrive.

The possibility of precipitating opioid withdrawal symptoms: In subjects who are physically dependant on opioids, naloxone may cause moderate to severe withdrawal symptoms that appear within a few minutes following administration and they may decrease after approximately 2 hours.

• The severity of withdrawal symptoms depends on the dose of naloxone, as well as the degree and type of opioid dependence. Some people may behave aggressively when they wake up.

The Patient Information Card for patients and caregivers in this package provides healthcare professionals with the material that can be used to go through these topics with patients and caregivers in an easier, stepwise way and utilizes the same points as in the Quick Start Guide which may be found inside the pebble. In addition, there is a link to a short tutorial video that provides a comprehensive review of the treatment procedure.

Reporting of adverse events:

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

Yours sincerely

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For more information, please see www.naloxone.uk or scan the QR code

1. Naloxone 1.26 mg nasal spray SPC
2. European Monitoring Centre for Drug Addiction, European Drug Report, 2017
3. Bird SM et al Effectiveness of Scotland's National Naloxone Programme for reducing opioid-related deaths: Addiction.2016 May; 111(5): 883-91
4. Madah-Amiri D et al Rapid widespread distribution of intranasal naloxone for overdose prevention. Drug Alcohol Depend. 2017 Apr 1;173: 17-23
5. Mundin G,et al Pharmacokinetics of concentrated naloxone nasal spray over first 30 minutes postdosing. Addiction. 2017 Sep; 112(9):1647-1652.

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