Guidance document for Healthcare Professionals

Educational material for how to use

Ventizolve (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 Ventizolve 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 Ventizolve nasal spray and to manage the risks associated with Ventizolve.

- This education is also intended for their families, friends and caregivers.

Available educational material for Ventizolve:

1. **Guidance document for Healthcare Professionals (this document):**
   An educational guidance for healthcare professionals with instructions for Ventizolve that consists of:
   • Information for healthcare professionals

2. **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.

3. **Quick Start Guide:**
   The Quick Start Guide, to be used on site for bystanders, is a series of six user-friendly pictograms with text, that show steps to take when using Ventizolve in treating a patient with opioid overdose. The Quick Start Guide is included in each and every pack. The pictograms summarize the instructions given in the patient information leaflet.

OTHER INFORMATION ABOUT VENTIZOLVE AND USE

1 pack of Ventizolve 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 Ventizolve is used.
• A package leaflet with information about this medicinal product and stepwise instructions for use

INSTRUCTIONS FOR HEALTHCARE PROFESSIONALS:

The healthcare professional should take appropriate steps to ensure that the patient and/or any other person who might be in a position to administer Ventizolve thoroughly understands the indications and use of Ventizolve. The patient should be encouraged to read the Patient Information leaflet (PIL) included in the medicinal product outer carton, and also to familiarize

with the pictograms which are summarised in the Quick Start Guide inside the pebble. They should also make sure the patients understand how to access the video.

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 in adults as manifested by respiratory and/or central nervous system depression, in both non-medical and healthcare settings.
Ventizolve is not a substitute for emergency medical care.

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: Ventizolve is administered in opioid-dependent subjects, especially when expected to be at risk of severe opioid withdrawal. In some cases, further doses may be necessary. The appropriate maximum dose of Ventizolve is situation specific.

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.

The patient is expected to respond within 2-3 minutes following administration.
If the patient does not respond, the second dose should be administered. If the patient responds to the first administration but then relapses again into respiratory depression, the second dose should be administered immediately. Further doses (if available) should be administered in alternate nostrils and the patient should be monitored whilst awaiting arrival of the emergency services.

IMPORTANT INFORMATION ABOUT THE USE OF VENTIZOLVE THAT MUST BE SHARED WITH THE PATIENT/CAREGIVER. THIS INFORMATION IS ALSO INCLUDED IN THE PATIENT INFORMATION LEAFLET.

The healthcare professional should describe the symptoms which allow presumptive diagnosis of central nervous system (CNS) / respiratory depression, the indication and the instructions for use with the patient and/or person who might be in a position to administer this product to a patient experiencing a known or suspected opioid overdose event.

Patients and care takers should receive proper instructions on how to use the device, and that it should not be primed or tested prior to administration and that it cannot be reused after administration of the dose.

Detailed instructions on how to use Ventizolve are provided in the Package Leaflet in the outer carton, it is summarized in the Quick Start Guide and the video is available on www.ie.ventizolve.com or scan the QR code below. These links are also printed on the outer carton.

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 Ventizolve, 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 Ventizolve: Ventizolve comes in ready-made sprays for delivery in the nostril.

• After inserting the nozzle into the nose, 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: Ventizolve is not a substitute for emergency medical care (such as CPR).

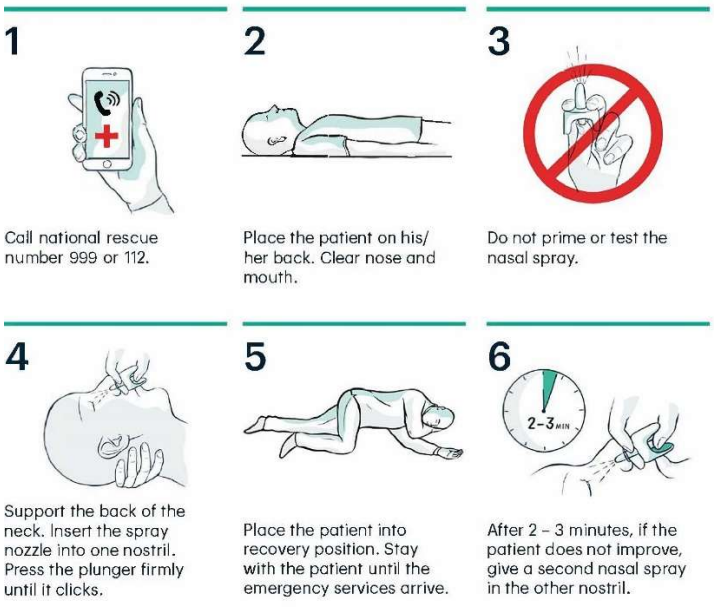
• If the bystander is waiting with the patient, they can place the patient into the recovery position. Give the second dose if the patient is not responding to the first one or has experienced a relapse of respiratory depression. Give CPR and watch for relapsing respiratory depression or withdrawal symptoms.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

QUICK START GUIDE



According to guidelines for your hospital or healthcare centre you should inform the patient or caretaker about the local way of getting new packages if:

- The original Ventizolve pack has exceeded the expiration date, or
- The patient has been treated with the original Ventizolve pack, but he/she is still in danger of an overdose and is therefore in the need of a new pack.

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.
Call for reporting: Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, website: www.hpra.ie or to the Marketing Authorisation Holder; dne pharma, website: www.dnepharma.com.

For more information, please see www.ie.ventizolve.com or scan the QR code

dne pharma as
Karihaugveien 22
1086 Oslo – Norway

+47 21 60 87 00
post@dnepharma.com
dnepharma.com