NALOXONE HIKMA®

(Naloxone HCl)

ACTION

Naloxone (Naloxone HCl) is a specific semisynthetic opiate antagonist, presented as a sterile, clear, colourless solution for IV, IM, or SC administration.

Naloxone prevents and reverses the effect of opioids, including respiratory depression, sedation and hypotension, also it can reverse the psychotomimetic and dysphoric effects of agonist-antagonists such as pentazocine.

Naloxone has little or no agonistic activity and when administered in usual doses to patients who have not recently received opiates it exerts little or no pharmacologic effect.

Naloxone doesn't produce tolerance or physical or psychological dependency, the clear mechanism of action for Naloxone is not known, but it is thought to act as a competitive antagonist at opiate receptors in the CNS. The onset of action of Naloxone following IV administration is 1-2 minutes and following IM or SC administration is 2-5 minutes, the duration of action depend on dose and route of administration. Following parenteral administration,Naloxone is rapidly distuributed into body tissues and fluids, then metabolized in the liver mainly by conjugation and excreted in the urine.

INDICATIONS

Naloxone is indicated in the following conditions:

- Post operative opioids central depression including respiratory depression induced by natural or synthetic opioids.
- In known or suspected opioids overdose or dependency.
- In the treatment of opiate-induced asphyxia neonatorum, resulting from administration of opiates to the mother during labour and delivery.
- Naloxone is recommended as a screening test (the Naloxone challenge test) prior to induction of therapy with naltrexone for opiate cessation in patients formerly dependant on opiate, who have completed detoxification.

DOSAGE AND ADMINISTRATION

The drug could be given via IV, IM or SC route. it is preferable to use IV injection in emergency situation, and to use IM or SC injection when longer duration of action is needed.

- To prepare IV-infusion: The addition of 2 mg Naloxone to 500 ml of either normal saline or 5% dextrose solutions, provides a concentration of 0.004 mg/ml.
  Titrate the administration rate in accordance with patients within 24 hours, after that, discard the solution.

Usual dosage

- **In postoperative opioids depression**

Adults: Inject in increments of 0.1 to 0.2 mg IV Naloxone at 2-3 minutes intervals to the desired degree of reversal, repeated doses may be required Within 1 or 2 hours intervals depending on the amount, type and time interval since last administration of opioid.

Children: Inject increments of 0.005-0.01 mg IV Naloxone at 2-3 minutes intervals to desired degree of reversal.

- **In opioid overdose**

Adults: initial dose of 0.4 - 2 mg IV may be repeated at 2-3 minutes intervals, if no response is observed after 10 mg has been administered, the diagnosis of opioids overdose must be questioned.

Children: initial dose is 0.01 mg/kg; give subsequent dose of 0.1 mg/kg if needed.

- **In asphyxia neonatorum**

Initial dose is 0.01 mg, administered into the umbilical vein of the neonate at 2-3 minutes intervals until the desired response is obtained, if necessary additional doses may be given at 1-2 hours intervals.

CONTRAINDICATIONS

History of allergic reactions to Naloxone HCl, cardiac irritable patients and in current opioid dependence.

WARNINGS

Avoid excessive dosage of Naloxone following the use of opiate during surgery
because it may result in excitement, increase in blood pressure and clinically important reversal of analgesic action of opiates.

The duration of action of some opiates may exceed that of Noxone, so careful monitoring to the patients must be considered and when necessary, repeated doses of Naloxone should be used.

- Naloxone Is not effective against respiratory depression caused by non-opioid drugs.

PRECAUTIONS

Due to the necessity to adjust the treatment, it is important During the management of acute opiate overdose using Naloxone, other resuscitative measures such as maintenance of adequate air way, artificial respiration , cardiac massage, vasopressor agent, should readily be available and used when necessary.

Naloxone should be used with caution in patients with pre-existing cardiovascular disease or those receiving potentially cardiotoxic drugs. Naloxone should be used with caution in patients known or suspected to be physically dependent on opiates.

Pregnancy: Naloxone should be used with caution in pregnant women (Naloxone is FDA pregnancy category B).

Lactation: It is not known whether Naloxone is excreted in human milk or not, so caution should be exercised when administrated to a nursing mother.

SIDE EFFECTS

Nausea, vomiting, sweating, tachycardia, increased blood pressure and tremor may occur following abrupt reversal of opioid depression.

Excitement, reversal of analgesia, hypotension, hypertension, pulmonary edema, ventricular tachycardia and fibrillation, and seizures may occur due to excessive dosage of Naloxone.

OVERDOSAGE

There is no clinical experience with Naloxone HCl overdose.

STORAGE

Store below 25°C. Protect from light. Protect from freezing.

PRESENTATIONS

Ampoules:

NALOXONE HIKMA 0.02: Naloxone HCl USP 0.02 mg/ml
NALOXONE HIKMA 0.4: Naloxone HCl USP 0.4 mg/ml

Excipients: *Sodium chloride, methyl paraben, propyl paraben, hydrochloride acid, water for injection.*

THIS IS A MEDICAMENT

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous.
- Follow the doctor's prescription strictly, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

Manufactured by
Hikma Farmacêutica, Portugal
For
Hikma Pharmaceuticals, Amman - Jordan

Keep medicament out of the reach of children

2INNAXL-AE-02/2010