CLONIDINE INJECTION BP
150 mcg / 1 ml

COMPOSITION:
Each ml contains:
Clonidine Hydrochloride BP 150 mcg
Water for injection BP q.s.

CATEGORY:
Alpha-2-adrenergic agonist; Treatment of hypertension
MOA: Epidemic administered clonidine produces dose-dependent analgesia which is not antagonized by opioid antagonists. Analgesia is limited to areas of the body inervated by segments of the spine where concentrations of clonidine analgesics are present. Clonidine is believed to produce analgesia in presynaptic and post-functional alpha-2 adrenoreceptors in the spinal cord by preventing pain signal transmission to the brain.

INDICATIONS AND USAGE:
Epidural clonidine HCI is indicated in combination with opioids for the treatment of severe pain in cancer patients who are not sufficiently relieved by opioid analgesics. Epidural clonidine is more likely to be effective in patients with neuropathic pain than somatic or visceral pain. The safety of this drug product has only been established in a highly selected group of cancer patients and only after adequate testing of opioid analgesia. Any other use is for unproven safety and is not recommended. In a rare patient, the potential benefits may outweigh the known risks.

DOSAGE AND ADMINISTRATION:
The recommended starting dose of epidural clonidine HCI for continuous epidural infusion is 30 mcg / h. Although the dosage can be titrated up or down depending on pain relief and the occurrence of adverse events, experience with doses above 40 mcg / h is limited. Familiarity with the continuous epidural infusion set is essential. Patients receiving epidural clonidine from a continuous infusion set should be closely monitored for the first few days to assess their response. Dosage for impaired renal function: The dosage should be adjusted according to the degree of renal impairment and patients should be carefully monitored. Since only a minimal amount of clonidine is removed during routine hemodialysis, it is not necessary to give additional clonidine after dialysis. Epidural Clonidine HCI must not be used with a preservative.

CONTRAINDICATIONS:
Clonidine HCI is contraindicated in patients with a history of sensitization or allergic reactions to Clonidine. Epidural administration is contraindicated in the presence of infection at the injection site, in patients with anticoagulants and in those with a bleeding diathesis. Administration of epidural clonidine HCI over the C4 dermatome is contraindicated since there are no adequate data to support such use.

ADVERSE REACTIONS:
Adverse reactions observed with continuous epidural clonidine infusion are dose dependent and typical for a compound of this pharmacological class. The most frequently reported adverse reactions in the centralized controlled clinical trial of continuous administration of epidural clonidine were hypotension, postural hypotension, decreased heart rate, high blood pressure, dry mouth, nausea, confusion, dizziness, drowsiness and fever. Hypotension is the most common adverse event that requires treatment. Hypotension is usually sensitive to intravenous fluids and, if available, to parenteral ephedrine. Hypotension has been observed more frequently in women and in low body weight patients, but no dose-related response has been established.
Implantable epidural catheters are associated with a risk of catheter-related infections, including meningitis and / or epidural abscess. The risk depends on the clinical situation and the type of catheter used, but catheter-related infections occur between 5% and 20% of patients, depending on the type of catheter used, the technique of catheter placement, the quality of patient care. catheter and the duration of catheter placement. Inadvertent intrathecal administration of clonidine has not been associated with a significantly increased risk of adverse events, but there are insufficient safety and efficacy data to support the use of intrathecal clonidine. Epidural clonidine was compared with placebo in a two-week, double-blind study of 85 terminal cancer patients with intractable pain presenting with epidural morphine. Adverse events have been reported in two or more patients and may be related to the administration of Clon may mask the increased heart rate associated with hypovolaemia.

RESPIRATORY DEPRESSION AND SEDATION:
Administration of clonidine may cause sedation by activation of alpha receptor receptors in the brainstem. High doses of clonidine cause sedation and ventilatory abnormalities which are usually mild. Tolerance to these effects may develop with chronic administration. These effects have been reported with bolus doses that are significantly greater than the recommended infusion rate for treating cancer pain. Depression: Depression has been observed in a small percentage of patients treated with oral or transdermal clonidine. Depression usually occurs in cancer patients and can be exacerbated by treatment with clonidine. Patients, especially those with a history of affective disorders, should be monitored for signs and symptoms of depression. Pain of visceral or somatic origin: in clinical studies, at tested doses, epidural clonidine HCI was more effective in well-localized "neuropathic" pain characterized by electricity, burning or shooting in nature and localized To a dermatomal or peripheral nerve distribution. Epidural clonidine HCI may be less effective or possibly ineffective in treating diffuse, poorly localized, or visceral pain.

INTERACTIONS:
Clonidine may potentiate the CNS depressive effect of alcohol, barbiturates or other sedating drugs. Narcotic analgesics may potentiate the hypotensive effects of clonidine. Tricyclic antidepressants may antagonize the hypotensive effects of clonidine. The effects of tricyclic antidepressants on the analgesic actions of clonidine are not known. Beta-blockers may exacerbate the hypertensive response seen with withdrawal of clonidine. Additionally, due to the potential for additive effects such as bradycardia and AV block, caution is warranted in patients receiving clonidine with agents known to affect sinus node function or AV node conduction (eg. Ex., Digitalis, calcium channel blockers and beta blockers). There is one reported case of a patient with acute delirium associated with the simultaneous use of fluphenazine and oral clonidine. Symptoms resolved when the clonidine was withdrawn and recurred when the patient was repelled with clonidine. Epidural clonidine may prolong the duration of pharmacological effects of epidural local anesthetics, including sensory and motor blockade.

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