Sedative for mechanically ventilated patients in intensive care setting

Piramal Critical Care

Dexmedetomidine Injection, USP

Piramal's Dexmedetomidine Injection, USP is available through the wholesaler or distributor of your choice

Wholesaler / Distributor Name	25 Single-Dose Fliptop Vials in a carton: NDC - 66794-230-42 Dexmedetomidine Injection, USP (2 mL per vial) Catalog numbers
AmerisourceBergen	10254344
Cardinal	5704192
McKesson	3748546
Morris & Dickson	982017

DEXMEDETOMIDINE Injection, USP

ABBREVIATED PRESCRIBING INFORMATION

PRODUCT NAME AND COMPOSITION: DEXMEDETOMIDINE Injection USP, for intravenous use (dexmedetomidine hydrochloride) 200 mcg/2 mL (100 mcg/mL) is clear and colorless and available in 2 mL clear glass vials with pink caps, supplied in packages of 25.

Please refer to Full Prescribing Information (FPI) before prescribing.

INDICATIONS: Dexmedetomidine injection is a relatively selective alpha 2-adrenergic agonist indicated for sedation of initially intubated and mechanically ventilated patients during treatment in an intensive care setting. Administer dexmedetomidine injection by continuous infusion not to exceed 24 hours. Sedation of non-intubated patients prior to and/or during surgical and other procedures. It is not necessary to discontinue dexmedetomidine injection prior to extubation listed in the FPI.

DOSAGE AND ADMINISTRATION: *See FPI for full details*. Individualize and titrate dexmedetomidine injection dosing to desired clinical effect. Administer dexmedetomidine injection using a controlled infusion device. Dilute the 200 mcg/2 mL (100 mcg/mL) vial contents in 0.9% sodium chloride solution to achieved equired concentration (4 mcg/mL) prior to administration.

For Adult Intensive Care Unit Sedation: Generally initiate at one mcg/kg over 10 minutes, followed by a maintenance infusion of 0.2 to 0.7 mcg/kg/hour.

For Adult Procedural Sedation: Generally initiate at one mcg/kg over 10 minutes, followed by a maintenance infusion initiated at 0.6 mcg/kg/hour and titrated to achieve desired clinical effect with doses ranging from 0.2 to 1 mcg/kg/hour. Alternative Doses: Recommended for patients over 65 years of age and awake fiberoptic intubation patients.

CONTRAINDICATIONS: None.

COMMON SIDE EFFECTS: The most common adverse reactions (incidence >2%) are hypotension, bradycardia, and dry mouth. Adverse reactions associated with infusions >24 hours in duration include ARDS, respiratory failure, and agitation. *See FPI for a complete list.*

WARNINGS AND PRECAUTIONS: Continuously monitor patients while receiving dexmedetomidine injection. Bradycardia and sinus arrest have occurred in young healthy volunteers with high vagal tone or with different routes of administration, e.g., rapid intravenous or bolus administration. Hypotension and bradycardia may necessitate medical intervention. May be more pronounced in patients with hypovolemia, diabetes mellitus, or chronic hypertension, and in the elderly. Use with caution in patients with advanced heart block or severe ventricular dysfunction. Co-administration with other vasodilators or negative chronotropic agents: Use with caution due to additive pharmacodynamic effects. Transient hypertension observed primarily during the loading dose. Consider reduction in loading infusion rate. Patients can become

aroused/alert with stimulation; this alone not be considered as lack of efficacy. Tolerance and tachyphylaxis: Prolonged exposure to dexmedetomidine beyond 24 hours maybe associated with tolerance, tachyphylaxis, and a dose-related increase in adverse events. *See FPI for full details.*

OVERDOSAGE: The tolerability of dexmedetomidine injection studied in one study in which healthy adult subjects were administered doses at and above the recommended dose of 0.2 to 0.7 mcg/kg/hr. The maximum blood concentration achieved in this study was approximately 13 times the upper boundary of the therapeutic range. The most notable effects observed in two subjects who achieved the highest doses were first-degree atrioventricular block and second-degree heart block. No hemodynamic compromise noted with the atrioventricular block and the heart block resolved spontaneously within one minute. Five adult patients received an overdose of dexmedetomidine injection in the intensive care unit sedation studies. Two of these patients had no symptoms reported; one patient received a 2 mcg/kg loading dose over 10 minutes (twice the recommended loading dose) and one patient received a maintenance infusion of 0.8 mcg/kg/hr. Two other patients who received a 2 mcg/kg loading dose over 10 minutes, experienced bradycardia and/or hypotension.

For more information, please contact Piramal Customer Service at +1-800-414-1901 during business hours (8 a.m. EST to 5 p.m. EST) or e-mail at pcc.customerservice@piramal.com

- Full prescribing information of Dexmedetomidine Injection, USP can be seen at https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=b93a71ed-0f9e-1ff9-e053-2995a90a789d.
- Adverse events should be reported to Piramal Critical Care at http://pcc-chex.force.com/SiteComplaintForm.
- You are encouraged to report adverse events of prescription drugs to the FDA. Visit MedWatch or call 1-800-FDA-1088.

"Saving and Improving Patients' Lives."

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