Precedex Package Insert

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use PRECEDEX safely and effectively. See full prescribing information for PRECEDEX.

Precedex (dexmedetomidine hydrochloride) Injection
Precedex (dexmedetomidine hydrochloride) Injection, Concentrate
For intravenous infusion of injection following dilution of concentrate
Initial U.S. Approval: 1999

----------INDICATIONS AND USAGE----------

Precedex 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 Precedex by continuous infusion not to exceed 24 hours. (1.1)
- Sedation of non-intubated patients prior to and/or during surgical and other procedures. (1.2)

----------DOSAGE AND ADMINISTRATION----------

- Individualize and titrate Precedex dosing to desired clinical effect. (2.1)
- Administer Precedex using a controlled infusion device. (2.1)
- Dilute the 200 mcg/2 mL (100 mcg/mL) vial contents in 0.9% sodium chloride solution to achieve required concentration (4 mcg/mL) prior to administration.
- The 200 mcg/50mL and 400 mcg/100 mL single-use bottles do not require further dilution prior to administration.(2.4)

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**. (2.2)

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**. (2.2)

Alternative doses recommended for patients over 65 years of age and awake fiberoptic intubation patients. (2.2)

----------DOSAGE FORMS AND STRENGTHS----------

Precedex Injection, **Concentrate**, 200 mcg/2 mL (100 mcg/mL) in a glass vial. (3)

Precedex Injection 200 mcg/50 mL (4 mcg/mL) in a 50 mL glass bottle. (3)

Precedex Injection 400 mcg/100 mL (4 mcg/mL) in a 100 mL glass bottle. (3)

----------CONTRAINDICATIONS----------

None (4)

----------WARNINGS AND PRECAUTIONS----------

- Monitoring: Continuously monitor patients while receiving Precedex. (5.1)
- 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. (5.2)
- 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. (5.2)
- Co-administration with other vasodilators or negative chronotropic agents: Use with caution due to additive pharmacodynamic effects. (5.2)
- Transient hypertension: Observed primarily during the loading dose. Consider reduction in loading infusion rate. (5.3)
- Arousability: Patients can become aroused/alert with stimulation; this alone should not be considered as lack of efficacy (5.4)
- Prolonged exposure to dexmedetomidine beyond 24 hours may be associated with tolerance and tachyphylaxis and a dose-related increase in adverse events (5.6)

----------ADVERSE REACTIONS----------

- The most common adverse reactions (incidence greater than 2%) are hypotension, bradycardia, and dry mouth. (6.1)
- Adverse reactions associated with infusions greater than 24 hours in duration include ARDS, respiratory failure, and agitation. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Hospira, Inc. at 1-800-441-4100 or electronically at ProductComplaintsPP@hospira.com, or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch*.

----------DRUG INTERACTIONS----------

Anesthetics, sedatives, hypnotics, opioids: Enhancement of pharmacodynamic effects. Reduction in dosage of Precedex or the concomitant medication may be required. (7.1)

----------USE IN SPECIFIC POPULATIONS----------

- Geriatric patients: Dose reduction should be considered (2.2, 2.3, 5.1, 8.5)
- Hepatic impairment: Dose reduction should be considered (2.1, 2.2, 2.3, 5.6, 8.6)
- Pregnancy: Based on animal data, may cause fetal harm (8.1)
- Nursing Mothers: Caution should be exercised when administered to a nursing woman (8.3)

See 17 for PATIENT COUNSELING INFORMATION

Revised: 06/2013

From Grace's Death Certificate:

41. PART I. The conditions listed are the diseases, injuries, or complications that caused death. Conditions leading to the immediate cause are listed sequentially and the underlying cause is listed last.

Immediate Cause: (a) ACUTE RESPIRATORY FAILURE WITH HYPOXEMIA

Due to or as a consequence of: (b) COVID 19 PNEUMONIA