Precedex®

(dexmedetomidine HCl) in 0.9% Sodium Chloride Injection

PRODUCT INFORMATION

- Available in 20 mL, 50 mL, 100 mL, and 250 mL premix presentations
- Ready to use
- Colored flip-off bottle and vial caps
- Integrated hanger label for 50 mL, 100 mL, and 250 mL presentations
- Labels can be read upright and inverted for 50 mL, 100 mL, and 250 mL presentations
- Standard sizes that fit automated dispensing machines
- 24-month shelf life

WHOLESALER INFORMATION

Unit of Sale NDC	Precedex®	Minimum Order Size	Case Size	AmerisourceBergen	Cardinal Health	McKesson	Morris & Dickson
00409-1660-20	80 mcg/20 mL (4 mcg/mL) vial	10	60	10146559	5044540	3415742	016261
00409-1660-50	200 mcg/50 mL (4 mcg/mL) bottle	20	20	10116802	4845012	1907559	129585
00409-1596-10	400 mcg/100 mL (4 mcg/mL) bottle	10	10	10284658	5889167	2880458	324210
00409-1434-01	1000 mcg/250 mL (4 mcg/mL) bottle	1	15	10238863	5670823	1566652	912840

For direct product ordering, contact customer service or reach out to your Pfizer Representative directly with any questions or concerns: **1-844-646-4398** | PrimeHospital.Pfizer.com

For Pfizer medical information, please contact: **1-800-438-1985** | PfizerMedinfo.com

For more information on PRECEDEX®, including product bar codes, please visit ***PfizerHospitalUS.com/products/dexmedetomidine***

Only Pfizer offers a 250 mL premix presentation

INDICATIONS

Precedex® (dexmedetomidine hydrochloride) is a relatively selective alpha2-adrenergic agonist indicated for:

- Sedation of initially intubated and mechanically ventilated adult patients during treatment in an intensive care setting. Administer Precedex® by continuous infusion not to exceed 24 hours.
- Sedation of non-intubated adult patients prior to and/or during surgical and other procedures.
- Sedation of non-intubated pediatric patients aged 1 month to less than 18 years prior to and during non-invasive procedures.

IMPORTANT SAFETY INFORMATION

Monitoring: Continuously monitor patients while receiving Precedex®.

Bradycardia and Sinus Arrest: Clinically significant episodes of 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.

(Important Safety Information continued on next page)

Click here for Full Prescribing Information, also available at PrecedexUSPI.com.

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IMPORTANT SAFETY INFORMATION *(continued)*

Hypotension and Bradycardia: Reports of hypotension and bradycardia have been associated with Precedex® infusion. Some of these cases have resulted in fatalities. 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.

Arousability: Patients can become aroused/alert with stimulation; this alone should not be considered lack of efficacy.

Tolerance and Tachyphylaxis: Prolonged exposure to dexmedetomidine beyond 24 hours may be associated with tolerance and tachyphylaxis and a dose-related increase in adverse events.

Withdrawal

Intensive Care Unit Sedation: With administration up to 7 days, regardless of dose, 12 (5 %) Precedex® adult subjects experienced at least 1 event related to withdrawal within the first 24 hours after discontinuing study drug and 7 (3 %) Precedex® adult subjects experienced at least 1 event 24 to 48 hours after the end of study drug. The most common events were nausea, vomiting, and agitation.

In adult subjects, tachycardia and hypertension requiring intervention in the 48 hours following study drug discontinuation occurred at frequencies of <5 %. If tachycardia and/or hypertension occurs after discontinuation of Precedex®, supportive therapy is indicated.

Procedural Sedation: In adult subjects, withdrawal symptoms were not seen after discontinuation of short-term infusions of Precedex® (<6 hours).

In pediatric patients, mild transient withdrawal symptoms of emergence delirium or agitation were seen after discontinuation of short-term infusions.

Specific Populations

Dosage reductions should be considered for adult patients with hepatic impairment and for geriatric patients.

Adverse Reactions

The most common adverse reactions: (Incidence greater than 2 %) in adults are hypotension, bradycardia, and dry mouth. (Incidence greater than 5 %) in pediatrics aged 1 month to less than 17 years are bradypnea, bradycardia, hypertension, and hypotension. Adverse reactions associated with infusions greater than 24 hours in duration include acute respiratory distress syndrome, respiratory failure, and agitation.

Drug Interactions

Co-administration of Precedex® with anesthetics, sedatives, hypnotics, and opioids is likely to lead to an enhancement of effects. Specific studies have confirmed these effects with sevoflurane, isoflurane, propofol, alfentanil, and midazolam. No pharmacokinetic interactions between Precedex® and isoflurane, propofol, alfentanil, and midazolam have been demonstrated. However, due to possible pharmacodynamic interactions, when co-administered with Precedex®, a reduction in dosage of Precedex® or the concomitant anesthetic, sedative, hypnotic, or opioid may be required.

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