

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, for intravenous use

PRECEDEX™ (dexmedetomidine hydrochloride) in sodium chloride injection, for intravenous use

Initial U.S. Approval: 1999

RECENT MAJOR CHANGES

Dosage and Administration, Preparation of Solution (2.4) 10/2024

INDICATIONS AND USAGE

PRECEDEX is a α_2 -adrenergic receptor 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. (1.1)
- Sedation of non-intubated adult patients prior to and/or during surgical and other procedures. (1.2)
- Sedation of non-intubated pediatric patients aged 1 month to less than 18 years prior to and during non-invasive 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. (2.4)
- The 80 mcg/20 mL single-dose vial, and 200 mcg/50 mL, 400 mcg/100 mL, and 1,000 mcg/250 mL single-dose bottles and single-dose flexible containers do not require further dilution prior to administration. (2.4)
- **For Adult Intensive Care Unit Sedation:** Initiate at one mcg/kg over 10 *minutes*, followed by a maintenance infusion of 0.2 mcg/kg/hour to 0.7 mcg/kg/hour. (2.2)
- **For Adult Procedural Sedation:** 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 mcg/kg/hour to 1 mcg/kg/hour. (2.2)
- **For Sedation of Pediatric Patients During Non-invasive Procedures:** Patients 1 month to less than 2 years old initiate at 1.5 mcg/kg over 10 *minutes* followed by a maintenance infusion of 1.5 mcg/kg/hour and titrated to achieve desired clinical effect with dosage ranging from 0.5 mcg/kg/hour to 1.5 mcg/kg/hour; patients 2 to less than 18 years old initiate at 2 mcg/kg over 10 *minutes* followed by a maintenance infusion of 1.5 mcg/kg/hour and titrated to achieve desired clinical effect with dosage ranging from 0.5 mcg/kg/hour to 1.5 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, 200 mcg/2 mL (100 mcg/mL) in a single-dose vial. To be used after dilution. (3)

- PRECEDEX in 0.9% Sodium Chloride Injection, 80 mcg/20 mL (4 mcg/mL) in a single-dose vial. Ready to use. (3)
- PRECEDEX in 0.9% Sodium Chloride Injection, 200 mcg/50 mL, 400 mcg/100 mL, and 1,000 mcg/250 mL (4 mcg/mL) in single-dose glass bottles. Ready to use. (3)
- PRECEDEX in 0.9% Sodium Chloride Injection, 200 mcg/50 mL, 400 mcg/100 mL, and 1,000 mcg/250 mL (4 mcg/mL) in single-dose flexible containers. Ready to use. (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)
- **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. (5.6)

ADVERSE REACTIONS

- The most common adverse reactions (incidence >2%) in adults are hypotension, bradycardia, and dry mouth. (6.1)
- The most common adverse reactions (incidence >5%) in pediatric patients aged 1 month to less than 17 years are bradypnea, bradycardia, hypertension, and hypotension. (6.1)
- Adverse reactions in adults, associated with infusions >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 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, 5.2, 8.5)
- Hepatic Impairment: Dose reduction should be considered. (2.2, 2.3, 5.8, 8.6)

See 17 for PATIENT COUNSELING INFORMATION.

Revised: 10/2024

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FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

1.1 Intensive Care Unit Sedation

PRECEDEX is indicated for sedation of initially intubated and mechanically ventilated adult patients during treatment in an intensive care setting. PRECEDEX should be administered by continuous infusion not to exceed 24 hours.

PRECEDEX has been continuously infused in mechanically ventilated adult patients prior to extubation, during extubation, and post-extubation. It is not necessary to discontinue PRECEDEX prior to extubation.

1.2 Procedural Sedation

PRECEDEX is indicated for sedation of non-intubated adult patients prior to and/or during surgical and other procedures.

PRECEDEX is indicated for sedation of non-intubated pediatric patients aged 1 month to less than 18 years prior to and during non-invasive procedures.

2 DOSAGE AND ADMINISTRATION

2.1 Administration Instructions

- PRECEDEX dosing should be individualized and titrated to desired clinical response.
- PRECEDEX is not indicated for infusions lasting longer than 24 hours.
- PRECEDEX should be administered using a controlled infusion device.

2.2 Recommended Dosage

Table 1: Recommended Dosage in Adult Patients

INDICATION	DOSAGE AND ADMINISTRATION
Initiation of Intensive Care Unit Sedation	<p><u>For adult patients:</u> a loading infusion of one mcg/kg over 10 <i>minutes</i>.</p> <p><u>For adult patients being converted from alternate sedative therapy:</u> a loading dose may not be required.</p> <p><u>For patients over 65 years of age:</u> Consider a dose reduction [<i>see Use in Specific Populations (8.5)</i>].</p> <p><u>For adult patients with impaired hepatic function:</u> Consider a dose reduction [<i>see Use in Specific Populations (8.6), Clinical Pharmacology (12.3)</i>].</p>
Maintenance of Intensive Care Unit Sedation	<p><u>For adult patients:</u> a maintenance infusion of 0.2 mcg/kg/<i>hour</i> to 0.7 mcg/kg/<i>hour</i>. The rate of the maintenance infusion should be adjusted to achieve the desired level of sedation.</p> <p><u>For patients over 65 years of age:</u> Consider a dose reduction [<i>see Use in Specific Populations (8.5)</i>].</p> <p><u>For adult patients with impaired hepatic function:</u> Consider a dose reduction [<i>see Use in Specific Populations (8.6), Clinical Pharmacology (12.3)</i>].</p>

INDICATION	DOSAGE AND ADMINISTRATION
Initiation of Procedural Sedation	<p><u>For adult patients:</u> a loading infusion of one mcg/kg over 10 <i>minutes</i>. For less invasive procedures such as ophthalmic surgery, a loading infusion of 0.5 mcg/kg given over 10 <i>minutes</i> may be suitable.</p> <p><u>For awake fiberoptic intubation in adult patients:</u> a loading infusion of one mcg/kg over 10 <i>minutes</i>.</p> <p><u>For patients over 65 years of age:</u> a loading infusion of 0.5 mcg/kg over 10 <i>minutes</i> [<i>see Use in Specific Populations (8.5)</i>].</p> <p><u>For adult patients with impaired hepatic function:</u> Consider a dose reduction [<i>see Use in Specific Populations (8.6), Clinical Pharmacology (12.3)</i>].</p>
Maintenance of Procedural Sedation	<p><u>For adult patients:</u> the maintenance infusion is generally initiated at 0.6 mcg/kg/<i>hour</i> and titrated to achieve desired clinical effect with doses ranging from 0.2 mcg/kg/<i>hour</i> to 1 mcg/kg/<i>hour</i>. Adjust the rate of the maintenance infusion to achieve the targeted level of sedation.</p> <p><u>For awake fiberoptic intubation in adult patients:</u> a maintenance infusion of 0.7 mcg/kg/<i>hour</i> is recommended until the endotracheal tube is secured.</p> <p><u>For patients over 65 years of age:</u> Consider a dose reduction [<i>see Use in Specific Populations (8.5)</i>].</p> <p><u>For adult patients with impaired hepatic function:</u> Consider a dose reduction [<i>see Use in Specific Populations (8.6), Clinical Pharmacology (12.3)</i>].</p>

Table 2: Recommended Dosage in Pediatric Patients

INDICATION	DOSAGE AND ADMINISTRATION
Initiation of Sedation During Non-invasive Procedures	<p><u>For pediatric patients:</u></p> <ul style="list-style-type: none"> 1 month to less than 2 years: a loading infusion of 1.5 mcg/kg over 10 <i>minutes</i>. 2 to less than 18 years: a loading infusion of 2 mcg/kg over 10 <i>minutes</i>. <p>Consider a reduction in dosage if clinically indicated.</p>
Maintenance of Sedation During Non-invasive Procedures	<p><u>For pediatric patients:</u></p> <ul style="list-style-type: none"> 1 month to less than 18 years: the maintenance infusion is generally initiated at 1.5 mcg/kg/<i>hour</i> and titrated to achieve desired clinical effect with dosage ranging from 0.5 mcg/kg/<i>hour</i> to 1.5 mcg/kg/<i>hour</i>. <p>As clinically warranted, titrate the maintenance dose to individual patient clinical response.</p>

2.3 Dosage Adjustment

Due to possible pharmacodynamic interactions, a reduction in dosage of PRECEDEX or other concomitant anesthetics, sedatives, hypnotics or opioids may be required when co-administered [*see Drug Interactions (7.1)*].

Dosage reductions may need to be considered for adult patients with hepatic impairment, and geriatric patients [*see Warnings and Precautions (5.8), Use in Specific Populations (8.6), Clinical Pharmacology (12.3)*].

2.4 Preparation of Solution

Strict aseptic technique must always be maintained during handling of PRECEDEX.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Do not use if product is discolored or if precipitate matter is present.

PRECEDEX Presentations Requiring Dilution:

- PRECEDEX Injection, 200 mcg/2 mL (100 mcg/mL)

PRECEDEX must be diluted with 0.9% sodium chloride injection to achieve required concentration (4 mcg/mL) prior to administration. Preparation of solutions is the same, whether for the loading dose or maintenance infusion.

To prepare the infusion, withdraw 2 mL of PRECEDEX Injection, and add to 48 mL of 0.9% sodium chloride injection to a total of 50 mL. Shake gently to mix well.

PRECEDEX Presentations that are Ready to Use:

PRECEDEX in 0.9% Sodium Chloride Injection is supplied in glass containers and flexible containers:

- 80 mcg/20 mL (4 mcg/mL) in glass vials
- 200 mcg/50 mL (4 mcg/mL) in glass bottles and flexible containers
- 400 mcg/100 mL (4 mcg/mL) in glass bottles and flexible containers
- 1,000 mcg/250 mL (4 mcg/mL) in glass bottles and flexible containers

These presentations contain a premixed, ready to use dexmedetomidine hydrochloride solution in 0.9% sodium chloride in water. No further dilution of these preparations is necessary.

Instructions for Use for Flexible Containers:

1. Tear outer wrap at the notch and remove solution container.
2. Check the container for minute leaks by squeezing it firmly. If leaks are found, or if the seal is not intact, discard the solution as the sterility may be compromised.
3. Do not use if the solution is cloudy or a precipitate is present.
4. Use aseptic technique.

Preparation for Administration:

1. Close flow control clamp of administration set.
2. Remove twist-off cap from administration port at bottom of flexible container.
3. Insert spike of administration set into administration port with a twisting motion until the spike is firmly seated. **NOTE: See full directions on administration set carton.**
4. Suspend container from hanger.
5. Squeeze and release drip chamber to establish proper fluid level in chamber during infusion.
6. Open flow control clamp to expel air from set. Close clamp.
7. Regulate rate of administration with flow control clamp.

2.5 Administration with Other Fluids

PRECEDEX infusion should not be co-administered through the same intravenous catheter with blood or plasma because physical compatibility has not been established.

PRECEDEX has been shown to be incompatible when administered with the following drugs: amphotericin B, diazepam.

PRECEDEX has been shown to be compatible when administered with the following intravenous fluids:

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