DEXMEDETOMIDINE

Newborn use only

2020

<table>
<tr><td>Alert</td><td>Use only where cardiac monitoring and cardiorespiratory resuscitation equipment are available.
Dexmedetomidine is not FDA or TGA approved for use in children.
There are insufficient trial data evaluating the use of dexmedetomidine in newborn infants.</td></tr>
<tr><td>Indication</td><td>Sedation for agitated ventilated patients.
Adjunct therapy with inhalational anaesthesia for both perioperative and postoperative procedures.
Sedation with nerve blocking agents for surgical procedures.</td></tr>
<tr><td>Action</td><td>Centrally acting α2-agonist with sedative, anxiolytic, sympatholytic and analgo-sedative properties. Haemodynamic effects including transient hypertension, bradycardia and hypotension resulting from the drug's peripheral vasoconstrictive and sympatholytic properties. Dexmedetomidine exerts its hypnotic action through activation of central pre- and postsynaptic α2-receptors in the locus coeruleus, inducing a state of unconsciousness similar to natural sleep, except patients remain rousable.[1, 2]</td></tr>
<tr><td>Drug type</td><td>Central Nervous System - Sedative, hypnotic - centrally acting α2-agonist</td></tr>
<tr><td>Trade name</td><td>Dexmedetomidine Mylan Concentrate for infusion
Dexmedetomidine Ever Pharma Concentrate for infusion
Dexmedetomidine Sandoz Concentrate for infusion
Dexmedetomidine-Teva Concentrate for infusion
Precedex Concentrate for infusion
Precedex Ready to Use Solution for infusion</td></tr>
<tr><td>Presentation</td><td>Dexmedetomidine Mylan Concentrate for infusion – 100 microgram/mL 2 mL vial.
Dexmedetomidine Ever Pharma Concentrate for infusion – 100 microgram/mL 2 mL, 4 mL, 10 mL vials; 50 microgram/mL 2 mL ampoule.
Dexmedetomidine Sandoz Concentrate for infusion – 100 microgram/mL 2 mL vial.
Dexmedetomidine-Teva Concentrate for infusion – 100 microgram/mL 2 mL vial.
Precedex Concentrate for infusion – 100 microgram/mL; 2 mL vial.
Precedex Ready to Use Solution for infusion – 4 microgram/mL; 20 mL vial; 4 microgram/mL 50 mL and 100 mL glass bottles.</td></tr>
<tr><td>Dose</td><td>IV
<table>
<tr><th>Refs: [3-5]</th><th>Loading dose [if needed] over 15 minutes</th><th>Infusion</th><th>Maximum dose</th></tr>
<tr><td>Preterm <37 weeks gestation</td><td>0.2 microgram/kg/dose</td><td>0.2 microgram/kg/hour</td><td>1 microgram/kg/hour</td></tr>
<tr><td>Term infants ≤14 days</td><td>0.35 microgram/kg/dose</td><td>0.3 microgram/kg/hour</td><td>1.2 microgram/kg/hour</td></tr>
<tr><td>Infants >14 days</td><td>0.5 microgram/kg/dose</td><td>0.5 to 0.75 microgram/kg/hour</td><td>1.5 microgram/kg/hour</td></tr>
</table>
Incremental increase
Every 30 minutes, either increase the rate by 0.1-0.2 microgram/kg/hour increments to a maximum dose of 1.5 microgram/kg/hour; and/or use a rescue dose of other sedative (midazolam) or analgesic (opioid) agent to achieve the desired effect.
Incremental decrease
Infusion should usually be weaned rather than discontinued abruptly, especially if used for greater than 72 hours.
Either:
Decrease the dose by 0.1 microgram/kg/hour every 30 minutes, OR
Decrease the infusion rate by 0.2 microgram/kg/hour every 8 hours.

It is not necessary to discontinue dexmedetomidine prior to extubation especially in postoperative patients.</td></tr>
<tr><td>Dose adjustment</td><td>Therapeutic hypothermia: No information.
ECMO: Reduce dose to 0.24 microgram/kg/hour for neonates and 0.29 microgram/kg/hour for infants aged ≥3 months. [4, 5,27]
Renal: Not applicable.
Hepatic: Clearance decreases in impairment; consider reducing the dose and titrating carefully.</td></tr>
</table>

Maximum dose	1.5 microgram/kg/hour.
Total cumulative dose	
Route	IV infusion. NOT FOR IV BOLUS ADMINISTRATION.
Preparation	Low concentration (consider for loading dose and initial infusion rate) Add 25 microgram/kg dexmedetomidine to sodium chloride 0.9% or glucose 5% to make a final volume of 50 mL with a concentration of 0.5 microgram/kg/mL. Gently mix the solution. 1 mL/hour = 0.5 microgram/kg/hour. **Consider higher concentrations if fluid restriction is required:** High concentration (consider this for an infusion dose higher than 0.5 microgram/kg/hour) Add 50 microgram/kg dexmedetomidine to sodium chloride 0.9% or glucose 5% to make a final volume of 50 mL with a concentration of 1.0 microgram/kg/mL. Gently mix the solution. 1 mL/hour = 1 microgram/kg/hour. Very high concentration (consider this for an infusion dose of 1 microgram/kg/hour or in fluid restricted infants) Add 100 microgram/kg dexmedetomidine to sodium chloride 0.9% or glucose 5% to make a final volume of 50 mL with a concentration of 2.0 microgram/kg/mL. Gently mix the solution. 1 mL/hour = 2 microgram/kg/hour. Precedex Ready to Use® solution (4 microgram/mL) can be diluted if required (as per consensus).
Administration	IV infusion using a syringe infusion pump. Infusion should not be placed on any infusion line where boluses may be given.
Monitoring	Continuous electrocardiogram (ECG), blood pressure and oxygen saturation monitoring. Continuous or frequent temperature monitoring. Monitor infant pain and comfort when used for sedation in ventilated patients.
Contraindications	1. Hypersensitivity to the medication or any of the excipients. 2. Heart block or severe ventricular dysfunction.
Precautions	1. If a patient is on vasodilators, haemodynamics must be monitored closely. If the patient becomes hypotensive, it may be necessary to decrease and/or stop dexmedetomidine or use vasopressors as needed to increase blood pressure. 2. Hypovolaemia. 3. Bradycardia. 4. Dosage reductions should be considered in patients with hepatic impairment or with concomitant use of other sedatives and analgesics. 5. To prevent inadvertent bolus of residual medication, sodium chloride 0.9% or glucose 5% should be infused at the same rate as the discontinued dexmedetomidine infusion until the volume of the IV line has been cleared.
Drug interactions	Enhances the effects of anaesthetics, sedatives, hypnotics and opioids.
Adverse reactions	• Severe bradycardia, arrhythmias and cardiac arrest. • Patients who are hypovolaemic may become hypotensive. • In situations where other vasodilators or negative chronotropic agents are administered, co-administration of dexmedetomidine could have an additive pharmacodynamic effect causing hypotension and bradycardia. • Bradycardia and hypotension may be potentiated when dexmedetomidine is used concurrently with propofol or midazolam. • Nausea, fever, vomiting, hypoxia and anaemia. • Hypothermia. • Seizures.
Compatibility	Fluids: Glucose 5% and sodium chloride 0.9%. Y site: Giving other drugs via Y-site may change the infusion rate of dexmedetomidine.

	Adrenaline (epinephrine), alfentanil, amikacin, aminophylline, amiodarone, amphotericin B liposome, ampicillin, azithromycin, aztreonam, calcium gluconate, cefazolin, cefepime, cefotaxime, cefoxitin, ceftazidime, ceftriaxone, ciprofloxacin, cisatracurium, clindamycin, dexamethasone, digoxin, dobutamine, dolasetron, dopamine, droperidol, ephedrine sulfate, erythromycin, esmolol, fentanyl, fluconazole, furosemide (frusemide), gentamicin, glyceryl trinitrate, glycopyrronium bromide (glycopyrrolate), heparin, hydromorphone, ketamine, lidocaine (lignocaine), linezolid, magnesium sulfate, methylprednisolone sodium succinate, metoclopramide, metronidazole, midazolam, milrinone, morphine, naloxone, noradrenaline (norepinephrine), pancuronium, paracetamol, piperacillin-tazobactam (EDTA-free), phenobarbital (phenobarbitone0, potassium chloride, promethazine, propofol, ranitidine, remifentanil, rocuronium, sodium bicarbonate, sodium nitroprusside, suxamethonium, thiopental sodium, tobramycin, trimethoprim-sulfamethoxazole, vancomycin, vecuronium, verapamil.
Incompatibility	Amphotericin B conventional colloidal, amphotericin B lipid complex, diazepam, pantoprazole, phenytoin.
Stability	Reconstituted dexmedetomidine infusion is stable for 24 hours.
Storage	Store below 25°C in the original container.
Excipients	Sodium chloride 9 mg/mL, water for injections.
Special comments	
Evidence	Refer to full version.
Practice points	**Sedation for agitated ventilated patients:** There is insufficient trial data evaluating the use of dexmedetomidine in newborn infants. (LOE IV, dose escalation study) **For sedation with nerve blocks for surgical procedures:** Dexmedetomidine sedation loading dose 2-3 microgram/kg with maintenance dose 0.2 microgram/kg/hour with caudal block provides a feasible alternative to general anaesthesia in infants undergoing hernia surgery although supplemental anaesthesia was required in 9.8%. [18] [LOE II neonates] **Acute withdrawal from opioids:** There are insufficient data of the use of Dexmedetomidine for treatment of NAS so its use is not recommended for this indication. Clonidine may be preferred with its reduced sedative properties.
References	Refer to full version.

VERSION/NUMBER	**DATE**
Original	28/05/2020
REVIEW (5 years)	28/05/2025

Authors Contribution

Original author/s	Dr Srinivas Bolisetty, Assoc Prof David Osborn
Evidence Review	Assoc Prof David Osborn
Expert review	Dr Hari Ravindranathan, Dr Donald Hannah, Dr David Schell
Nursing Review	Ms Eszter Jozsa
Pharmacy Review	Ms Michelle Jenkins, Ms Cindy Chen, Ms Carmen Burman
ANMF Group contributors	Dr Himanshu Popat, Dr Nilkant Phad, Ms Carmen Burman, Ms Thao Tran, Ms Chantelle Smith, Mr James Marceau, Ms Emily Do, Ms Wendy Huynh
Final editing and review of the original	Dr Ian Whyte, Dr Srinivas Bolisetty, Assoc Prof David Osborn, Ms Wendy Huynh, Ms Thao Tran,
Electronic version	Dr Ian Callander, Ms Cindy Chen
Facilitator	Dr Srinivas Bolisetty