
DEXMEDETOMIDINE (Igalmi) Fact Sheet

Bottom Line:

Dexmedetomidine is an alpha-2 agonist (think clonidine) that is used at higher doses intravenously (as Precedex) for ICU sedation. This new lower-dose sublingual formulation is approved for acute agitation associated with schizophrenia and bipolar disorder. However, its high cost, absence of data beyond 24 hours, potential adverse effects, and need for patient cooperation for sublingual administration limit its utility.

FDA Indications:

Agitation associated with schizophrenia or bipolar disorder.

Off-Label Uses:

Agitation associated with Alzheimer's dementia.

Dosage Forms:

SL film strips: 120 mcg, 180 mcg.

Dosage Guidance:

- A health care provider should supervise the administration, monitoring vital signs and patient alertness to prevent falls and syncope.
- Mild to moderate agitation: Start with 120 mcg administered buccally/sublingually. An additional 60 mcg dose can be given, up to two times, if systolic blood pressure (SBP) is above 90, diastolic blood pressure (DBP) is above 60, heart rate (HR) is above 60, and no orthostatic hypotension is present. Separate doses by at least two hours. Do not exceed 240 mcg/day.
- Severe agitation: Start with 180 mcg administered buccally/sublingually. An additional 90 mcg dose can be given, up to two times, under the same conditions as mentioned above. Do not exceed 360 mcg/day.
- Elderly patients may require lower doses.

Monitoring: Blood pressure (hold doses for BP <90/60 or HR <60).

Cost: \$\$\$\$ (over \$1,000 for 10 films of the 120 mcg dose)

Side Effects:

- Most common: Somnolence, abnormal or loss of oral sensation, dizziness, dry mouth, hypotension, orthostasis hypotension.
- Serious but rare: Bradycardia, syncope, QT interval prolongation.
- Pregnancy/breastfeeding: No data with new SL formulation. Data with IV formulation suggest no major malformations; crosses into breast milk, so infants should be monitored.

Mechanism, Pharmacokinetics, and Drug Interactions:

- Acts centrally as a selective alpha-2 adrenergic agonist.
- Primarily metabolized by CYP2A6 with a half-life of 2.8 hours.
- Avoid use with drugs that prolong QT interval. Caution with CNS depressants and antihypertensives.

Clinical Pearls:

- Not a controlled substance.
- Sublingual or buccal self-administration could foster a more cooperative therapeutic alliance with patients, but acceptance may vary.
- FDA approval is based on two clinical trials demonstrating reductions in poor impulse control, tension, hostility, uncooperativeness, and excitement better than placebo. There are no studies comparing it to other medications typically used for agitation.
- Nearly one in five patients experienced orthostatic hypotension at the higher dose. Use caution in all patients, particularly those at higher risk (patients with cardiac illness, dehydration or hypovolemia, diabetes, hypertension, older age). Patients should be encouraged to sit or lie down until vital signs are within normal limits; if this isn't possible, implement fall risk precautions.
- This formulation hasn't been studied beyond 24 hours; hence, the risk of tolerance and tachyphylaxis (decreasing response with ongoing use), a recognized issue with IV use of this agent, is unknown.
- Dosage adjustments can be made by cutting the strips in half if needed. Patients should not chew or swallow strips and should refrain from consuming food or drink for at least 15 minutes after sublingual administration or one hour after buccal administration.

Fun Fact:

The IV version is sometimes used off-label in the ICU as an adjunct in severe alcohol withdrawal delirium.