Igalmi®
(dexmedetomidine)
sublingual film · 120 mcg, 180 mcg

Dosage and Administration Guide

INDICATION

IGALMI® is indicated for the acute treatment of agitation associated with schizophrenia or bipolar I or II disorder in adults.
Limitations of Use: The safety and effectiveness of IGALMI have not been established beyond 24 hours from the first dose.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Hypotension, Orthostatic Hypotension, and Bradycardia: IGALMI causes dose-dependent hypotension, orthostatic hypotension, and bradycardia. Because IGALMI decreases sympathetic nervous system activity, hypotension and/or bradycardia may be more pronounced in patients with hypovolemia, diabetes mellitus, or chronic hypertension, and in geriatric patients. Avoid use of IGALMI in patients with hypotension, orthostatic hypotension, advanced heart block, severe ventricular dysfunction, or history of syncope. After IGALMI administration, patients should be adequately hydrated and should sit or lie down until vital signs are within normal range. If a patient is unable to remain seated or lying down, precautions should be taken to reduce the risk of falls. Ensure that a patient is alert and not experiencing orthostatic hypotension or symptomatic hypotension prior to allowing them to resume ambulation.

Please see additional Important Safety Information throughout and full Prescribing Information.

For adults with schizophrenia or bipolar disorders I or II,

IGALMI IS THE FIRST AND ONLY ORALLY DISSOLVING SUBLINGUAL FILM FOR THE ACUTE TREATMENT OF AGITATION[1]

IGALMI is a film formulation of dexmedetomidine[1]

- **Noninvasive,** self-administered film[1-4]
- **Rapid absorption** of dexmedetomidine into the bloodstream via the oral mucosa[1]
- Mucoadhesive film, designed so it **cannot be spit out or swallowed**[1,2,4]
- **Sublingual** or **buccal** placement[1]
- **Mint-flavored**[1]

Two dosage strengths are available to treat the spectrum of agitation[1]

For adults <65 years of age:

Lower dosages are recommended for geriatric patients (≥65 years of age) or those with hepatic impairment. On page 5, see the table for dosage recommendations.[1]

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (continued)

QT Interval Prolongation: IGALMI prolongs the QT interval. Avoid use of IGALMI in patients at risk of torsades de pointes or sudden death, including those with known QT prolongation, a history of other arrhythmias, symptomatic bradycardia, hypokalemia, or hypomagnesemia, and in patients receiving other drugs known to prolong the QT interval.

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ADMINISTRATION INSTRUCTIONS[1]

STEP 1

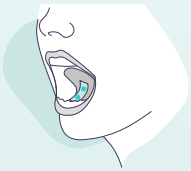
OPEN POUCH

A healthcare provider should **open the pouch and give it to the patient**. IGALMI should be kept in the foil pouch until ready to administer. Ensure hands are clean and dry when handling the film.

STEP 2

PLACE FILM

IGALMI should be immediately administered once the pouch is opened. Instruct the patient to remove the film from the pouch and **place the film either**:



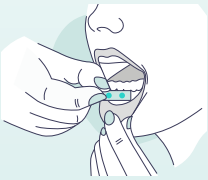
SUBLINGUALLY
(under tongue)

wait 15 minutes
to eat or drink

OR

BUCCALLY
(behind lower lip)

wait 1 hour
to eat or drink



The patient should **not chew or swallow the film**.

Supervision and monitoring required for IGALMI

- IGALMI should be administered under the supervision of a healthcare provider and vital signs and alertness should be monitored after administration to prevent falls and syncope

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (continued)

Somnolence: IGALMI can cause somnolence. Patients should not perform activities requiring mental alertness, such as operating a motor vehicle or operating hazardous machinery, for at least eight hours after taking IGALMI.

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Dosing instructions

- If agitation persists after the initial dose, up to two additional doses may be administered at least two hours apart. The dosage recommendations for additional doses vary depending upon the patient population and agitation severity, as shown in the table on page 5[1]
- Assess vital signs, including orthostatic measurements, prior to the administration of any subsequent doses due to risk of hypotension[1]
  - Additional half doses are not recommended in patients with systolic blood pressure (SBP) less than 90 mmHg, diastolic blood pressure (DBP) less than 60 mmHg, heart rate (HR) less than 60 beats per minute, or postural decrease in SBP ≥20 mmHg or in DBP ≥10 mmHg
- Half doses[1]:
  - If the 60 mcg or 90 mcg dose is required, remove the film and cut it between the dots with clean, dry scissors. Discard unused half in waste container before placing the half film back into the pouch for the patient
- Please see the full Prescribing Information for complete preparation and administration instructions

IMPORTANT SAFETY INFORMATION

ADVERSE REACTIONS

The most common adverse reactions (incidence ≥5% and at least twice the rate of placebo) were somnolence, oral paresthesia or oral hypoesthesia, dizziness, dry mouth, hypotension, and orthostatic hypotension.

DRUG INTERACTIONS

Drugs That Prolong the QT Interval: Avoid use.

Anesthetics, Sedatives, Hypnotics, and Opioids: Concomitant use may cause enhanced CNS-depressant effects. Reduction in dosage of IGALMI or the concomitant medication should be considered.

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Dosage recommendations[1]

Agitation Severity	Initial Dose*	Optional 2nd/3rd Doses*	Maximum Recommended Total Daily Dosage
Adult patients			
Mild or Moderate	120 mcg	60 mcg	240 mcg
Severe	180 mcg	90 mcg	360 mcg
Patients with mild or moderate hepatic impairment†			
Mild or Moderate	90 mcg	60 mcg	210 mcg
Severe	120 mcg	60 mcg	240 mcg
Patients with severe hepatic impairment†			
Mild or Moderate	60 mcg	60 mcg	180 mcg
Severe	90 mcg	60 mcg	210 mcg
Geriatric patients (≥65 years old)			
Mild, Moderate, or Severe	120 mcg	60 mcg	240 mcg

*IGALMI 120 mcg and 180 mcg dosage strengths may be cut in half to obtain the 60 mcg and 90 mcg doses, respectively.[1]

†Hepatic impairment: Mild (Child-Pugh Class A); Moderate (Child-Pugh Class B); Severe (Child-Pugh Class C).[1]

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (continued)

Risk of Withdrawal Reactions, Tolerance, and Tachyphylaxis: IGALMI was not studied for longer than 24 hours after the first dose. There may be a risk of physical dependence, a withdrawal syndrome, tolerance, and/or tachyphylaxis if IGALMI is used in a manner other than indicated.

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IMPORTANT SAFETY INFORMATION

USE IN SPECIFIC POPULATIONS

Hepatic Impairment and Geriatric Patients (≥65 years old): A lower dose is recommended in patients with hepatic impairment and geriatric patients. See the full Prescribing Information for the recommended dosage depending on the agitation severity.

Please see Important Safety Information throughout and full Prescribing Information.

To report SUSPECTED ADVERSE REACTIONS, contact BioXcel Therapeutics, Inc. at 1-833-201-1088 or medinfo@bioxceltherapeutics.com, or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

REFERENCES: 1. IGALMI. Package insert. BioXcel Therapeutics, Inc.; 2022. **2.** Data on file. BXCL501-301 CSR (SERENITY I). BioXcel Therapeutics, Inc.; January 2021. **3.** Preskorn SH, Zeller S, Citrome L, et al. Effect of sublingual dexmedetomidine vs placebo on acute agitation associated with bipolar disorder: a randomized clinical trial. *JAMA*. 2022;327(8):727-736. doi:10.1001/jama.2022.0799 **4.** Data on file. BXCL501-302 CSR (SERENITY II). BioXcel Therapeutics, Inc.; January 2021.

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