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Dear Healthcare Provider,

Thank you for your inquiry regarding IGALMI™ (dexmedetomidine) sublingual film and pediatric use.

IGALMI is an alpha-2 adrenergic receptor agonist indicated in adults for the acute treatment of agitation associated with schizophrenia or bipolar I or II disorder.

IGALMI is an orally dissolving film formulation for sublingual or buccal use under the supervision of a health care provider.

Limitations of Use: The safety and effectiveness of IGALMI has not been established beyond 24 hours from the first dose.

The approved IGALMI package insert/prescribing information contains the following information:

- The safety and effectiveness of IGALMI have not been established in pediatric patients.

Additional published information may be available for intravenous (IV) or intrathecal dexmedetomidine. Please refer to the bibliography below. This bibliography is not comprehensive but may provide additional information relevant to your query. These references were identified from the National Library of Medicine (PubMed) on 12 June 2023 using search terms [dexmedetomidine] and [pediatric] and may include information outside the FDA approved indication for IGALMI. They are included as a professional courtesy and are not intended to recommend use of IGALMI outside the FDA approved indication.

Important Information

BioXcel Therapeutics does not recommend the use of IGALMI outside of the FDA approved prescribing information. Please refer to the IGALMI FDA approved package insert for important safety information and full prescribing information at https://www.igalmihcp.com/igalmi-pi.pdf

If you have any additional questions and would like to speak with our Medical Affairs team, please contact medicalaffairs@bioxceltherapeutics.com.

Reference: IGALMI [Prescribing Information]. New Haven, CT: BioXcel Inc; 2022

Selected Dexmedetomidine Bibliography

1. Gan L, Zhao X, Chen X. The Safety and Efficacy Evaluation of Dexmedetomidine for Procedural Sedation and Postoperative Behaviors in Pediatric Populations: A Systematic Review and Meta-analysis. *Ann Pharmacother.* 2022;56(1):16-26.
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3. Kim JY, Kim KN, Kim DW, Lim HJ, Lee BS. Effects of dexmedetomidine sedation for magnetic resonance imaging in children: a systematic review and meta-analysis. *J Anesth.* 2021;35(4):525-535.
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10. Tervonen M, Pokka T, Kallio M, Peltoniemi O. Systematic review and meta-analysis found that intranasal dexmedetomidine was a safe and effective sedative drug during paediatric procedural sedation. *Acta Paediatr.* 2020;109(10):2008-2016.
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12. Wang Q, Chen C, Wang L. Efficacy and safety of dexmedetomidine in maintaining hemodynamic stability in pediatric cardiac surgery: a systematic review and meta-analysis. *J Pediatr (Rio J).* 2022;98(1):15-25.

For U.S. Healthcare Professionals Use Only
This information is provided as a professional courtesy in response to your unsolicited request for information and may contain information that is not part of the FDA-approved labeling. This information is intended to provide pertinent data that may assist you in forming your own conclusions and making your own decisions. It is not intended to recommend any use of IGALMI other than recommended in the FDA-approved prescribing information.

The information contained in this letter is for the sole use of the intended recipient(s). It is for informational purposes only and not intended for publication or distribution.

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