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Dear Healthcare Provider,

Thank you for your inquiry regarding IGALMI™ (dexmedetomidine) sublingual film and chemical restraint.

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 have not been established beyond 24 hours from the first dose.

- The Centers for Medicare & Medicaid Services (CMS) define a restraint as any manual method, physical or mechanical device, material, or equipment that immobilizes or reduces the ability of a patient to move his or her arms, legs, body, or head freely; or a drug or medication when it is used as a restriction to manage the patient's behavior or restrict the patient's freedom of movement and is not a standard treatment or dosage for the patient's condition.[1]
- Igalmi is not a chemical restraint and is not intended to subdue, sedate, or restrain an individual. In BioXcel Therapeutics clinical trials, all patients were able to interact with healthcare providers and cooperate in their own assessments, with no movement restrictions, confusion, disorientation, or stupor. No patient was sedated to the point of being unable to be aroused.[2,3]
- Rather than inducing non-specific sedation, the pharmacologic activity of dexmedetomidine is thought to reduce agitation by specifically targeting sympathetic hyperactivation – a key mechanism responsible for signs and symptoms of acute psychomotor agitation.[4]
- Igalmi administration is not coercive; it is self-administered by the patient, under supervision of a healthcare provider who hands the film to the patient to place into their mouth.

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.

References:

1. Department of Health and Human Services. Condition of participation: patient's rights. Federal Register 482.13. 2006;71426–71428.

2. Citrome L, Preskorn SH, Lauriello J, et al. Sublingual Dexmedetomidine for the Treatment of Acute Agitation in Adults With Schizophrenia or Schizoaffective Disorder: A Randomized Placebo-Controlled Trial. J Clin Psychiatry. 2022;83(6):22m14447. Published 2022 Oct 3. doi:10.4088/JCP.22m14447

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. Karlin DM, Nelson LA, Campbell AR. Dexmedetomidine Sublingual Film: A New Treatment to Reduce Agitation in Schizophrenia and Bipolar Disorders. Ann Pharmacother. 2023:10600280231171179.

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

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