

Letybo® for Platysma Bands: Evidence-based Treatment and Dosing

RELEVANT PRESCRIPTION INFORMATION LABEL INFORMATION

The information provided relates to a use for Letybo® (letibotulinumtoxinA-wlbg) that is not approved by the US Food and Drug Administration (FDA).

CLINICAL DATA

A search of the published medical literature was conducted regarding Letybo[®] and treatment of platysma bands.

The relevant citations referenced in this communication are listed below. The hyperlinks to publicly available abstracts are included. Findings were limited to peer-reviewed consensus statements, which may not be reflective of findings from controlled studies or to outcomes in a broader population, and should be considered when evaluating the data.

Some references cited in this response may discuss additional treatment areas that were not specified in this Medical Information Request.

Letybo[®] is an acetylcholine release inhibitor and a neuromuscular blocking agent indicated for the temporary improvement in the appearance of moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity in adult patients. Hugel Inc. and BENEV Inc. do not endorse the use of Letybo[®] in a manner not consistent with the approved label.

Units of biological activity of Letybo[®] cannot be compared to nor converted into Units of any other botulinum toxin or any toxin assessed with any other specific assay method.

CITATIONS

- 1. Letybo[®] Prescribing Information, 2024.
- 2. Liu S, Cong L, Pongprutthipan M, et al. Use of LetibotulinumtoxinA for Aesthetic Treatment of Asians: A Consensus. *Aesthet Surg J*. 2023;43(11):NP962-NP974. doi:10.1093/asj/sjad151

https://pmc.ncbi.nlm.nih.gov/articles/PMC10575620/



REVIEW OF RESEARCH AND CLINICAL PRACTICE INFORMATION

<u>Liu et al. 2023</u>² is an expert consensus statement that provides clinical guidance on the aesthetic use of Letybo[®] (letibotulinumtoxinA-wlbg) for treating wrinkles, contour adjustment, and facial lifting in Asian patients. The publication highlights the importance of understanding facial musculature, patient preferences, and botulinum toxin pharmacology to optimize treatment. It underscores that cultural nuances, such as the preference for natural-looking results among Asian patients, inform injection techniques and dosing strategies. The panel recommends starting with conservative dosing, individualizing treatment plans, and adjusting based on patient feedback to achieve high satisfaction. This guidance is especially relevant for applications including platysmal band treatment, where anatomical knowledge and precision are critical.



Platysma Bands Treatment²

The contraction of the platysma muscle pulls down the cheek and jawline, which contributes to an undefined jawline and cervicomental contouring. Microdroplet injection of BotulinumtoxinA releases the downward tension of the superficial muscle fibers of the platysma muscle and alleviates the depressor effect of the muscle, while the deeper muscle fibers continue to function normally and render the platysma muscle more tightly attached, creating a

more defined cervicomental angle and an elevated jawline².

Consensus Recommendations for Platysma Bands Treatment With LetibotulinumtoxinA (adapted from Liu et al. 2023)².

Indication	Target Muscle	Injection points (n)	Dose per Injection Point (Units)	Typical total Dose rage (Units)	Perferred Injection Level
Mandibular	Platysma	40-60/side	0.25-0.5 (md)	60-100 (md)	Microdroplet
margin lifting		(md)			(md)

md, microdroplet



Anatomy²: The platysma muscle ascends to the lower facial areas after crossing the mandibular border and ramus. In the lower facial area, the platysma fibers usually terminate behind the depressor anguli oris muscle (DAO) and at the lower margin of the risorius muscle. However, in the cheek area, just anterior to the auricle, some muscle fibers terminate in the zygomatic arch area. These fibers are called the facial portion of the platysma. The platysma muscle draws the mouth angle downward together with the DAO muscle and draws the lip downward together with the depressor labii inferioris (DLI) muscle. Injection into the platysma muscle can achieve face lifting.

Injection Technique²: BotulinumtoxinA is injected into the dermis or the junction of the dermis and subcutaneous tissue to lift the jaw and jawline. To avoid undesired consequences, it is recommended:

- LetibotulinumtoxinA be administered where it is bounded by areas of 1 finger-width above the mandibular margin, behind the marionette line, behind the anterior border of the platysma muscle, and above the clavicle.
- The needle should be carefully injected as superficially as possible into the skin.
 To evaluate this, resistance should be felt when pressing the plunger, and a small,
 raised, blanched bleb in the skin should be observed, indicating a good injection
 depth. This injection results in an improved cervicomental angle, and elevation and
 flattening of jowls.



Approved Indication for Letybo®

Letybo[®] (**letibotulinumtoxinA-wlbg**) is an acetylcholine release inhibitor and a neuromuscular blocking agent indicated for the temporary improvement in the appearance of moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity in adult patient¹.

Important Safety Information:

WARNING: DISTANT SPREAD OF TOXIN EFFECT

Postmarketing safety data from other approved botulinum toxins suggest that botulinum toxin effects may be observed beyond the site of local injection. The symptoms are consistent with the mechanism of action of botulinum toxin and may include asthenia, generalized muscle weakness, diplopia, ptosis, dysphagia, dysphonia, dysarthria, urinary incontinence, blurred vision and breathing difficulties. These symptoms have been reported hours to weeks after injection. Swallowing and breathing difficulties can be life threatening and there have been reports of death related to spread of toxin effects. In unapproved uses and approved indications, symptoms consistent with spread of toxin effects have been reported at doses comparable to or lower than the maximum recommended total dose. LETYBO is not approved for any conditions other than glabellar lines. Patients or caregivers should be advised to seek immediate medical care if swallowing, speech or respiratory difficulties occur.

Letybo is contraindicated in individuals with known hypersensitivity to any botulinum toxin preparation or to any of the components in the LETYBO formulation and/or have an infection at the injection site.

The potency Units of Letybo[®] are specific to the preparation and assay method utilized. Letybo[®] is not equivalent to other preparations of botulinum toxin products, and therefore, Units of biological activity of Letybo[®] cannot be compared to nor converted into Units of any other botulinum toxin products assessed with any other specific assay method.

This response contains information that is not included in the approved Product Information label. Hugel Inc. and BENEV Inc. do not endorse the use of its products in a manner not consistent with the approved label. For approved products, please refer to the full Prescribing Information for additional information. The Prescribing Information label for Letybo[®] is available at: bit.ly/3UbRZtP