



## Xeomin<sup>®</sup> (incobotulinumtoxinA) – New indication

- On July 3, 2018, [Merz North America announced](#) the FDA approval of [Xeomin \(incobotulinumtoxinA\)](#), for the treatment of chronic sialorrhea in adult patients.
  - Xeomin is the first and only neurotoxin approved for chronic sialorrhea in the United States.
- Xeomin is also indicated for adult patients with upper limb spasticity, cervical dystonia, blepharospasm with prior [Botox<sup>®</sup> \(onabotulinumtoxinA\)](#) treatment, and temporary improvement in the appearance of moderate to severe glabellar lines with corrugator and/or procerus muscle activity.
- Sialorrhea is a common symptom among patients who suffer from neurological disorders including Parkinson's disease, amyotrophic lateral sclerosis (ALS), cerebral palsy, or who have experienced a stroke.
- The new indication approval for Xeomin is based on data from a phase 3 placebo-controlled trial that enrolled a total of 184 patients with chronic sialorrhea. The primary endpoints were the change in unstimulated Salivary Flow Rate (uSFR) and the change in Global Impression of Change Scale (GICS) at week 4 post-injection.
  - A statistically significant improvement was observed in the change in uSFR and GICS from baseline in subjects administered Xeomin 100 units vs. placebo ( $p = 0.004$  and  $p = 0.002$ , respectively).
  - Xeomin 75 units was not significantly better than placebo.
- Xeomin carries a boxed warning for the distant spread of toxin effect.
- In chronic sialorrhea, the most common adverse reactions ( $\geq 4\%$ ) with Xeomin use were tooth extraction, dry mouth, diarrhea, and hypertension.
- The recommended dose of Xeomin for adult patients with chronic sialorrhea is 100 units per treatment session, consisting of 30 units injected into each parotid gland and 20 units injected into each submandibular gland (ie, 4 injections per treatment session), no sooner than every 16 weeks.
  - Refer to the Xeomin drug label for details on dosing in other indications.



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