

Use of Bacteriostatic Saline in reconstitution of Botulism Toxin

Refine Beauty Aesthetics

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Clinical decision and foresight to use unlicensed Bacteriostatic Sodium Chloride Solution in reconstitution of Botulism Toxin Type A:

This policy is an add on to the medications management policy created by Refine Beauty Aesthetics.

Refine Beauty Aesthetics uses Botox® and Azzalure® in the clinic dependent on which area of the face is being treated. Azzalure® in licensed in the UK for upper face cosmetic treatments, whilst Botox® is licensed for the upper and lower parts of the face. Manufacturer guidelines for reconstitution of both Botox® and Azzalure® are to use non-preserved 0.9% sodium chloride, however, Refine Beauty Aesthetics has made the clinical judgement to use bacteriostatic saline for reconstitution which is an unlicensed product. 0.9% bacteriostatic saline (Tor-bac®) is unlicenced in the UK.

Unlicensed medications may be prescribed for an individual patient based on a thorough assessment and face to face consultation by a suitably qualified practitioner. This practitioner can conclude that the unlicensed medication would benefit the patient and meet their needs based on medical knowledge, experience, and judgement. Unlicensed medications can be used when licensed medications are not available that will meet the needs of the patient which could be minimizing pain or discomfort.

Refine Beauty Aesthetics is satisfied that there is sufficient evidence and experience to demonstrate the efficacy of bacteriostatic saline and takes full responsibility for prescribing the medication. RBA also takes full responsibility for the patient’s care, treatment, monitoring and follow up.

Refine Beauty Aesthetics documents all medications used within each client’s profile on Fresha, including the medicine prescribed, batch number, expiry date and reason for use.

When a patient expresses a wish to book a treatment consisting of Botulism Toxin injections, a form consisting of information regarding Bacteriostatic saline will be sent alongside their consent and medical history forms. This is to ensure they are aware of the use of an unlicensed product and the reason for this. Patients can ask any potential questions they have before treatment and can request to use 0.9% sodium chloride instead. On the form an option for product to be used will be provided. The clinic holds stock of 0.9% sodium chloride.

Refine Beauty Aesthetics has made the decision to use bacteriostatic saline as it significantly reduces pain on injection compared to 0.9% sodium chloride. As nurses, our first and foremost responsibility is to “do no harm” to patients. Reducing pain to a patient is therefore ensuring this is upheld in a safe manner.

Many clinical trials and papers written to support this, and in the use of bacteriostatic saline in reconstitution of Botulism Toxin Type A with focus on efficacy, safety and reducing pain on injection site. Below are some of the supporting evidences.

Allen, S.B. and Goldenberg, N.A. (2012) ‘Pain Difference Associated with Injection of AbobotulinumtoxinA Reconstituted with Preserved Saline and Preservative‐Free Saline: A Prospective, Randomized, Side‐by‐Side, Double‐Blind Study’, *Dermatologic surgery*, 38(6), pp. 867–870. Available at: <https://doi.org/10.1111/j.1524-4725.2011.02284.x>.

Felber, E.S. (2006) ‘Botulinum toxin in primary care medicine’, *The Journal of the American Osteopathic Association*, 106(10).

Goddard, R. (2023) ‘A study on the reconstitution of botulinum toxin type A: normal saline versus bacteriostatic saline’, *Journal of aesthetic nursing*, 12(1), pp. 8–18. Available at: <https://doi.org/10.12968/joan.2023.12.1.8>.

Hunt, S.V. and Malhotra, R. (2022) ‘Bacteriostatic preserved saline for pain-free periocular injections: review’, *Eye (London)*, 36(8), pp. 1546–1552. Available at: <https://doi.org/10.1038/s41433-021-01925-z>.

Liu, A. *et al.* (2012) ‘Recommendations and current practices for the reconstitution and storage of botulinum toxin type A’, *Journal of the American Academy of Dermatology*, 67(3), pp. 373–378. Available at: <https://doi.org/10.1016/j.jaad.2011.10.008>.

Sarifakioglu, N. and Sarifakioglu, E. (2005) ‘Evaluating effects of preservative-containing saline solution on pain perception during botulinum toxin type-a injections at different locations: a prospective, single-blinded, randomized controlled trial’, *Aesthetic plastic surgery*, 29(2), pp. 113–115. Available at: <https://doi.org/10.1007/s00266-004-0062-0>.

Traill, F.T., Williams, A. and Beaumount-Thomas, T. (2012) ‘Reconstitution of botulinum toxins: preserved saline versus normal saline’, *Journal of aesthetic nursing*, 1(5), pp. 246–249. Available at: <https://doi.org/10.12968/joan.2012.1.5.246>.