BOCOUTURE® (incobotulinumtoxinA): Animal Testing

BOCOUTURE® (incobotulinumtoxinA or NT 201) is a purified botulinum neurotoxin type A preparation, free of complexing proteins such as hemagglutinins and other non-hemagglutinin proteins.[1] Botulinum type A toxins inhibit the release of acetylcholine from peripheral cholinergic nerve endings, resulting in the blockade of cholinergic transmission at the neuromuscular and salivary neuroglandular junctions. Each vial of incobotulinumtoxinA contains 50, 100, or 200 Units (U) of sterile lyophilized incobotulinumtoxinA powder, human albumin (1 mg), and sucrose (4.7 mg).

IncobotulinumtoxinA is also marketed as Bocouture®, Xeomeen®, and Xeomin Cosmetic™ in some countries. These products contain the same active ingredient in the same formulation; therefore, adverse events observed with each are interrelated. Please refer to local product labeling for complete information.

OVERVIEW

Despite progress in the development of alternative methods, animal testing is sometimes still required to evaluate the safety and efficacy of a medicinal product. There are instances in which non-animal testing has not yet been established as a scientifically valid and available option. At Merz, when animal testing is required, it is performed in accordance with Food and Drug Administration regulation, Good Laboratory Practice for Nonclinical Laboratory Studies (21 CFR Part 58), and the rigorous guidelines of the Animal Welfare Act.[2-4] Merz is also committed to the '3R' principles to reduce, refine, and replace animal testing wherever possible.[5,6]

Merz has made advancements in the incobotulinumtoxinA manufacturing process to minimize animal testing and continues to work on strategies for reduction. Animal testing is only performed if explicitly requested by local regulatory authorities.

Please refer to product labeling for details on required developmental and toxicity animal testing conducted as part of the incobutulinumtoxinA development process.[1]

REFERENCES

1. Merz Pharmaceuticals, LLC. Xeomin (incobotulinumtoxinA) *US Full Prescribing Information.*
2. U.S. Food & Drug Administration. Advancing New Alternative Methodologies at FDA. Available at: https://www.fda.gov/media/144891/download. Accessed: March 11, 2021.
3. U.S. Food & Drug Administration. CFR- Code of Federal Regulations Title 21. Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=58. Accessed: January 17, 2023.
4. Federal Ministry of Judiciary and for Consumer Protection Germany. Animal protection act. Available at: http://www.gesetze-im-internet.de/tierschg/index.html. Accessed: January 17, 2023.
5. National Centre for the Replacement Refinement & Reduction of Animals in Research. The 3Rs. Available at: https://nc3rs.org.uk/the-3rs. Accessed: January 17, 2023.
6. Hubrecht RC, Carter E. The 3Rs and Human Experimental Technique: Implementing Change. *Animals (basel).* 2019;9(10):754. Open access; accessible at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6826930/.

Very kind regards