

Thymosin Beta-4 — Research Summary

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1. What It Is

Thymosin Beta-4 (Tβ4) is a 43-amino-acid peptide, ubiquitous in mammalian tissues, best known as the major intracellular G-actin-sequestering protein regulating actin polymerization. Extracellularly, it participates in wound healing, angiogenesis, cardiac repair, and anti-inflammatory signaling.

Tβ4 was originally isolated from thymosin fraction 5 (TF5), a preparation with a history of FDA-authorized clinical investigation for DiGeorge syndrome in pediatric patients.

2. Reported Effects in Research Literature

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- Animal data: Reviewed extensively across dermal, ocular, and cardiac animal wound-healing models — corneal alkali-injury healing with reduced inflammation, reduced lethality and inflammatory mediators in endotoxin-induced septic shock, and chemoattraction of myoblasts during skeletal muscle regeneration in mice.
- Human clinical data: A completed Phase 2b trial (RGN-259, a Tβ4 ophthalmic solution) evaluated safety/efficacy for dry eye disease in humans.
- Human clinical data: A completed Phase 2 trial of recombinant Tβ4 (NL005) for acute myocardial infarction in human patients evaluated continuous administration over 7 days at two dose levels versus placebo.

3. Clinical & Preclinical Study References

Crockford D, Turjman N, Allan C, Angel J. Thymosin beta4: structure, function, and biological properties supporting current and future clinical applications. *Ann N Y Acad Sci.* 2010;1194:179-89. PMID: 20536467

Goldstein AL, Hannappel E, Sosne G, Kleinman HK. Thymosin β4: a multi-functional regenerative peptide. *Expert Opin Biol Ther.* 2012;12(1):37-51. PMID: 22074294

Sosne G, et al. Thymosin beta 4 promotes corneal wound healing and decreases inflammation in vivo following alkali injury. *Exp Eye Res.* 2002. PMID: 11950239

NCT01387347 — Safety and Efficacy of Thymosin Beta 4 Ophthalmic Solution in Patients With Dry Eye (Phase 2, human).

NCT05984134 — Efficacy and Safety of Recombinant Human Thymosin β4 for Injection in Patients With Acute Myocardial Infarction (Phase 2b, human).

Regulatory/Safety Note: No FDA-approved systemic/injectable Tβ4 product exists; the ophthalmic and cardiac formulations cited are investigational, studied under IND in formal trials — not equivalent to unregulated research-labeled material.

This compound has not been evaluated by the FDA and is not intended to diagnose, treat, cure, or prevent any disease in humans or animals.

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