RonanRx
PERSONALIZED MEDICINE

CLINICAL MONOGRAPH · TISSUE REPAIR (UNDER FDA REVIEW)

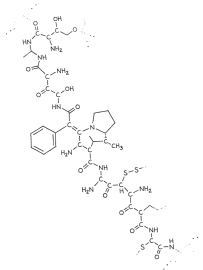
TB-500 / Thymosin Beta-4

Thymosin beta-4 fragment with physician-request review

TB-500 is a research peptide that is sold online and through compounding supply channels as a short fragment of a natural human protein called thymosin beta-4. Thymosin beta-4 is a small protein that every cell in the body makes; it helps cells move and supports wound healing and blood-vessel formation. TB-500 is the marketing name for a 17-amino-acid synthetic piece derived from this larger protein.

TB-500 has no FDA approval in the United States. This ingredient is part of an evolving FDA review process. Physicians may submit patient-specific prescription requests for pharmacy review. Availability is determined case by case, and availability may change after FDA review, PCAC discussion, final agency action, or state-board guidance.

Most of the published research on this peptide family is preclinical (cell and animal experiments) on the full-length thymosin beta-4 protein, not on the 17-residue fragment that is actually sold as TB-500 [goldstein2005; goldstein2012_review]. The small number of human studies that exist used intravenous full-length thymosin beta-4, not the TB-500 fragment, and that drug candidate was not advanced to FDA approval [crockford2010_structure; ruff2010_phase1; fda_503a_bulk_substances].



EVIDENCE POSTURE PRECLINICAL

REVIEWED **2026-05-11**

State-licensed 503A

Pharmacist reviewed

Doctor led

Cold-chain ready

Patient choice preserved

Contents

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FOR CLINICIANS

TB-500 is the marketing designation for a synthetic, N-acetylated peptide commonly described by suppliers as a 17-residue fragment of thymosin beta-4 (Tβ4) corresponding to the central actin-binding region of the parent 43-amino-acid endogenous peptide [crockford2010_structure, sosne2010_active_sites]. Identity of material sold as 'TB-500' from research-grade vendors is not consistently characterized; analytical chemistry literature developed for equine doping control has characterized the marketed compound and published mass-spectrometry detection methods [ho2012_tb500, kwok2013_horse_peptides].

Preclinical mechanism work supports Tβ4 as a G-actin-sequestering cytosolic peptide that, when delivered exogenously, accelerates cell migration, angiogenesis, and tissue repair across multiple models, dermal wound healing [malinda1999_wound, philp2004_angiogenesis, treadwell2012_dermal], corneal epithelial repair [sosne2002_cornea, malinda1997_huvec, sosne2018_eye_review], hair-follicle stem-cell mobilization [philp2007_hair, philp2004_angiogenesis], and cardiac repair via epicardial progenitor activation and cardiomyocyte protection. These data are nearly all generated with full-length recombinant or synthetic thymosin beta-4, not with the 17-residue TB-500 fragment [bock_marquette2004; smart2007_epicardium; bollini2015_cardiac_review].

Human exposure data are limited to intravenous full-length thymosin beta-4 (the ReGeneRx drug candidate, designated RGN-352 in some references). A randomized phase 1 single- and multiple-dose study established a tolerable IV exposure range in healthy volunteers [ruff2010_phase1]; a phase 2 multicenter European venous-stasis-ulcer trial reported topical Tβ4 dose-response signals [guarnera2010_venous]; and a phase 2 ophthalmic-solution trial in dry eye disease using a controlled-adverse-environment chamber design reported symptom and sign improvement [sosne2015_dryeye_p2, sosne2012_dryeye]. None of these programs reached FDA approval. The marketed TB-500 17-residue fragment has not been studied in any randomized clinical trial of which we are aware.

TB-500 has no FDA approval in the United States. This ingredient is part of an evolving FDA review process. Physicians may submit patient-specific prescription requests for pharmacy review. Availability is determined case by case, and availability may change after FDA review, PCAC discussion, final agency action, or state-board guidance.

Why Personalized TB-500 / Thymosin Beta-4

The evidence base for TB-500 is not the same as the evidence base for full-length thymosin beta-4. The marketed 17-amino-acid fragment has no large randomized clinical trial program, while the limited human exposure literature mainly involves full-length thymosin beta-4 preparations.

Physicians may submit patient-specific prescription requests for TB-500 for pharmacy review. Certain preparations may be available now when clinically appropriate, lawfully prescribed, supported by patient-specific documentation, and approved by the dispensing pharmacy. Availability is determined case by case. This is not a consumer access promise; it is a clinical, sourcing, formulation, and regulatory review process. FDA has scheduled TB-500-related bulk drug substances for discussion at the 23-24 Jul 2026 Pharmacy Compounding Advisory Committee meeting.

The regulated path is not a research vial sold to consumers. It is a physician request for a named patient, with pharmacy review of the evidence, formulation feasibility, source documentation, sterile status, and state requirements.

Quick Facts About TB-500 / Thymosin Beta-4

Category: Research peptide marketed as a synthetic thymosin beta-4 (Tβ4) fragment

Marketed identity: TB-500 is sold as an N-acetylated 17-amino-acid peptide derived from the central active region of endogenous thymosin beta-4 (43-amino-acid Tβ4); identity of supplied material from research-grade vendors is not consistently characterized

Endogenous parent peptide: Thymosin beta-4, a 43-residue, ubiquitously expressed cytosolic G-actin-sequestering protein originally isolated from calf thymus

FDA-approval status: Category 2, evolving FDA review process. Valid patient-specific prescription required; supporting clinical rationale may be requested.

FDA 503A compounding status: Physicians may submit patient-specific prescription requests for pharmacy review. Availability is determined case by case.

WADA status: Category 2, evolving FDA review process. Valid patient-specific prescription required; supporting clinical rationale may be requested.

Evidence posture: Preclinical only for the marketed TB-500 fragment. Most published human exposure data are for intravenous full-length thymosin beta-4 (phase 1, phase 2 wound healing), not for the 17-residue fragment sold as TB-500. No randomized controlled trials of the marketed TB-500 product exist.

SPECIALS: PATIENT-SPECIFIC PRESCRIPTION ONLY

Physicians may submit patient-specific prescription requests for TB-500 / Thymosin Beta-4 for pharmacy review. Certain preparations may be available now when clinically appropriate, lawfully prescribed, and approved by the dispensing pharmacy. Availability is determined case by case.

- **Made to order, not off a shelf.** No batch sits in a warehouse waiting for buyers. Your prescription triggers the prep.
- **Named-patient label.** The bottle carries one patient's name. The batch records carry one prescription.
- **Dose, strength, and route chosen for the patient.** A prescriber decides what gets compounded, not a manufacturer who set the strength for a trial population.
- **Licensed pharmacist on the hook.** A real person, with a license that can be pulled, signs off on every prep. State inspectors check the facility.
- **Compounded drugs are not FDA-approved.** They should not be evaluated using branded-drug trial data alone. Availability varies by state and prescribed medication.

How This Differs from a Research-Use-Only Website

A research-use-only website ships a vial from a warehouse. There is no prescription, no pharmacist, no facility inspection, and no way to recall the product if something is wrong with it. If the vial is mislabeled, contaminated, or under-potent, there is nobody whose license is at stake.

A 503A compounding pharmacy is the other thing. The doctor writes the prescription. A licensed pharmacist, whose name is on the label, prepares the medicine in a facility the state inspects. If something goes wrong, there is a person and a license on the hook, and a documented chain of custody on every lot. That accountability is what makes it safe.

What is TB-500 / Thymosin Beta-4?

TB-500 is the trade designation under which a synthetic, N-terminally acetylated peptide is marketed by research-chemical suppliers and offered through some compounding supply channels. Vendors typically describe TB-500 as a 17-amino-acid sequence (frequently rendered Ac-LKKTETQEKNPLPSKETIEQEKQAGES or a related fragment) drawn from the central actin-binding region of endogenous thymosin beta-4 (Tβ4) [crockford2010_structure, sosne2010_active_sites]. Endogenous Tβ4 itself is a 43-residue, highly conserved, ubiquitously expressed cytosolic peptide first isolated from calf thymus and originally characterized as a thymic immune factor; subsequent work established its primary biochemical role as a G-actin-sequestering protein [goldstein2005, goldstein2012_review].

Independent identity characterization of material sold as 'TB-500' is not performed by buyers as a matter of course. Analytical chemistry literature developed for equine doping control has characterized the marketed compound by LC-MS and published detection methods for TB-500 in equine urine and plasma [ho2012_tb500] and for TB-500 alongside six other bioactive peptides in horse plasma [kwok2013_horse_peptides]. These analytical papers are the most rigorous publicly available identity descriptions of the substance as sold in the research-peptide marketplace.

TB-500 is not bioequivalent to, and is not the same substance as, endogenous full-length thymosin beta-4. The published preclinical and limited human evidence base for thymosin beta-4 (described below) was generated with full-length recombinant or synthetic 43-residue Tβ4, not with the 17-residue fragment marketed as TB-500. Extrapolation of effects from full-length Tβ4 to the fragment is not supported by published equivalence studies.

How TB-500 / Thymosin Beta-4 Works

Endogenous thymosin beta-4 is the principal G-actin-sequestering peptide in mammalian cells, binding monomeric G-actin in a 1:1 stoichiometry and regulating the cellular pool of polymerization-competent actin. This actin-sequestering activity is the molecular basis for Tβ4's effects on cell motility: by modulating the balance between G-actin and F-actin, Tβ4 influences lamellipodial extension, directional migration, and the cytoskeletal remodeling required for wound closure, angiogenesis, and tissue repair [goldstein2005, goldstein2012_review].

Sosne and colleagues mapped the biological activities of Tβ4 to discrete short peptide sequences within the parent 43-residue protein and identified the central region as the principal contributor to wound-healing and anti-inflammatory activity in vitro and in vivo [sosne2010_active_sites]. This active-site mapping is the published rationale that suppliers cite for marketing the 17-residue fragment as 'TB-500.' Whether the truncated fragment recapitulates the full activity profile of intact Tβ4 in vivo is not established in published comparative data.

Downstream cellular effects of full-length Tβ4 in preclinical models include accelerated endothelial cell migration and angiogenesis [malinda1997_huvec, philp2004_angiogenesis], promotion of dermal wound closure [malinda1999_wound, treadwell2012_dermal], corneal epithelial healing with reduced inflammation [sosne2002_cornea, sosne2018_eye_review], hair-follicle stem-cell mobilization and follicular neogenesis [philp2007_hair, philp2004_angiogenesis], and cardiac protection mediated by integrin-linked kinase signaling and adult epicardial progenitor activation [bock_marquette2004, smart2007_epicardium, smart2011_denovo_cardiomyocytes]. A more recent mechanistic line of work positions Tβ4 as a modulator of autophagy in inflammatory contexts [renga2018_autophagy].

Biological Role of TB-500 / Thymosin Beta-4

Endogenous thymosin beta-4 is one of the most abundant cytosolic peptides in mammalian cells [smart2007_epicardium; sosne2002_cornea; di2026_kidney]. Its primary biochemical function is sequestration of monomeric G-actin in a 1:1 complex, which regulates the cellular pool of polymerization-competent actin and consequently the rate and direction of actin-filament assembly required for cell motility and morphogenesis [goldstein2005, goldstein2012_review] [philp2007_hair].

In the regenerative-biology literature, Tβ4 has been implicated in coordinating cell migration, angiogenesis, anti-apoptotic signaling, and reduction of inflammation following tissue injury, a phenotype that has been observed across cardiac, dermal, corneal, hair-follicle, and renal tissue models [philp2004_angiogenesis; bock_marquette2004; smart2011_denovo_cardiomyocytes]. The biological role of the truncated 17-residue TB-500 fragment, independent of full-length Tβ4, is less well characterized.

TB-500 / Thymosin Beta-4 Research History

Thymosin beta-4 was originally isolated from calf thymus in the 1980s and proposed as a thymic immune factor; subsequent biochemical work re-identified it as a ubiquitously expressed cytosolic G-actin-sequestering peptide rather than as a secreted immune hormone [goldstein2005]. The repositioning of Tβ4 from immune factor to actin-regulator drove a second wave of research focused on regenerative biology, wound healing, angiogenesis, and tissue repair, through the late 1990s and 2000s [malinda1999_wound; philp2004_angiogenesis].

Clinical-stage development of Tβ4 was led by ReGeneRx Biopharmaceuticals through the late 2000s. A randomized phase 1 IV single- and multiple-dose study in healthy volunteers established a tolerable exposure range [ruff2010_phase1]. A multicenter European phase 2 trial of topical Tβ4 in venous stasis ulcers reported dose-response wound-closure signals [guarnera2010_venous]. A retrospective pre-clinical-and-clinical synthesis covering the dermal-healing data was published in 2012 [treadwell2012_dermal]. Phase 2 ophthalmic-solution trials in dry eye disease, including a controlled-adverse-environment chamber study, reported symptom and sign improvement [sosne2015_dryeye_p2, sosne2012_dryeye]. Cardiac-indication development was supported by the discovery work of Bock-Marquette (2004) on integrin-linked-kinase activation [bock_marquette2004] and the epicardial-progenitor work of Smart and colleagues (2007, 2011) [smart2007_epicardium, smart2011_denovo_cardiomyocytes], with a clinical-development proposal published by Crockford in 2007 [crockford2007_cardiac_dev]; a cardioprotection proposal for congenital heart surgery was published in 2012 [stromberg2012_cardiac_surgery]. None of these programs reached FDA approval.

In parallel with the clinical-development arc for full-length Tβ4, the 17-residue 'TB-500' fragment emerged in the research-chemical and veterinary-doping spaces. Analytical chemistry literature characterized TB-500 by LC-MS [ho2012_tb500, kwok2013_horse_peptides] in response to thoroughbred-racing doping casework, the most rigorous publicly available material on the identity and behavior of the marketed compound. The World Anti-Doping Agency added the substance class to the Prohibited List under S2 (Peptide Hormones), and equine racing authorities issued bans and detection programs in parallel [wada_list]. The FDA Pharmacy Compounding Advisory Committee evaluated thymosin beta-4 / TB-500 for the 503A bulk-drug-substances list and placed it in Category 2 (insufficient information to evaluate) [fda_503a_bulk_substances, fda_pcac] [malinda1997_huvec]. A 2026 narrative review of unapproved peptide therapies marketed for musculoskeletal and athletic-performance indications [mendias2026]

documents the persistent gap between the marketing of TB-500 and the absence of randomized clinical evidence for the fragment in humans [goldstein2012_review].

TB-500 / Thymosin Beta-4 Timeline

1980s • Thymosin beta-4 isolated from calf thymus and initially characterized as a thymic immune factor; subsequent biochemical work re-identifies it as a ubiquitously expressed cytosolic G-actin-sequestering peptide [goldstein2005]

1997 • Malinda et al [malinda1997_huvec]. (FASEB J), thymosin beta-4 stimulates directional migration of human umbilical vein endothelial cells; first endothelial-migration mechanism paper

1999 • Malinda et al [malinda1999_wound]. (J Invest Dermatol), thymosin beta-4 accelerates dermal wound healing in rodent models

2002 • Sosne et al [sosne2002_cornea]. (Exp Eye Res), thymosin beta-4 promotes corneal wound healing and reduces inflammation following alkali injury

2004 • Philp et al [philp2004_angiogenesis]. (Mech Ageing Dev), thymosin beta-4 promotes angiogenesis, wound healing, and hair-follicle development

2004 • Bock-Marquette et al [bock_marquette2004]. (Nature), thymosin beta-4 activates integrin-linked kinase and promotes cardiac cell migration, survival, and repair after infarction

2005 • Goldstein, Hannappel, Kleinman (Trends Mol Med), thymosin beta-4 repositioned from thymic immune factor to actin-sequestering protein with tissue-repair function [goldstein2005]

2007 • Smart et al [smart2007_epicardium]. (Nature), thymosin beta-4 induces adult epicardial progenitor mobilization and neovascularization

2007 • Crockford (Annals NYAS), development plan published for thymosin beta-4 in ischemic heart disease at ReGeneRx [crockford2007_cardiac_dev]

2007 • Philp et al [philp2007_hair]. (Annals NYAS), thymosin beta-4 induces hair growth via stem cell migration and differentiation

2010 • Ruff et al [ruff2010_phase1]. (Annals NYAS), randomized, placebo-controlled, single- and multiple-dose phase 1 study of intravenous full-length thymosin beta-4 in healthy volunteers establishes a tolerable IV exposure range

2010 • Guarnera et al [guarnera2010_venous]. (Annals NYAS), multicenter European phase 2 of topical full-length thymosin beta-4 in venous stasis ulcers reports dose-response wound-closure signals

2010 • Crockford et al [crockford2010_structure]. (Annals NYAS), structure, function, and biological-property review supporting the thymosin beta-4 clinical program

2010 • Philp and Kleinman (Annals NYAS), synthesis of animal studies with thymosin beta-4 as a multifunctional tissue-repair peptide [philp2010_animal_studies]

2010 • Sosne et al [sosne2010_active_sites]. (FASEB J), biological activities of thymosin beta-4 mapped to discrete short peptide sequences within the parent 43-residue protein; published rationale for fragment-based agents

2011 • Smart et al [smart2011_denovo_cardiomyocytes]. (Nature), de novo cardiomyocyte generation from within the activated adult heart after injury, building on the epicardial-progenitor mechanism

2012 • Ho et al [ho2012_tb500]. (J Chromatogr A), doping-control LC-MS analysis of TB-500 (a synthetic version of an active region of thymosin beta-4) in equine urine and plasma; among the most rigorous public identity characterizations of the marketed compound

2012 • Treadwell et al [treadwell2012_dermal]. (Annals NYAS), synthesis of preclinical and patient data on the dermal-healing program for thymosin beta-4

2012 • Sosne et al [sosne2012_dryeye]. (Annals NYAS), thymosin beta-4 evaluated as a dry-eye therapy; controlled-adverse-environment chamber data summarized

2012 • Stromberg et al [stromberg2012_cardiac_surgery]. (Annals NYAS), proposal to combine thymosin beta-4 and dexrazoxane for cardioprotection during congenital heart surgery

2012 • Goldstein et al [goldstein2012_review]. (Expert Opin Biol Ther), thymosin beta-4 multifunctional regenerative-peptide review covering basic properties and clinical applications

2013 • Kwok et al [kwok2013_horse_peptides]. (Anal Bioanal Chem), LC-MS analysis of TB-500 and six other bioactive peptides in horse plasma in the doping-control workflow

2015 • Sosne and Ousler (Clin Ophthalmol), phase 2 randomized placebo-controlled trial of thymosin beta-4 ophthalmic solution for dry eye in a controlled-adverse-environment chamber design [sosne2015_dryeye_p2]

2015 • Bollini, Riley, Smart (Expert Opin Biol Ther), review of thymosin beta-4 functions in protection, repair, and regeneration of the mammalian heart [bollini2015_cardiac_review]

2015 • Goldstein and Kleinman (Expert Opin Biol Ther), advances in the basic and clinical applications of thymosin beta-4 [goldstein2015_advances]

2018 • Sosne (Expert Opin Biol Ther), thymosin beta-4 and the eye: bench-to-bedside narrative covering corneal healing, dry eye, and neurotrophic keratopathy [sosne2018_eye_review]

2018 • Renga et al [renga2018_autophagy]. (Expert Opin Biol Ther), thymosin beta-4 limits inflammation through autophagy, extending mechanism beyond actin sequestration

2023 • FDA Pharmacy Compounding Advisory Committee evaluates thymosin beta-4 / TB-500 for the 503A bulk-drug-substances list and places it in Category 2 (insufficient information to evaluate), substance ineligible for 503A compounding pending further data [fda_503a_bulk_substances; fda_pcac]

2026 • Mendias and Awan (Sports Med), safety and efficacy review of approved and unapproved peptide therapies (including TB-500) for musculoskeletal injuries and athletic performance; documents persistent absence of randomized clinical evidence for the marketed TB-500 fragment in humans [mendias2026]

2026 • Di et al [di2026_kidney]. (Peptides), review positioning thymosin beta-4 as an emerging therapeutic candidate for kidney diseases (preclinical)

Clinical Contexts for TB-500 / Thymosin Beta-4

Marketing-claimed: musculoskeletal injury recovery and athletic performance enhancement

PRECLINICAL

Common consumer-facing marketing claim for TB-500. Not supported by randomized clinical trials of the marketed 17-residue fragment in humans. WADA-prohibited at all times.

Online supplier and athletic-performance marketing positions TB-500 as a soft-tissue and tendon-healing peptide. A 2026 narrative review of unapproved peptide therapies for musculoskeletal injury and athletic performance [mendias2026] documents that no randomized clinical trial evidence supports the marketing claims for the 17-residue TB-500 fragment in humans. The preclinical evidence base [malinda1999_wound, philp2004_angiogenesis, treadwell2012_dermal] was generated with full-length thymosin beta-4, not with the marketed fragment, and animal-to-human extrapolation is not validated. WADA prohibits the substance class at all times [wada_list]; equine racing authorities ban its use and detect it in casework [ho2012_tb500, kwok2013_horse_peptides].

Dermal wound healing (full-length Tβ4 preclinical and limited human signal) PRECLINICAL

Preclinical wound-healing evidence is for full-length thymosin beta-4, not for the marketed TB-500 fragment. Phase 2 venous-stasis-ulcer data exist for topical full-length Tβ4 and were not advanced to FDA approval.

Animal-model wound-healing data for full-length Tβ4 include rodent dermal wound closure [malinda1999_wound], angiogenesis and hair-follicle responses [philp2004_angiogenesis], and a clinical-translation synthesis [treadwell2012_dermal]. Human-stage data from ReGeneRx include a phase 1 IV safety trial [ruff2010_phase1] and a multicenter European phase 2 of topical Tβ4 in venous stasis ulcers reporting dose-response wound-closure signals [guarnera2010_venous]. The program did not reach FDA approval. None of this work used the 17-residue TB-500 fragment.

Corneal and ocular surface repair (full-length Tβ4 preclinical and phase 2) PRECLINICAL

Preclinical and phase 2 ophthalmic data are for full-length Tβ4 ophthalmic solution, not for the marketed TB-500 fragment.

Sosne and colleagues characterized full-length Tβ4 as a corneal wound-healing and anti-inflammatory peptide in rodent alkali-injury models [sosne2002_cornea] and reviewed the bench-to-bedside arc through corneal, dry-eye, and neurotrophic-keratopathy applications [sosne2018_eye_review]. A phase 2 randomized placebo-controlled trial of full-length Tβ4 ophthalmic solution in dry eye disease using a controlled-adverse-environment chamber design [sosne2015_dryeye_p2, sosne2012_dryeye] reported symptom and sign improvement. The program did not reach FDA approval. No ophthalmic clinical data exist for the marketed TB-500 fragment.

Cardiac repair after ischemic injury (full-length Tβ4 preclinical) PRECLINICAL

Preclinical cardiac-repair signal is for full-length Tβ4. No completed cardiac human program; the ReGeneRx development plan was published as a proposal and did not progress to approval.

Bock-Marquette et al. (Nature 2004) demonstrated that exogenous Tβ4 activates integrin-linked kinase and promotes cardiac-cell migration, survival, and post-infarction repair [bock_marquette2004]. Smart and colleagues described thymosin-beta-4-induced mobilization of adult epicardial progenitor cells and de novo cardiomyocyte generation from activated adult heart [smart2007_epicardium, smart2011_denovo_cardiomyocytes]. Reviews [bollini2015_cardiac_review] summarized cardiac-repair mechanism candidates. The clinical-development proposal for ischemic heart disease [crockford2007_cardiac_dev] and a pediatric cardiac-surgery cardioprotection proposal [stromberg2012_cardiac_surgery] were published but no completed phase 3 program followed.

Compounded TB-500 / Thymosin Beta-4 (503A)

Physicians may submit patient-specific prescription requests for pharmacy review. For TB-500, certain preparations may be available now when clinically appropriate, lawfully prescribed, and approved by the dispensing pharmacy. Availability is determined case by case and may depend on patient-specific documentation, ingredient status, source qualification, formulation feasibility, state requirements, and pharmacist judgment. The review starts with the evidence constraint: The evidence base for TB-500 is not the same as the evidence base for full-length thymosin beta-4. The marketed 17-amino-acid fragment has no large randomized clinical trial program, while the limited human exposure literature mainly involves full-length thymosin beta-4 preparations.

This ingredient is part of an evolving FDA review process. RonanRx is monitoring FDA's PCAC process and any subsequent agency action. FDA has scheduled TB-500-related bulk drug substances for discussion at the 23-24 Jul 2026 Pharmacy Compounding Advisory Committee meeting. Availability may change after FDA review, PCAC discussion, final agency action, or state-board guidance. For TB-500, RonanRx ties that monitoring to the evidence limits described above and to any patient-specific documentation submitted by the prescriber.

Valid patient-specific prescription required. Supporting clinical rationale may be requested. Compounded medications are not FDA-approved. No consumer self-ordering, no office stock, no bulk dispensing. Requests for TB-500 are reviewed before any preparation is made or released. The regulated path is not a research vial sold to consumers. It is a physician request for a named patient, with pharmacy review of the evidence, formulation feasibility, source documentation, sterile status, and state requirements.

TB-500 / Thymosin Beta-4 Formulations and Routes

Form	Concentration	Description
Research-grade lyophilized peptide (not for human administration)	—	Material sold as 'TB-500' in the research-chemical marketplace is typically supplied as lyophilized powder from non-pharmaceutical vendors, reconstituted in bacteriostatic water by the end user. Identity, purity, and sterility are not subject to USP <797> sterile compounding standards; analytical characterization of marketed material has been performed by equine doping-control laboratories rather than by pharmaceutical-grade release testing.

Routes used in published literature: subcutaneous, intramuscular, intravenous.

TB-500 / Thymosin Beta-4 Safety

Human safety data are limited and do not pertain to the marketed 17-residue TB-500 fragment. A randomized phase 1 single- and multiple-dose IV study of full-length thymosin beta-4 in healthy volunteers [12] established a tolerable IV exposure range with no severe drug-related adverse events at the doses tested. A multicenter European phase 2 topical Tβ4 trial in venous stasis ulcers [13] reported no unexpected safety signals at the topical doses studied. A phase 2 ophthalmic-solution dry-eye trial [23] reported acceptable tolerability for ocular administration of full-length Tβ4. None of these data characterize the safety of subcutaneously or intramuscularly injected research-grade TB-500 from non-pharmaceutical suppliers.

Material marketed as TB-500 is research-grade peptide; impurity profile, endotoxin content, sterility, and identity verification are not subject to pharmaceutical-grade quality control in the consumer supply chain. Practice-facing reviews of unapproved peptide therapies [27] catalog reports of injection-site reactions, sterility-related events, and adulteration or mis-identification of supplied material as the most concrete safety considerations for the consumer marketplace. Theoretical concerns include immunogenicity to a non-physiologic peptide fragment and unintended effects of chronic cytoskeletal modulation; published data do not characterize these risks for chronic dosing in humans.

TB-500 is prohibited at all times under WADA S2 [31] and is the subject of equine doping detection programs [18][22]. Athletes, racehorse trainers, and any individual subject to anti-doping testing should be aware that exposure produces detectable findings.

Contraindications

Honest gap. No FDA-approved product exists for TB-500 or full-length thymosin beta-4; no labeled contraindications are published. Physicians may submit patient-specific prescription requests for pharmacy review. Availability is determined case by case.

Searched: PubMed, FDA Drugs@FDA, DailyMed on 2026-05-11 · terms *TB-500 contraindications; thymosin beta-4 contraindications; thymosin beta-4 prescribing information*.

Drug interactions

Honest gap. No FDA-approved labeling and no published clinical drug-interaction data for TB-500 or full-length thymosin beta-4. Thymosin beta-4 is a peptide cleared by proteolytic catabolism; cytochrome P450-mediated interactions are not anticipated mechanistically but no human DDI studies are published.

Searched: PubMed, FDA Drugs@FDA, DailyMed on 2026-05-11 · terms *TB-500 drug interactions; thymosin beta-4 drug interactions; thymosin beta-4 cytochrome*.

Adverse events

Published adverse-event data pertain to full-length thymosin beta-4 from ReGeneRx clinical trials, not to the marketed TB-500 fragment. In the phase 1 IV single- and multiple-dose study in healthy volunteers [12], the most commonly reported events were mild and not consistently attributable to study drug. In the multicenter European phase 2 venous-stasis-ulcer trial of topical full-length Tβ4 [13], the topical formulation was reported as well tolerated at the doses studied. The phase 2 dry-eye ophthalmic-solution trial [2320] reported tolerability consistent with topical ocular use of a peptide solution.

For research-grade material marketed as TB-500 and self-administered by injection, no systematic adverse-event reporting framework exists. Practice-facing reviews [27] catalog injection-site reactions, sterility-related events, dosing errors, and identity/adulteration concerns as the principal real-world safety considerations and emphasize the absence of pharmacovigilance infrastructure for the consumer supply chain.

Monitoring TB-500 / Thymosin Beta-4 Therapy

No RonanRx-specific monitoring protocol has been established for TB-500. If a patient-specific prescription is submitted, supporting clinical rationale may be requested, and monitoring expectations would be reviewed case by case against the published evidence, route, sterile or nonsterile status, concomitant therapies, and patient risk factors.

TB-500 / Thymosin Beta-4 in Special Populations

TB-500 / Thymosin Beta-4 Evidence Quality

Evidence supporting any human use of the marketed 17-residue TB-500 fragment is absent. No randomized clinical trial of TB-500 in humans has been published, and the analytical chemistry literature that does describe the marketed substance was developed for equine doping control rather than for therapeutic claims [ho2012_tb500, kwok2013_horse_peptides]. A practice-facing 2026 review of unapproved peptide therapies marketed for musculoskeletal injury and athletic performance [mendias2026] confirms the persistent gap between marketing claims for TB-500 and the absence of human randomized clinical evidence for the fragment.

Evidence supporting the related but distinct full-length thymosin beta-4 peptide is mostly preclinical. Core mechanism work, G-actin sequestration [goldstein2005, goldstein2012_review], endothelial migration and angiogenesis [malinda1997_huvec, philp2004_angiogenesis], dermal wound healing [malinda1999_wound, treadwell2012_dermal], corneal repair [sosne2002_cornea, sosne2018_eye_review], hair-follicle effects [philp2007_hair, philp2004_angiogenesis], cardiac repair via ILK and epicardial progenitors [bock_marquette2004, smart2007_epicardium,

smart2011_denovo_cardiomyocytes], and inflammation/autophagy [renga2018_autophagy], is supported by animal-model and cell-culture data. The small set of human studies of full-length Tβ4, phase 1 IV [ruff2010_phase1], phase 2 topical venous ulcer [guarnera2010_venous], phase 2 ophthalmic solution [sosne2015_dryeye_p2, sosne2012_dryeye], did not progress to FDA approval, and the development sponsor's program is no longer active. Independent active-region mapping [sosne2010_active_sites] established the rationale for fragment-based agents but did not validate the marketed 17-residue TB-500 sequence as therapeutically equivalent to full-length Tβ4 in humans.

The FDA Pharmacy Compounding Advisory Committee placed thymosin beta-4 / TB-500 in Category 2 (insufficient information to evaluate) on the 503A bulk drug substances list [fda_503a_bulk_substances, fda_pcac]; Category 2 substances are part of an evolving FDA review process for 503A compounding. WADA prohibits the substance class at all times under S2 [wada_list].

Major TB-500 / Thymosin Beta-4 Clinical Studies

Study	Design	Participants	Duration	Finding
Ruff et al. (2010, Annals NYAS), Phase 1 IV full-length Tβ4	Randomized, placebo-controlled, single- and multiple-dose phase 1 study of intravenous full-length thymosin beta-4 in healthy volunteers	—	Single- and multiple-dose, short-term	Established a tolerable IV exposure range for full-length Tβ4 with no severe drug-related adverse events at the doses tested; not a study of the marketed 17-residue TB-500 fragment [ruff2010_phase1]
Guarnera et al. (2010, Annals NYAS), Phase 2 topical Tβ4 in venous ulcers	Multicenter European phase 2 randomized trial of topical full-length thymosin beta-4 in patients with venous stasis ulcers	—	Per-protocol topical dosing schedule	Dose-response wound-closure signals reported for topical full-length Tβ4; program did not advance to FDA approval; not a study of the marketed 17-residue TB-500 fragment [guarnera2010_venous]
Sosne and Ousler (2015, Clin Ophthalmol), Phase 2 Tβ4 ophthalmic for dry eye	Randomized placebo-controlled phase 2 trial of full-length thymosin beta-4 ophthalmic solution in dry eye	—	—	Symptom and sign improvement reported for full-length Tβ4 ophthalmic solution; program did not advance to FDA approval [sosne2015_dryeye_p2]

Study	Design	Participants	Duration	Finding
	disease using a controlled-adverse-environment chamber design			
Bock-Marquette et al. (2004, Nature), Cardiac repair via ILK	Preclinical mechanistic study in rodent myocardial-infarction models	—	—	Exogenous thymosin beta-4 activates integrin-linked kinase, promotes cardiac-cell migration and survival, and improves post-infarction cardiac function [bock_marquette2004]
Smart et al. (2007, Nature), Epicardial progenitor activation	Preclinical mechanistic study of adult epicardial progenitor cells in murine cardiac injury	—	—	Thymosin beta-4 induces adult epicardial progenitor mobilization and neovascularization [smart2007_epicardium]
Smart et al. (2011, Nature), De novo cardiomyocytes	Preclinical lineage-tracing study in adult murine heart following injury and Tβ4 priming	—	—	De novo cardiomyocyte generation from within the activated adult heart after injury [smart2011_denovo_cardiomyocytes]
Malinda et al. (1999, J Invest Dermatol), Dermal wound healing	Rodent full-thickness dermal wound model with topical or systemic full-length Tβ4	—	—	Thymosin beta-4 accelerates wound closure relative to vehicle; angiogenesis and re-epithelialization improved [malinda1999_wound]
Sosne et al. (2002, Exp Eye Res), Corneal alkali injury	Murine corneal alkali-injury model with topical full-length Tβ4	—	—	Promotes corneal wound healing and reduces inflammation in vivo following alkali burn [sosne2002_cornea]
Malinda et al. (1997, FASEB J), Endothelial migration	In vitro HUVEC chemotaxis assay with synthetic Tβ4	—	—	Thymosin beta-4 stimulates directional migration of human umbilical vein endothelial cells; mechanistic basis for angiogenesis effects [malinda1997_huvec]
Philp et al. (2004, Mech Ageing Dev),	Preclinical in vivo and ex vivo studies of full-length Tβ4	—	—	Thymosin beta-4 promotes angiogenesis, wound healing, and hair-follicle

Study	Design	Participants	Duration	Finding
Angiogenesis and hair follicle	in angiogenesis, wound healing, and hair-follicle assays			development in rodent models [philp2004_angiogenesis]
Philp et al. (2007, Annals NYAS), Hair growth via stem cells	Rodent hair-growth model with topical and intradermal full-length Tβ4	—	—	Thymosin beta-4 induces hair growth via stem-cell migration and differentiation in murine skin [philp2007_hair]
Sosne et al. (2010, FASEB J), Active-site mapping	Synthetic short-peptide screening across the parent 43-residue Tβ4 sequence in wound-healing and migration assays	—	—	Biological activities of Tβ4 are localized to discrete short sequences in the central region of the parent peptide; rationale for fragment-based agents (cited by suppliers of marketed TB-500) [sosne2010_active_sites]
Ho et al. (2012, J Chromatogr A), TB-500 doping LC-MS	Analytical chemistry development of LC-MS detection for TB-500 in equine urine and plasma	—	—	Among the most rigorous publicly available identity characterizations of the marketed 'TB-500' substance; established detection windows and reference spectra used in equine doping control [ho2012_tb500]
Kwok et al. (2013, Anal Bioanal Chem), Seven peptides in horse plasma	Multiplexed LC-MS detection of seven bioactive peptides including TB-500 in horse plasma	—	—	Detection method development supporting equine racing doping-control program [kwok2013_horse_peptides]
Renga et al. (2018, Expert Opin Biol Ther), Tβ4 and autophagy	Preclinical mechanistic review and primary data on autophagy regulation by thymosin beta-4	—	—	Thymosin beta-4 limits inflammation through autophagy modulation; extends mechanism beyond actin sequestration [renga2018_autophagy]
Mendias and Awan (2026, Sports Med),	Narrative review of safety and efficacy of approved and	—	—	Documents persistent absence of randomized clinical evidence for the marketed TB-500 fragment in humans

Study	Design	Participants	Duration	Finding
Unapproved peptide review	unapproved peptide therapies for musculoskeletal injuries and athletic performance			and catalogs supply-chain quality concerns in the consumer peptide marketplace [mendias2026]

TB-500 / Thymosin Beta-4 Pharmacokinetics & Pharmacodynamics

Pharmacokinetics

Pharmacokinetic data are limited to the phase 1 IV single- and multiple-dose study of full-length thymosin beta-4 in healthy volunteers [ruff2010_phase1]. As a peptide, thymosin beta-4 is expected to be cleared by proteolytic catabolism; cytochrome P450-mediated metabolism is not anticipated. No human PK data are published for subcutaneously or intramuscularly administered TB-500 fragment material from research-grade suppliers.

TB-500 / Thymosin Beta-4 Compounding & Operations

503A compounding

Physicians may submit patient-specific prescription requests for pharmacy review. For TB-500, certain preparations may be available now when clinically appropriate, lawfully prescribed, and approved by the dispensing pharmacy. Availability is determined case by case and may depend on patient-specific documentation, ingredient status, source qualification, formulation feasibility, state requirements, and pharmacist judgment. The review starts with the evidence constraint: The evidence base for TB-500 is not the same as the evidence base for full-length thymosin beta-4. The marketed 17-amino-acid fragment has no large randomized clinical trial program, while the limited human exposure literature mainly involves full-length thymosin beta-4 preparations.

This ingredient is part of an evolving FDA review process. RonanRx is monitoring FDA's PCAC process and any subsequent agency action. FDA has scheduled TB-500-related bulk drug substances for discussion at the 23-24 Jul 2026 Pharmacy Compounding Advisory Committee meeting. Availability may change after FDA review, PCAC discussion, final agency action, or state-board guidance. For TB-500, RonanRx ties that monitoring to the evidence limits described above and to any patient-specific documentation submitted by the prescriber.

Valid patient-specific prescription required. Supporting clinical rationale may be requested. Compounded medications are not FDA-approved. No consumer self-ordering, no office stock, no bulk dispensing.

Requests for TB-500 are reviewed before any preparation is made or released. The regulated path is not a research vial sold to consumers. It is a physician request for a named patient, with pharmacy review of the evidence, formulation feasibility, source documentation, sterile status, and state requirements.

Pharmacist review

For TB-500, the pharmacist review starts before any preparation is made. Valid patient-specific prescription required. Supporting clinical rationale may be requested. The pharmacist reviews ingredient status, sourcing, formulation feasibility, state requirements, patient-specific documentation, and whether dispensing is appropriate case by case.

Quality and traceability

If a TB-500 preparation is approved after pharmacy review, RonanRx applies source documentation, formulation records, lot traceability, release checks, and storage controls appropriate to the actual dosage form. Research-use vial storage practices do not substitute for pharmacy-assigned storage, beyond-use dating, sterility controls when applicable, or recallable batch records. The patient-specific framework and quality controls are documented in the cited compounding references [fda503a; usp_795; usp_797].

Frequently Asked Questions About TB-500 / Thymosin Beta-4

Can physicians request TB-500 through RonanRx?

Physicians may submit patient-specific prescription requests for pharmacy review. Certain preparations may be available now when clinically appropriate, lawfully prescribed, and approved by the dispensing pharmacy. Availability is determined case by case. Compounded medications are not FDA-approved, and no consumer self-ordering, office stock, or bulk dispensing is offered.

Why do I see TB-500 sold online by 'research peptide' vendors?

Material marketed as TB-500 in the consumer and athletic-performance marketplace is research-grade peptide from non-pharmaceutical suppliers and is sold without FDA approval, pharmaceutical-grade release testing, or pharmacovigilance [mendias2026]. The most rigorous public identity characterizations of the marketed substance were developed by equine doping-control laboratories rather than by pharmaceutical-quality release testing [ho2012_tb500]. RonanRx is not part of that supply chain [kwok2013_horse_peptides].

Is TB-500 the same thing as thymosin beta-4?

No. Endogenous thymosin beta-4 (Tβ4) is a 43-amino-acid peptide naturally expressed in every cell [crockford2010_structure]. TB-500 is the marketing designation for a synthetic 17-amino-acid peptide derived from the central active region of Tβ4 [sosne2010_active_sites]. The published preclinical and

limited human evidence base is overwhelmingly for the full-length 43-residue protein, not for the 17-residue marketed fragment [goldstein2005]. Equivalence of the fragment to the full-length peptide in humans is not established.

Are there human clinical trials of TB-500?

No published randomized clinical trial of the marketed 17-residue TB-500 fragment in humans is available. The small number of human studies in the thymosin beta-4 literature used full-length intravenous or topical thymosin beta-4 (from the ReGeneRx development program) and did not advance to FDA approval [ruff2010_phase1; guarnera2010_venous]. A 2026 review of unapproved peptide therapies for musculoskeletal injury and athletic performance documents the persistent absence of randomized clinical evidence for the marketed fragment [sosne2015_dryeye_p2; mendias2026].

Is TB-500 banned in sport?

Yes. TB-500 is prohibited at all times under the World Anti-Doping Agency Prohibited List S2 class (Peptide Hormones, Growth Factors, Related Substances and Mimetics) [wada_list]. LC-MS detection methods for TB-500 in equine and human matrices are published and in use by anti-doping laboratories [ho2012_tb500; kwok2013_horse_peptides].

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How to Access TB-500 / Thymosin Beta-4

Compounded TB-500 / Thymosin Beta-4 is dispensed under 503A on a patient-specific prescription. Depending on your role, the next step looks different.

FOR PRESCRIBING CLINICIANS

Offer this medication

A pharmacist will follow up within two business days. We'll cover state availability, supported formulations, and what integration looks like for your clinic.

ronanrx.com/request-partnership-call

PATIENT WITH A DOCTOR

Receive your prescription

If your doctor has prescribed TB-500 / Thymosin Beta-4, sign up so we can prepare and ship your medication. The signup wizard collects intake and connects you to the prescribing workflow.

ronanrx.com/patients

PATIENT WITHOUT A DOCTOR

Find a partner clinic

RonanRx prescribes through partner clinics — we don't initiate prescriptions on this site. Read how the referral process works and how to find a partner clinic in your state.

ronanrx.com/find-clinic

Other compounds RonanRx makes

This monograph is one of many in the RonanRx formulary. Every compound below is prepared under 503A on a patient-specific prescription. Browse the full catalog at ronanrx.com/medications and ronanrx.com/peptides, or scan the codes at right for each index.

Medications

Peptides

MEDICATIONS (40)

Alpha-Lipoic Acid (ALA) — Antioxidant & mitochondrial
Coenzyme Q10 (CoQ10) — Antioxidant & mitochondrial
Glutathione — Antioxidant & mitochondrial
NAD+ / NMN — Antioxidant & mitochondrial
Compounded Topical Anesthetics (BLT, LET) — Dermatology
Topical Minoxidil — Dermatology
Topical Tretinoin — Dermatology
Compounded Magnesium — Energy & nutritional
Cyanocobalamin — Energy & nutritional
High-Dose Vitamin D — Energy & nutritional
Hydroxocobalamin — Energy & nutritional
Iron (Compounded) — Energy & nutritional
L-Carnitine — Energy & nutritional
Methylcobalamin (B12) — Energy & nutritional
Methylfolate — Energy & nutritional
Anastrozole — Hormone optimization
Clomiphene & Enclomiphene — Hormone optimization
DHEA — Hormone optimization
Estradiol — Hormone optimization
Estriol — Hormone optimization
Human Chorionic Gonadotropin (HCG) — Hormone optimization
Pregnenolone — Hormone optimization
Progesterone — Hormone optimization
Testosterone — Hormone optimization
Compounded Metformin — Metabolic & weight
Compounded Semaglutide — Metabolic & weight
Compounded Tirzepatide — Metabolic & weight
Lipotropic Injection (MIC, MICC) — Metabolic & weight
Low-Dose Naltrexone (LDN) — Metabolic & weight
Naltrexone-Bupropion Combination — Metabolic & weight
Topiramate — Metabolic & weight
Bremelanotide / PT-141 — Sexual health
Compounded Sildenafil — Sexual health
Compounded Tadalafil — Sexual health
Trimix Injection — Sexual health
Compounded Gabapentin — Sleep & recovery
Compounded Melatonin — Sleep & recovery
Compounded T3 (Liothyronine) — Thyroid
Compounded T3/T4 Combinations — Thyroid
Compounded T4 (Levothyroxine) — Thyroid

PEPTIDES (21)

Sermorelin — Available now

Tesamorelin — Available now

AOD-9604 — Growth-hormone axis (under FDA review)

CJC-1295 — Growth-hormone axis (under FDA review)

GHRP-2 / GHRP-6 — Growth-hormone axis (under FDA review)

Hexarelin — Growth-hormone axis (under FDA review)

Ipamorelin — Growth-hormone axis (under FDA review)

MK-677 / Ibutamoren — Growth-hormone axis (under FDA review)

5-Amino 1MQ — Metabolic & longevity (under FDA review)

Epitalon / Epithalon — Metabolic & longevity (under FDA review)

MOTS-C — Metabolic & longevity (under FDA review)

Thymosin Alpha-1 / Thymalin — Metabolic & longevity (under FDA review)

DSIP, Delta Sleep-Inducing Peptide — Neuro & cognitive (under FDA review)

Selank — Neuro & cognitive (under FDA review)

Semax — Neuro & cognitive (under FDA review)

Vasoactive Intestinal Peptide (VIP) — Neuro & cognitive (under FDA review)

BPC-157 — Tissue repair (under FDA review)

KPV — Tissue repair (under FDA review)

LL-37 — Tissue repair (under FDA review)

Pentadeca Arginate (PDA) — Tissue repair (under FDA review)

TB-500 / Thymosin Beta-4 — Tissue repair (under FDA review)