

PATIENT GUIDE

# TB-500 *for tissue repair*

A clear look at thymosin beta-4, the short fragment of it sold as TB-500, and what the research in people does and does not yet show.

| COMPOUND     | CLASS          | ROUTES             | RESEARCH          | SOURCES          |
|--------------|----------------|--------------------|-------------------|------------------|
| TB-500 / Tβ4 | Repair peptide | Injection, topical | Early, mostly Tβ4 | 30 · PMID linked |

§ 01

## Why we are talking about TB-500

TB-500 is one of the peptides patients ask us about most, usually in connection with a tendon, muscle or joint injury that is slow to settle. The interest has a real scientific origin. It comes from thymosin beta-4, a repair protein your own body makes and releases at the site of an injury, and from a large body of laboratory and animal research showing how that protein helps tissue heal. <sup>1</sup>

There is one point we want every patient to understand from the start. The human trials were done with the whole thymosin beta-4 protein, while the product sold as TB-500 is usually a short synthetic piece of it. This guide explains the difference, what each has and has not been tested for, the ways they are given, and what your first visit would involve. The research is listed at the end with links so you can read it yourself.

**43 Amino acids in thymosin beta-4.** The natural protein is small, found in almost every cell, and is the main molecule cells use to hold actin, the building block of their internal scaffolding, in reserve. <sup>2</sup>

**7 Amino acids in the TB-500 fragment.** Analysis of TB-500 identified Ac-LKKTETQ, a copy of positions 17 to 23 of thymosin beta-4 with a small chemical cap added to one end. <sup>3</sup>

**40 Healthy volunteers in the first safety trial.** Intravenous thymosin beta-4, given daily for 14 days at doses up to 1,260 mg, caused no dose limiting side effects and no serious adverse events. <sup>4</sup>

**6 of 10 Eyes fully healed at four weeks.** In a small trial of thymosin beta-4 eye drops for a hard to heal corneal condition, 6 of 10 treated patients healed completely, compared with 1 of 8 on placebo. <sup>5</sup>

## What TB-500 is

Thymosin beta-4, often written Tβ4, is a naturally occurring protein of 43 amino acids. It is present in nearly all cells and body fluids, and its best understood job is to bind actin, the protein that lets cells change shape and move.<sup>2</sup> After an injury it is released by platelets, by immune cells called macrophages and by many other cell types, which is one reason researchers began to study it as a repair signal.<sup>1</sup>

Researchers found that different short stretches of the protein carry different activities. A stretch of seven amino acids in the middle, positions 17 to 23 and spelled LKKTETQ, is the part that binds actin, and in laboratory work it promotes cell migration, new blood vessel growth and wound healing.<sup>2</sup> TB-500 emerged as a veterinary preparation, and when analytical chemists examined it, its key ingredient was a synthetic copy of that stretch with an acetyl group added to the front, written Ac-LKKTETQ.<sup>3 6</sup>

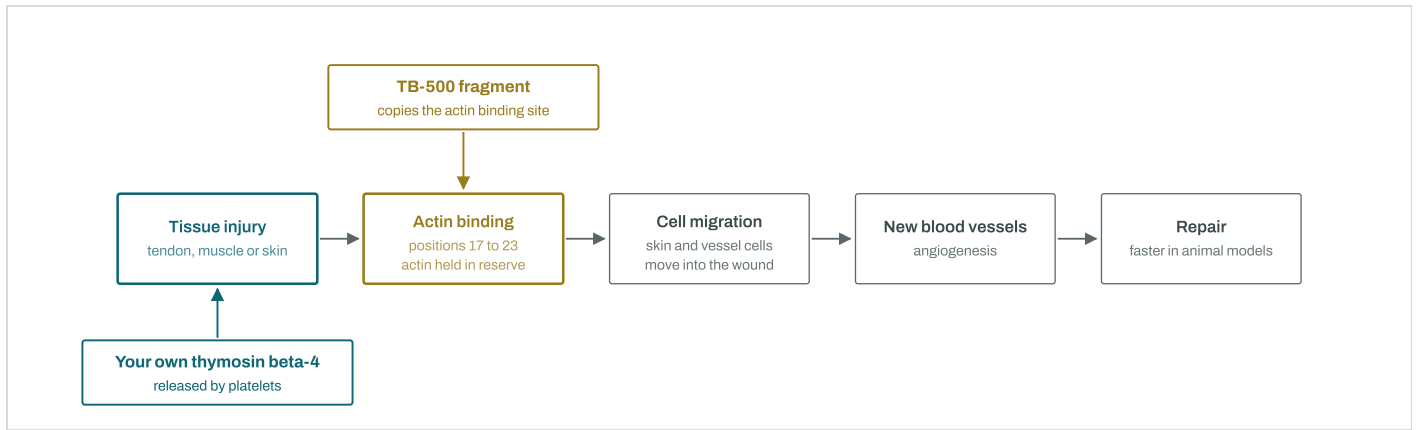
This distinction matters. When you read that “TB-500 was studied in patients”, the study almost always used the full protein. A 2024 laboratory study of the fragment itself noted that its biological effects had not been documented, and found that it is broken into smaller pieces in human serum and in rats, one of which showed the wound healing activity in cell culture.<sup>7</sup>

| TWO RELATED MOLECULES They share a name in marketing, but they are not the same thing. |                                                                                              |                                                            |
|----------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------|------------------------------------------------------------|
|                                                                                        | THYMOSIN BETA-4                                                                              | TB-500 (AS USUALLY SOLD)                                   |
| Also called                                                                            | Tβ4; timbetasin (in eye drop trials, as RGN-259) <sup>5</sup>                                | Thymosin beta-4 fragment; Ac-LKKTETQ <sup>3</sup>          |
| Structure                                                                              | 43 amino acids <sup>2</sup>                                                                  | 7 amino acids, positions 17 to 23, acetylated <sup>3</sup> |
| Origin                                                                                 | Made naturally by the body; synthetic and recombinant versions used in trials <sup>4 8</sup> | Synthetic only                                             |
| Class                                                                                  | Actin binding regenerative protein <sup>1</sup>                                              | Peptide fragment of that protein                           |
| Studied in people                                                                      | Yes: intravenous, topical gel and eye drop trials <sup>4 5 9</sup>                           | No published human trials <sup>7 10</sup>                  |
| How it is given                                                                        | Intravenous, on the skin, in the eye (research settings)                                     | Injection under the skin, prepared on prescription         |

## How TB-500 works

To move, a cell has to take its internal scaffolding apart at the back and build it again at the front. Thymosin beta-4 holds single actin units in reserve so the cell can draw on them,<sup>2</sup> and in laboratory and animal studies this translates into faster movement of the cells that close a wound: skin cells, the cells that line blood vessels, and the cells that lay down collagen.<sup>1</sup> Thymosin beta-4 made endothelial cells migrate toward it four to six times more than control medium, and it promoted new blood vessel growth.<sup>11</sup>

The actin binding stretch is the key to the part of this story that concerns TB-500. In laboratory tests of blood vessel sprouting and cell migration, the seven amino acid actin binding motif performed almost identically to the full protein, while pieces lacking that motif were inactive.<sup>12</sup>



**TB-500 copies the part of thymosin beta-4 that binds actin.** In laboratory tests this seven amino acid region matched the full protein for cell migration and blood vessel sprouting.<sup>12</sup> Whether an injected fragment does the same in people has not yet been studied.<sup>10</sup>

Thymosin beta-4 also calms inflammation. In human corneal cells exposed to an inflammatory signal, it reduced activation of NFκB, a central switch for inflammatory genes.<sup>13</sup> Of the regions identified so far, the one most clearly tied to calming inflammation is a four amino acid piece at the front end called Ac-SDKP, which the TB-500 fragment does not contain.<sup>2</sup>

In animals, these effects add up to faster healing. In rats with full thickness skin wounds, thymosin beta-4 increased the rate at which new skin covered the wound by 42 percent at four days and by as much as 61 percent at seven days, compared with saline.<sup>14</sup> In aged mice, the synthetic seven amino acid fragment promoted wound repair to a degree comparable with the full protein.<sup>15</sup> In a 2026 rat study of repaired Achilles tendons, TB-500 was associated with stronger tendons at four weeks and better organized tissue under the microscope.<sup>16</sup>

#### WHY THIS IS USEFUL TO KNOW

The fragment carries the actin binding part of the protein, which is the part most closely tied to cell movement and new blood vessel growth in the laboratory.<sup>12</sup> It does not carry Ac-SDKP, the region most clearly tied to calming inflammation.<sup>2</sup> That is why we do not assume every result reported for thymosin beta-4 applies equally to TB-500, and why we describe the two separately throughout this guide.

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## What the research shows

Thymosin beta-4 has a longer research history than most peptides patients ask about, including controlled trials in people. The important caveat is that every one of those trials used the full protein. Here is where things stand.

### What is well established

Full length thymosin beta-4 has been given to healthy people intravenously and was well tolerated. In the first randomized trial, 40 volunteers received placebo or doses from 42 to 1,260 mg, first as a single dose and then daily for 14 days. Side effects were infrequent and mild or moderate, with no dose limiting toxicity and no serious adverse events.<sup>4</sup> A separate trial of a recombinant version in 84 healthy volunteers reached the same conclusion, with no build up in the blood after 10 daily doses.<sup>8</sup>

Thymosin beta-4 applied to the skin has been tested in chronic wounds. In two phase 2 trials, in venous stasis ulcers and in pressure ulcers, patients whose wounds healed did so almost a month sooner with thymosin beta-4.<sup>9</sup> Phase 2 work in epidermolysis bullosa, a rare inherited blistering condition, also pointed to faster repair.<sup>17</sup>

Thymosin beta-4 eye drops (RGN-259) have been studied in several randomized trials. In 9 patients with severe dry eye, the drops reduced discomfort by 35.1 percent and corneal staining by 59.1 percent at day 56, compared with the inactive drops.<sup>18</sup> In a trial of 72 people with dry eye, the two main measures did not differ from placebo, although some secondary measures improved, including a 27 percent reduction in discomfort during a controlled dry air challenge.<sup>19</sup> In the phase 3 SEER-1 trial in neurotrophic keratopathy, 6 of 10 treated patients healed completely at four weeks, compared with 1 of 8 on placebo.<sup>5</sup>

Heart research in animals drew wide attention. In mice, thymosin beta-4 improved cell survival and heart function after a heart attack, and in adult mouse heart tissue it activated dormant repair cells in the heart's outer layer.<sup>20 21</sup> In pigs, a single dose delivered into a heart vein reduced the size of the damaged area.<sup>22</sup> These are animal findings, and a later mouse study found that hearts developed and worked normally even without the gene for thymosin beta-4, a reminder that the biology is still being worked out.<sup>23</sup>

## What is still being defined

Almost everything that matters for a patient using TB-500. There are no published trials of the TB-500 fragment in people, and reviews written for orthopaedic and sports physicians in 2026 describe human data for musculoskeletal injuries as lacking, with the right dose, frequency and duration unknown.<sup>10 24</sup> The encouraging tendon and wound results for the fragment come from rats and mice.<sup>15 16</sup>

Even for the full protein, the picture is still forming. The eye trials have given mixed results. The 72 person dry eye trial missed its main measures,<sup>19</sup> and an independent Cochrane review rated the evidence from SEER-1, a trial of 18 people, as low certainty.<sup>25</sup> The developer's ARISE-3 dry eye trial enrolled 700 patients, and its public summary highlighted secondary and pooled measures such as ocular grittiness; to our knowledge those phase 3 results have not been published in full in a peer reviewed journal.<sup>27</sup> No thymosin beta-4 product has yet been approved in the United States.

| <b>KEY HUMAN STUDIES</b> All used the full thymosin beta-4 protein, not the TB-500 fragment. |          |                                                          |                                                                              |
|----------------------------------------------------------------------------------------------|----------|----------------------------------------------------------|------------------------------------------------------------------------------|
| STUDY                                                                                        | N        | DESIGN                                                   | FINDING                                                                      |
| Ruff 2010 <sup>4</sup>                                                                       | 40       | Phase 1, randomized, intravenous, healthy volunteers     | Well tolerated up to 1,260 mg daily for 14 days; no serious adverse events   |
| Wang 2021 <sup>8</sup>                                                                       | 84       | Phase 1, randomized, intravenous recombinant protein     | No dose limiting toxicity; no accumulation after 10 days                     |
| Treadwell 2012 <sup>9</sup>                                                                  | 2 trials | Phase 2, topical, venous and pressure ulcers             | Ulcers that healed did so almost a month sooner                              |
| Sosne 2015 <sup>18</sup>                                                                     | 9        | Phase 2, randomized, eye drops, severe dry eye           | 35.1 percent less discomfort, 59.1 percent less staining at day 56           |
| Sosne 2015 <sup>19</sup>                                                                     | 72       | Phase 2, randomized, eye drops, dry eye                  | Main measures unchanged; some secondary measures improved; no adverse events |
| SEER-1, 2022 <sup>5</sup>                                                                    | 18       | Phase 3, randomized, eye drops, neurotrophic keratopathy | Complete healing in 6 of 10 versus 1 of 8; no significant adverse effects    |
| TB-500 fragment <sup>10</sup>                                                                | 0        | No published human trials                                | Evidence limited to laboratory and animal studies                            |

## HOW WE WOULD SUMMARIZE IT

Thymosin beta-4 is a well characterized repair protein with sound biology, a reassuring early safety record in people, and encouraging results in wound and eye trials. TB-500 carries the part of that protein most closely tied to cell movement and blood vessel growth, and it looks promising in animals, but it has not yet been tested in people. If we recommend it, we will be clear that we are reasoning from the protein and from animal work, and we will set expectations accordingly.

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## How TB-500 is given

Thymosin beta-4 and its fragment have been given in several ways. The routes studied in people are different from the route usually used in clinics, and that is worth understanding before you start.

### Injection under the skin

This is how TB-500 is usually prescribed: a small injection into the fatty tissue of the abdomen or thigh, using a fine needle similar to the ones used for insulin. It is also the route with the least published human research. No clinical trial has tested TB-500 or thymosin beta-4 given under the skin, and no regulator has set a dose, so the dose and schedule are set by your physician.<sup>10</sup> What is known about the fragment in the body comes from laboratory and animal work: it is cut into smaller pieces, and one of those pieces could still be found in rat urine 72 hours later.<sup>7</sup> As with any injection, some redness or tenderness where the needle went in is possible.

### Intramuscular injection

Some people ask about injecting close to an injured muscle or tendon. There are no published human studies of thymosin beta-4 or TB-500 given into muscle, and the animal tendon study used injections into the abdominal cavity rather than into the tendon itself.<sup>16</sup> We therefore have no evidence that injecting near an injury works better than injecting under the skin.

### Intravenous infusion

The full thymosin beta-4 protein has been given by vein in healthy volunteers at 42 to 1,260 mg daily for 14 days, in research developing it for heart attack treatment.<sup>4</sup> A recombinant version was given by vein at 0.05 to 25 micrograms per kilogram.<sup>8</sup> These were safety studies in a research setting. They did not test a benefit, and they did not use the TB-500 fragment.

### On the skin and in the eye

Thymosin beta-4 has been applied directly to chronic wounds as a topical preparation in phase 2 ulcer trials.<sup>9</sup> As an eye drop, a 0.1 percent solution was used six times a day for 28 days in severe dry eye, and five times a day in neurotrophic keratopathy.<sup>5 18</sup> These preparations were made for trials and are not available as approved products.

### By mouth or nasal spray

There are no published human studies of TB-500 or thymosin beta-4 taken by mouth or as a nasal spray. Because the fragment is broken down even in blood serum,<sup>7</sup> we would not expect it to survive digestion well, and we do not recommend these forms.

| COMPARING THE OPTIONS    |                                  |                               |                                                   |                                                            |                                                   |
|--------------------------|----------------------------------|-------------------------------|---------------------------------------------------|------------------------------------------------------------|---------------------------------------------------|
|                          | UNDER THE SKIN                   | INTO MUSCLE                   | INTRAVENOUS                                       | SKIN OR EYE                                                | ORAL OR NASAL                                     |
| <b>Molecule used</b>     | TB-500 fragment, on prescription | TB-500 fragment               | Full thymosin beta-4 <sup>4</sup>                 | Full thymosin beta-4 <sup>5 9</sup>                        | Various                                           |
| <b>Human research</b>    | NONE PUBLISHED                   | NONE PUBLISHED                | PHASE 1 SAFETY <sup>4 8</sup>                     | PHASE 2 AND 3 <sup>5 18</sup>                              | NONE PUBLISHED                                    |
| <b>Dose</b>              | Set by your physician            | Set by your physician         | 42 to 1,260 mg daily in trials <sup>4</sup>       | 0.1 percent drops, five or six times a day <sup>5 18</sup> | Not established                                   |
| <b>Common experience</b> | Possible tenderness at the site  | Possible soreness at the site | Infrequent, mild or moderate effects <sup>4</sup> | No significant adverse effects reported <sup>5</sup>       | Likely broken down before absorption <sup>7</sup> |

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## What to expect

Because TB-500 has not been studied in people, we cannot give you a timeline drawn from trials of the fragment, and we would be wary of anyone who offers one. The human studies of the full protein give some sense of scale: in the ulcer trials, wounds that healed did so almost a month sooner,<sup>9</sup> and in the corneal trial, healing was measured at four weeks.<sup>5</sup> Those are different conditions and a different molecule, so they are a guide to how repair is measured, not a promise about a tendon or muscle.

In practical terms, a visit usually involves learning to give the injection under the skin, or having it given in the clinic, and agreeing in advance what improvement you will be watching for, such as pain with a specific activity, range of movement, or return to a particular exercise. Healing tissue follows its own pace. Rest, loading and rehabilitation as advised by your physician or physical therapist remain the foundation, and any peptide is added to that plan rather than replacing it.

### BETWEEN VISITS

- Keep a short note of how the injured area feels during the activities you agreed to track.
- Tell us straight away about redness, warmth or swelling that spreads from an injection site, or any symptom that concerns you.

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## Safety

What is known about safety in people comes from the full protein, and it is reassuring. In the intravenous trial of 40 healthy volunteers, side effects were infrequent and mild or moderate at every dose up to 1,260 mg daily for 14 days, with no serious adverse events.<sup>4</sup> In the trial of a recombinant version in 84 volunteers, side effects were likewise mild to moderate, with no dose limiting toxicity.<sup>8</sup> In the eye trials, no adverse events were observed in 72 participants with dry eye, and no significant adverse effects were seen in neurotrophic keratopathy.<sup>5 19</sup> Reviewers describe thymosin beta-4 in the wound trials as safe and well tolerated.<sup>17</sup>

For the TB-500 fragment, rigorous human safety data are scarce, as a 2026 review of peptides in sports medicine makes clear.<sup>24</sup>

One question deserves a clear answer. Because thymosin beta-4 encourages cell movement and new blood vessel growth, researchers have asked whether it could help an existing tumor grow or spread. In a mouse study, melanoma cells engineered to make extra thymosin beta-4 formed larger tumors (21.7 mm against 13.3 mm) and more lung metastases (46.7 nodules against 10.9) than unaltered cells.<sup>26</sup> That concern is theoretical: the experiment was done in mice and changed the tumor cells themselves, rather than giving the peptide as a treatment. It is still the reason we ask about cancer history before starting.

**TELL YOUR PHYSICIAN BEFORE STARTING IF ANY OF THESE APPLY**

- You have a current or past cancer diagnosis, or you are under active surveillance.
- You are pregnant, trying to conceive, or breastfeeding.
- You compete in a sport that tests for banned substances (see §09).
- You have significant heart, kidney or liver disease, or an eye condition you are being treated for.
- You take any prescription medication, over the counter product or supplement. Please bring the full list.

Long term data do not yet exist. The human studies of the full protein followed people for weeks, not years, and there are no published human studies of repeated TB-500 injections at all.<sup>4 8 24</sup> That is one of the reasons we review how you are doing at set points rather than continuing indefinitely.

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## Is this right for you

TB-500 suits some patients and is not the right first step for others. The purpose of your consultation is to work out which group you are in.

### Before we begin

|                          |                                                                                                    |
|--------------------------|----------------------------------------------------------------------------------------------------|
| <input type="checkbox"/> | A review of your medical history, current medications and supplements                              |
| <input type="checkbox"/> | Relevant vital signs, and an examination of the area that is troubling you                         |
| <input type="checkbox"/> | Baseline bloodwork where your physician feels it is useful, so later results have a starting point |
| <input type="checkbox"/> | A clear written note of what you are hoping to improve, so we can tell together whether it worked  |

If an injury has not been properly diagnosed, that comes first. Imaging, a specific rehabilitation program, or referral to a specialist may be the right answer, and a clear diagnosis also tells us what improvement to look for if you do go on to use a peptide.

## Reviewing your progress

We will reassess against your documented starting point after a defined period rather than leaving treatment open ended. If you are improving, we will plan how long to continue. If you are not, we will say so and look at other options. You are welcome to stop at any time.

### QUESTIONS WORTH ASKING US

Is the evidence you are relying on from the full protein or from the fragment? What would you expect me to notice, and by when? How will we measure whether this is working? What would make you recommend stopping? We are glad to answer all of these, and a good clinic should welcome them.

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## Regulatory status, stated plainly

Neither TB-500 nor thymosin beta-4 is approved by the U.S. Food and Drug Administration for any indication, and there is no FDA approved product containing either one. When prescribed, TB-500 is prepared by a licensed compounding pharmacy on a physician's prescription. The FDA's review of its compounding status is ongoing. In April 2026 the FDA's list of bulk substances that may present significant safety risks in compounding, known as Category 2, no longer included the thymosin beta-4 fragment.<sup>28</sup> In July 2026 the FDA's Pharmacy Compounding Advisory Committee voted to recommend TB-500 for the list of substances pharmacies may compound, after FDA staff had recommended against it. That vote is advisory, and the FDA must still make its own decision.<sup>29</sup> Prescribing a compounded preparation is lawful and common in American medicine, and it is a decision your physician makes with you. It does mean no regulator has reviewed this preparation for your condition, and you should know that before you consent.

If you compete in sport, please tell us. The World Anti-Doping Agency lists “Thymosin-β4 and its derivatives e.g. TB-500” among prohibited growth factors, banned at all times, in and out of competition.<sup>30</sup> Laboratory methods to detect the fragment in blood and urine were published in 2012.<sup>3 6</sup>

If you would like details about the preparation used in your treatment, please ask.

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#### IMPORTANT NOTICE

This document is patient education prepared by Regen Therapy MD. It is not medical advice, not a prescription, and not a promise of any clinical outcome. **TB-500 and thymosin beta-4 are not approved by the U.S. Food and Drug Administration for any indication.** Statements in this document have not been evaluated by the FDA, and this therapy is not intended to diagnose, treat, cure or prevent any disease. Individual results vary, and no outcome can be predicted from the studies cited here.

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PATIENT SIGNATURE

DATE

REVIEWING PHYSICIAN

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