

PATIENT GUIDE

# Thymosin Alpha-1 *for immune support*

A clear look at what this thymic peptide does, how it is given, and what decades of human research support today.

| COMPOUND    | CLASS          | ROUTE          | RESEARCH          | SOURCES          |
|-------------|----------------|----------------|-------------------|------------------|
| Thymalfasin | Thymic peptide | Under the skin | Many human trials | 29 · PMID linked |

§ 01

## Why we are talking about thymosin alpha 1

Thymosin alpha 1 is a small peptide first isolated from the thymus, the gland where the immune system trains its T cells. Unlike most peptides discussed in longevity medicine, it has a long clinical history. A synthetic version, thymalfasin, has been studied in people for decades and is approved as a medicine in a number of countries outside the United States.<sup>2</sup> That gives us a larger body of human research to draw on than usual, including large randomized trials with both positive and neutral results.

This guide explains what it is, how it works, what the human trials have and have not shown, and where it stands with regulators. The research is listed at the end, with links so you can read it yourself.

**28 Amino acids long.** Thymosin alpha 1 was sequenced in 1977 as a heat stable peptide of 28 amino acids, one of several immune active peptides in a thymus extract called thymosin fraction 5.<sup>1</sup>

**35+ Countries with approval.** A 2009 review by the scientist whose team first isolated it reported that thymalfasin was approved in over 35 countries for hepatitis B and C and as an immune stimulant and adjuvant.<sup>2</sup>

**1,106 Adults in the largest trial.** A 2025 placebo controlled trial in adults with sepsis found no difference in 28 day survival, and side effects were no more common than with placebo.<sup>14</sup>

**1.6 mg The usual studied dose.** In published clinical studies the most common dose has been 1.6 mg given as a small injection under the skin, usually on a twice weekly schedule.<sup>25</sup>

# What thymosin alpha 1 is

In the 1960s and 1970s, researchers looking for the substances that let the thymus restore immune function prepared an extract of calf thymus called thymosin fraction 5. Allan Goldstein and colleagues isolated one of its active components and determined its full sequence: a highly acidic peptide of 28 amino acids that they named thymosin alpha 1.<sup>1</sup> It was originally identified as the component responsible for restoring immune function in mice whose thymus had been removed.<sup>3</sup>

The version used in medicine today is made by chemical synthesis rather than taken from animal tissue, and it is called thymalfasin. Its best known brand is Zadaxin.<sup>2 25</sup> Where it is approved, its uses have centered on chronic hepatitis B and C and on supporting the immune response to vaccines or during chemotherapy.<sup>25</sup> It is not approved in the United States, in Japan, or in Europe other than Italy.<sup>25</sup>

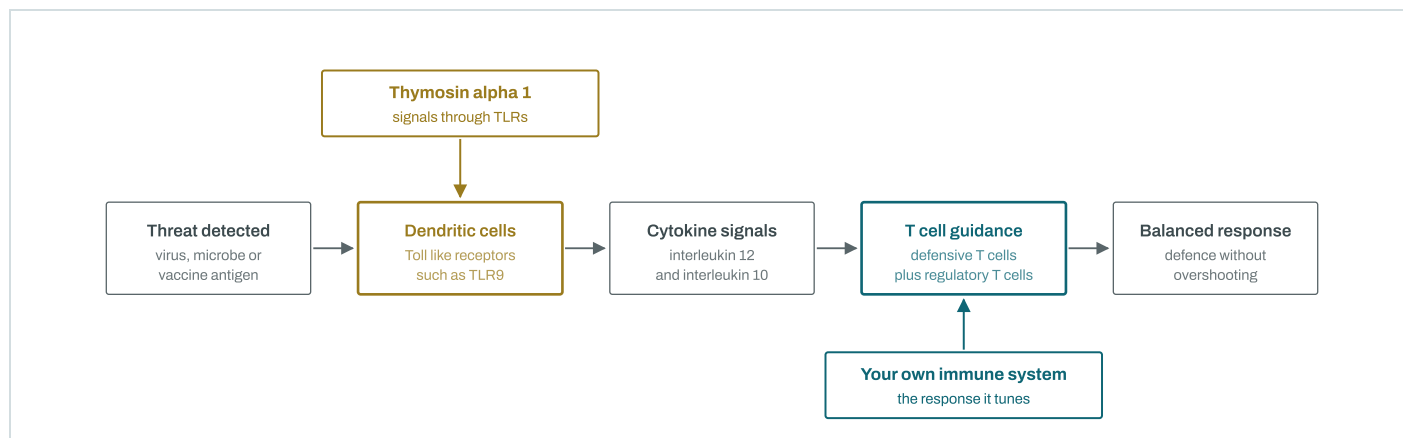
Despite the similar name, thymosin beta 4 and its fragment TB-500 are different molecules, covered in a separate guide.

| AT A GLANCE The basic facts about thymosin alpha 1. |                                                                                                      |
|-----------------------------------------------------|------------------------------------------------------------------------------------------------------|
| FEATURE                                             | DETAIL                                                                                               |
| Name                                                | Thymosin alpha 1                                                                                     |
| Also called                                         | Thymalfasin (the synthetic drug); Zadaxin (brand); often shortened to Tα1 in research papers         |
| Structure                                           | A chain of 28 amino acids; heat stable and highly acidic <sup>1</sup>                                |
| Origin                                              | First isolated from calf thymus (thymosin fraction 5) in 1977; now made synthetically <sup>1 2</sup> |
| Class                                               | Thymic peptide; immune modulator acting on dendritic cells and T cells <sup>3</sup>                  |
| How it is given                                     | Injection under the skin in nearly all clinical studies <sup>25</sup>                                |

# How thymosin alpha 1 works

Thymosin alpha 1 does not attack viruses or bacteria directly. Its effects run through the immune system itself, and in particular through dendritic cells, the sentinel cells that detect a threat and then teach T cells how to respond.

Dendritic cells carry sensors called Toll like receptors that recognize the signatures of microbes. Thymosin alpha 1 signals through these receptors, including TLR9, on both of the main dendritic cell types, which switches on internal signalling pathways and starts the production of immune messenger proteins called cytokines.<sup>3 25</sup> In laboratory and mouse studies, this led dendritic cells to mature and to release interleukin 12, a cytokine that pushes T cells toward the type of response used against viruses and fungi.<sup>4</sup>



**Thymosin alpha 1 acts on the cells that direct the immune response, not on the microbe itself.** It signals through Toll like receptors on dendritic cells, which then release cytokines that guide T cells toward both defence and regulation. These steps were mapped in laboratory and mouse studies. <sup>3 4 5</sup>

A second finding explains why researchers describe it as a regulator rather than a simple stimulant. In human and mouse dendritic cells studied in the laboratory, thymosin alpha 1 also switched on an enzyme called IDO, which led to production of interleukin 10 and to regulatory T cells, the cells that keep an immune response from overshooting. <sup>5</sup> The authors described the result as a balanced control of inflammation and tolerance. This dual action is the reason thymosin alpha 1 has been studied both in conditions where immunity is weak, such as chronic viral infection and older age, and in conditions where it is disordered, such as sepsis. <sup>3</sup>

#### WHY THIS IS USEFUL TO KNOW

Because thymosin alpha 1 adjusts your own immune response, its effects are measured in the immune system, such as T cell counts or antibody levels after a vaccine, rather than felt from day to day. The mechanism studies were done in cells and in mice; the human trials in §04 tell us whether that translates into benefit. <sup>4 5</sup>

#### § 04

## What the research shows

Thymosin alpha 1 has an unusually broad human research record for a peptide, with randomized trials in liver disease, sepsis, vaccination, cancer and COVID-19. The results are mixed in an informative way.

### What is well established

**It is well tolerated.** Across trials in very different patient groups, side effects have been mild and uncommon. In the largest trial, 1,089 adults with sepsis were analyzed, and adverse events occurred in 66.4 percent of those given thymosin alpha 1 and 67.6 percent of those given placebo, rates that reflect how ill these patients were rather than the treatment. <sup>14</sup> Studies in hepatitis, older adults and cancer reported similar findings. <sup>7 10 16 18</sup>

**It measurably changes immune markers in people.** In sepsis, it improved a marker of monocyte immune function called HLA-DR over the first week. <sup>13</sup> In older men given a flu vaccine, antibody levels at six weeks were higher with thymosin alpha 1 than with placebo, with the difference concentrated in men aged 77 and over. <sup>16</sup> In a pilot trial in people receiving dialysis, adding it to an adjuvanted pandemic flu vaccine improved antibody responses at 21 days.

<sup>17</sup>

**Hepatitis B is its most studied use.** In a randomized trial of 98 patients, a 26 week course cleared hepatitis B virus DNA and the e antigen in 40.6 percent of treated patients by 18 months, compared with 9.4 percent of untreated controls.<sup>7</sup> A meta analysis of five trials found the benefit was delayed: there was no difference at the end of treatment, but by 12 months afterward the odds of a virological response were 2.67 times higher.<sup>9</sup> Not every trial agreed. A United States phase 3 trial of 97 patients found a smaller difference that did not reach statistical significance.<sup>8</sup> Hepatitis B now has effective approved antiviral treatments,<sup>25</sup> so these trials matter today mainly as evidence of the peptide's immune effect.

## What is still being defined

**Sepsis.** A 2013 trial of 361 patients with severe sepsis reported 28 day mortality of 26.0 percent with thymosin alpha 1 and 35.0 percent without it, a difference that was borderline in statistical terms.<sup>13</sup> The same group then ran a much larger double blind trial in 1,106 adults across 22 centers. Mortality was 23.4 percent with thymosin alpha 1 and 24.1 percent with placebo, with no meaningful difference, and the authors concluded there was no clear evidence that it reduces deaths from sepsis.<sup>14</sup> A 2025 meta analysis found an apparent benefit across all trials but not when it was limited to the higher quality or multicenter trials, and suggested that any benefit may depend on the type of patient.<sup>15</sup>

**Cancer.** In a randomized trial of 488 people with metastatic melanoma, adding thymosin alpha 1 to chemotherapy increased tumor responses, and median survival was 9.4 months compared with 6.6 months, a difference that did not reach statistical significance.<sup>18</sup> A Cochrane review of thymic peptides found a trend toward longer survival with thymosin alpha 1 that was not statistically significant.<sup>19</sup> A 2022 lung cancer study found fewer cases of radiation lung inflammation and less severe loss of lymphocytes during chemoradiotherapy, compared with earlier matched patients rather than a randomized control group.<sup>20</sup> These findings are not conclusive, and thymosin alpha 1 is not a cancer treatment.

**Hepatitis C and COVID-19.** In hepatitis C, adding it to interferon therapy did not improve cure rates overall in a trial of 552 patients.<sup>12</sup> In COVID-19, an early hospital record review reported lower mortality with treatment,<sup>21</sup> but a meta analysis of nine studies found no overall effect on mortality,<sup>22</sup> and small randomized trials have been inconsistent.<sup>23</sup> Similarly, in a 690 patient trial in hepatitis B cirrhosis, adding it to antiviral treatment did not change rates of worsening liver disease, liver cancer or death.<sup>11</sup>

| KEY HUMAN STUDIES Randomized trials and meta analyses unless noted. |     |                                       |                                                                               |
|---------------------------------------------------------------------|-----|---------------------------------------|-------------------------------------------------------------------------------|
| STUDY                                                               | N   | DESIGN                                | FINDING                                                                       |
| Chien 1998 <sup>7</sup>                                             | 98  | RCT, chronic hepatitis B              | Viral clearance 40.6% vs 9.4% at 18 months <b>POSITIVE</b>                    |
| Mutchnick 1999 <sup>8</sup>                                         | 97  | Phase 3 RCT, hepatitis B, placebo     | 14% vs 4% complete response, not significant<br><b>NEUTRAL</b>                |
| Chan 2001 <sup>9</sup>                                              | 353 | Meta analysis, 5 hepatitis B trials   | Delayed benefit, odds ratio 2.67 at 12 months after treatment <b>POSITIVE</b> |
| Iino 2005 <sup>10</sup>                                             | 316 | RCT, 0.8 vs 1.6 mg, hepatitis B       | Similar responses at both doses; mild side effects                            |
| Ciancio 2012 <sup>12</sup>                                          | 552 | RCT, hepatitis C, added to interferon | Cure rate 12.7% vs 10.5%, not significant <b>NEUTRAL</b>                      |
| Wu 2013, ETASS <sup>13</sup>                                        | 361 | RCT, severe sepsis                    | Mortality 26.0% vs 35.0%, borderline <b>MIXED</b>                             |

| STUDY                          | N     | DESIGN                                      | FINDING                                                                        |
|--------------------------------|-------|---------------------------------------------|--------------------------------------------------------------------------------|
| Wu 2025, TESTS <sup>14</sup>   | 1,106 | Double blind RCT, sepsis                    | Mortality 23.4% vs 24.1%, no difference <b>NEUTRAL</b>                         |
| Gravenstein 1989 <sup>16</sup> | 90    | Double blind RCT, men 65 to 99, flu vaccine | Higher antibody response at 6 weeks, mainly age 77 and over <b>POSITIVE</b>    |
| Carraro 2012 <sup>17</sup>     | 99    | Pilot, dialysis patients, flu vaccine       | Better antibody response at day 21 <b>EARLY</b>                                |
| Maio 2010 <sup>18</sup>        | 488   | RCT, metastatic melanoma, with chemotherapy | More tumor responses; survival 9.4 vs 6.6 months, not significant <b>MIXED</b> |
| Wu 2018 <sup>11</sup>          | 690   | Open label RCT, hepatitis B cirrhosis       | No difference in liver events or death <b>NEUTRAL</b>                          |
| Shang 2023 <sup>22</sup>       | 5,352 | Meta analysis, 9 COVID-19 studies           | No overall effect on mortality <b>NEUTRAL</b>                                  |

#### HOW WE WOULD SUMMARIZE IT

Thymosin alpha 1 has decades of human use and a reassuring safety record. It shifts measurable immune markers in people, and the strongest clinical signals come from chronic hepatitis B and from vaccine responses in older or immunocompromised adults. The largest and most rigorous trial, in sepsis, did not show a survival benefit, and results in cancer and COVID-19 remain uncertain. We see it as a reasonable option for selected patients whose goal is immune support, offered with a clear account of where the evidence is strong and where it is still open.

#### § 05

## How thymosin alpha 1 is given

Almost all of the human research on thymosin alpha 1 used one route: a small injection under the skin. Other forms are sold, but they have not been studied in the same way.

### Injection under the skin

This is the route used in the hepatitis, vaccine, cancer and sepsis trials, and in the study of the approved product Zadaxin in healthy volunteers. <sup>6 25</sup> In a study of healthy volunteers, the peptide was well absorbed after injection, reached its highest blood level within one to two hours, and had a half life of under three hours. Blood levels after five daily doses were no higher than after one dose, meaning it does not build up in the body. <sup>6</sup>

The doses used in the published human studies were:

- **Chronic hepatitis B:** 1.6 mg twice a week for 26 or 52 weeks, <sup>7</sup> and 0.8 mg or 1.6 mg for 24 weeks, with similar results at both doses. <sup>10</sup>
- **Vaccine response in older men:** 900 micrograms per square meter of body surface twice a week for eight doses, given with the flu vaccine. <sup>16</sup>
- **Sepsis, in intensive care:** 1.6 mg every 12 hours for seven days. <sup>14</sup>
- **Melanoma, with chemotherapy:** 1.6 mg, 3.2 mg or 6.4 mg per dose in different study groups. <sup>18</sup>

No regulator in the United States has set a dose for thymosin alpha 1 for any purpose, including general immune support, so the dose and schedule are set by your physician in light of these studies and your own situation.

Intravenous use

At least one study in hospitalized patients in China has given thymosin alpha 1 through a vein.<sup>25</sup> It is not a route used for outpatient immune support.

Nasal sprays and oral forms

Thymosin alpha 1 is marketed online in the United States as a nasal spray as well as an injection.<sup>25</sup> We are not aware of any published clinical trial of a nasal or oral form, so there is no human data on how much of the peptide they deliver or whether they have any effect.

| COMPARING THE OPTIONS  |                                                                         |                                     |                   |
|------------------------|-------------------------------------------------------------------------|-------------------------------------|-------------------|
|                        | UNDER THE SKIN                                                          | INTRAVENOUS                         | NASAL OR ORAL     |
| How it is given        | Small injection, usually on a set weekly schedule                       | Through a vein, in hospital studies | Spray or by mouth |
| Doses in human studies | 0.8 to 6.4 mg per dose; 1.6 mg most common <sup>10 18 25</sup>          | Limited reports <sup>25</sup>       | None published    |
| Absorption known       | <div>YES</div> peak in 1 to 2 hours <sup>6</sup>                        | Direct to the blood                 | <div>NO</div>     |
| Human research         | Many randomized trials <sup>9 14</sup>                                  | Small studies in hospital           | Not yet studied   |
| Common experience      | Occasional redness or discomfort where the needle went in <sup>25</sup> | Not applicable to outpatient care   | Unknown           |

§ 06

What to expect

The injection itself is small and quick, and it is the same kind of injection under the skin used for many other medicines. The most commonly reported effects are local: some redness, irritation or discomfort at the injection site.<sup>25</sup> In the largest placebo controlled trial, side effects were no more common with thymosin alpha 1 than with placebo.<sup>14</sup>

It is helpful to set expectations about timing. Thymosin alpha 1 is not a medicine that produces a noticeable sensation or an immediate lift in energy. In the vaccine trial in older men, the difference in antibody levels was measured at six weeks.<sup>16</sup> In hepatitis B, the benefit was not visible at the end of treatment and only emerged in the months that followed, reaching its clearest point about a year after the last dose.<sup>7 9</sup> Immune changes tend to unfold slowly, so any assessment of whether it is helping you should be planned over weeks to months rather than days. If you give the injections yourself, ask us to show you the technique first, and tell us about any injection site reaction that spreads or persists.

## Safety

The safety record is one of the better documented parts of the thymosin alpha 1 story. In the 2025 sepsis trial, serious adverse events occurred in 26.8 percent of patients given thymosin alpha 1 and 29.3 percent given placebo, and no unexpected serious reactions related to the drug were found.<sup>14</sup> In the 316 patient hepatitis B dose trial, all drug reactions were mild; most were fluctuations in liver enzymes that the investigators attributed to the immune response against the virus.<sup>10</sup> The trial in older men observed no toxicity,<sup>16</sup> and adding it to chemotherapy for melanoma did not add side effects.<sup>18</sup>

The main questions concern people whose immune system is already overactive or deliberately suppressed. Product labels outside the United States include warnings for people with autoimmune disease, for those who are immunosuppressed, for pregnant and breastfeeding women, and for children, and FDA reviewers raised the possibility that an immune stimulant could interfere with stem cell transplant recovery.<sup>25</sup>

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

- You have an autoimmune condition, such as thyroid, joint, skin or bowel autoimmunity.
- You have had an organ or stem cell transplant, or you take medicine that suppresses the immune system.
- You have hepatitis B or C or other liver disease, since liver enzymes can fluctuate during treatment.<sup>10</sup>
- You have a current or past cancer diagnosis, or you are receiving cancer treatment.
- You are pregnant, trying to conceive, or breastfeeding.
- You take any prescription medication, over the counter product or supplement. Please bring the full list.

The longest courses in published trials lasted about a year.<sup>7</sup> Data on use over many years in healthy people does not exist, and FDA reviewers found no published studies of long term cancer risk in animals.<sup>25</sup> That is one reason we prefer defined courses with review points.

## Is this right for you

Thymosin alpha 1 suits some patients well and is not the right starting point for others. Your consultation is how we work out which group you are in.

### Before we begin

- ☐ A review of your medical history, current medications and supplements, including any autoimmune or liver conditions
- ☐ Relevant vital signs and a discussion of how often you get infections and how you recover from them
- ☐ Baseline bloodwork, so that anything we see later can be compared against a starting point
- ☐ A clear note of what you are hoping for, written down, so we can tell together whether it worked

Frequent infections or slow recovery can have specific, treatable causes, from gaps in routine vaccination to problems with sleep, blood sugar or nutrition. If your history or bloodwork points to one of those, we will address it first. Finding and correcting a cause is a better outcome for you than adding a new treatment on top of it.

## Reviewing your progress

We will reassess against your documented starting point after a defined period, timed with the slow pace of immune change in mind. If you are doing well, we will plan how to continue or when to stop. 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

What would you expect this to change for me, and how will we measure it? How long should a course last before we review it? Does anything in my history make it a poor fit? What would make you recommend stopping? We are glad to answer all of these, and a good clinic should welcome them.

§ 09

## Regulatory status, stated plainly

Thymosin alpha 1 is not approved by the U.S. Food and Drug Administration for any indication, and there is no FDA approved product containing it.<sup>25</sup> Outside the United States, thymalfasin (brand name Zadaxin) is approved in a number of countries, mainly in Asia, Latin America, Eastern Europe and the Middle East, as well as Italy, for uses that include hepatitis B and C and as an adjuvant to vaccines or chemotherapy. It is not approved in Japan or in the rest of Europe.<sup>25</sup> In the United States, the FDA has granted thymalfasin orphan drug designation, which supports research in rare conditions, for DiGeorge anomaly with immune defects and for hepatocellular carcinoma; designation is not approval.<sup>28</sup>

In the United States, thymosin alpha 1 is prepared by a licensed compounding pharmacy on a physician's prescription. An FDA advisory committee reviewed it in December 2024 and voted 17 to 4 against adding it to the list of substances that pharmacies may use for compounding.<sup>26</sup> In April 2026, thymosin alpha 1 was withdrawn from the FDA's Category 2 list of compounding substances flagged for possible safety risks.<sup>27</sup> It is not on the FDA's 503A bulks list, and the FDA's review of its compounding status is ongoing. Prescribing it is a decision your physician makes with you, and it means no regulator has reviewed this preparation for your use.

For athletes, thymosin alpha 1 is not named on the 2026 World Anti-Doping Agency Prohibited List. Thymosin beta 4 and TB-500, which are different molecules, are prohibited.<sup>29</sup> If you compete in a tested sport, confirm with your anti doping organization before starting any peptide.

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. **Thymosin alpha 1 is not approved by the U.S. Food and Drug Administration for any indication; the synthetic form, thymalfasin (Zadaxin), is approved in a number of other countries for uses that include hepatitis B.** 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

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DATE

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REVIEWING PHYSICIAN

RTMD-WP-021 · Version 1.0 · 26 September 2026 · Next scheduled literature review: March 2027 · Prepared with sources indexed in PubMed and FDA public records.