CLINICAL MONOGRAPH · METABOLIC & LONGEVITY (UNDER FDA REVIEW)

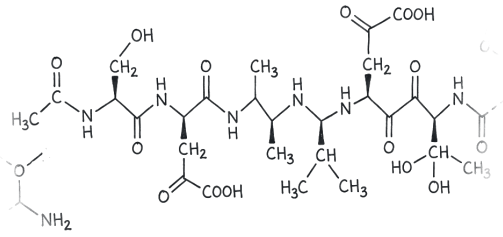
Thymosin Alpha-1 / Thymalin

International thymic peptide with US pharmacy review required

Thymosin alpha-1 (often called Tα1, or by its generic drug name thymalfasin and brand name Zadaxin) is a small immune-modulating peptide. It was first isolated in the 1970s from bovine thymus glands by Allan Goldstein's lab and is now made by chemical synthesis [goldstein1972]. The thymus is the organ where T-cells mature; Tα1 helps push immature T-cells toward functional maturity and tunes innate-immune signaling.

Outside the United States, Tα1 is sold under the brand name Zadaxin (by SciClone Pharmaceuticals) and is approved in roughly 30 countries, including Italy and China, for chronic hepatitis B, chronic hepatitis C, and as an adjunct to vaccines in patients with weakened immune systems. It has also been studied in severe sepsis and (during 2020) in patients hospitalized with COVID-19 in China [wu2013_etass].

thymosin alpha-1 is not FDA-approved for any US indication. 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.



EVIDENCE POSTURE EMERGING WELL STUDIED REVIEWED **2026-05-11**

State-licensed 503A | Pharmacist reviewed | Doctor led | Cold-chain ready | Patient choice preserved

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FOR CLINICIANS

Thymosin alpha-1 (Tα1, thymalfasin) is a 28-amino-acid N-acetylated peptide originally purified from bovine thymus by Goldstein and colleagues [goldstein1972, low1979, garaci2007] and now produced by solid-phase synthesis. Mechanistically Tα1 modulates both innate and adaptive immunity: dendritic-cell activation through Toll-like receptor signaling [romani2004_dc_tlr], dendritic-cell tryptophan catabolism establishing a regulatory cytokine milieu [romani2006_dc_ido], and pleiotropic effects on T-cell maturation, NK function, and intracellular proteostasis [romani2007_review, stincardini2018_proteostasis]. Practice-facing reviews characterize Tα1 as an endogenous immunoregulator with a favorable tolerability profile across decades of clinical use abroad [king2016_review, ancell2001] [zhang2022_ace2].

Internationally, thymalfasin is marketed by SciClone Pharmaceuticals as Zadaxin and has approvals in approximately 30 countries (including Italy and China) for chronic hepatitis B, chronic hepatitis C, and as a vaccine adjuvant in immunocompromised populations [camerini2015_history, ciancio2010]. Randomized evidence supports activity in chronic hepatitis B as monotherapy [andreone1996, mutchnick1999] and in combination with nucleos(t)ide analogs [zhang2009_lam_combo], with meta-analytic support for sustained virologic response advantage over interferon alfa [yang2008_hbv_meta]. In chronic hepatitis C the evidence base spans monotherapy and combination regimens with pegylated interferon and ribavirin [andreone2004_hcv, poo2008_triple, ciancio2012_hcv]. In severe sepsis the multicenter ETASS RCT [wu2013_etass] reported a 28-day mortality reduction with Tα1 versus standard care, and subsequent systematic reviews and meta-analyses have been broadly supportive [wang2016_ulinastatin_meta, liu2016_sepsis_meta, gu2025_sepsis_meta]. Oncology evidence includes a large randomized trial in metastatic melanoma in combination with dacarbazine [maio2010_melanoma], a preclinical mechanism for NSCLC myeloid-derived suppressor-cell suppression [yang2020_nsclc_mdsc], and a multicenter Chinese protocol for HBV-related hepatocellular carcinoma after curative resection [qiu2015_hcc_protocol].

COVID-19 evidence is dominated by Chinese retrospective and prospective cohort and quasi-randomized data published from mid-2020 onward. The Liu et al. (2020) Clinical Infectious Diseases analysis reported restoration of lymphocyte counts and reduction in 28-day mortality in critically ill COVID-19 patients with low CD8+ counts; the signal is encouraging but the evidence base is mostly retrospective and not generalizable to current SARS-CoV-2 variants or contemporaneous standard-of-care [liu2020_covid; sun2021_covid_mortality].

thymosin alpha-1 is not FDA-approved for any US indication. 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 Thymosin Alpha-1 / Thymalin

The evidence base for thymosin alpha-1 is broader than many Category 2 peptides because Zadaxin and related thymalfasin products have been studied and used abroad. That international record does not create an FDA-approved US product or automatic 503A availability.

Physicians may submit patient-specific prescription requests for thymosin alpha-1 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. This ingredient is part of an evolving FDA review process for peptide-related bulk substances used in compounding.

The regulated US route is not a wellness-clinic immune peptide protocol. A prescriber may submit a patient-specific request, and RonanRx reviews the clinical rationale, product identity, source documentation, and regulatory posture before any dispensing decision.

Quick Facts About Thymosin Alpha-1 / Thymalin

Category: Immunomodulatory thymic peptide (28-amino-acid acetylated peptide)

Active ingredient: Thymosin alpha-1 (thymalfasin), a 28-amino-acid N-acetylated peptide originally isolated from bovine thymus by Goldstein and colleagues in the 1970s and subsequently produced by chemical synthesis

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

International approval: Approved as Zadaxin (thymalfasin) by SciClone Pharmaceuticals in approximately 30 countries (including Italy and China) for chronic hepatitis B, chronic hepatitis C, and as an adjunct to influenza or hepatitis B vaccination in immunocompromised patients. Approval status varies by jurisdiction.

Route: Subcutaneous injection in published clinical trials, typically twice weekly at 1.6 mg per dose

Evidence posture: Multiple randomized controlled trials and meta-analyses in chronic hepatitis B, chronic hepatitis C, and severe sepsis support a well-studied evidence base in the indications where Zadaxin is approved abroad. In the United States the substance has no FDA-approved use and is classified as emerging.

Compounded under: Physicians may submit patient-specific prescription requests for pharmacy review. Availability is determined case by case.

RonanRx position: RonanRx does NOT source, compound, or dispense thymosin alpha-1. This monograph documents the international evidence base and US regulatory status for awareness only. RonanRx will reconsider compounding only if and when FDA reclassifies thymosin alpha-1 to Category 1.

SPECIALS: PATIENT-SPECIFIC PRESCRIPTION ONLY

Physicians may submit patient-specific prescription requests for Thymosin Alpha-1 / Thymalin 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 Thymosin Alpha-1 / Thymalin?

Thymosin alpha-1 (Tα1) is a 28-amino-acid N-acetylated peptide with the sequence Ac-SDAAVDTSSEITTKDLKEKKEVVEEAEN. It is the most-studied member of the thymosin alpha family, a group of immunoregulatory peptides originally isolated by Goldstein and colleagues from bovine thymus extracts in the 1970s [goldstein1972, low1979, garaci2007]. The endogenous peptide is cleaved from the precursor prothymosin alpha and is detectable in human thymic epithelial cells and serum.

The synthetic generic name is thymalfasin. The substance is manufactured by solid-phase peptide synthesis and marketed internationally as Zadaxin by SciClone Pharmaceuticals (originally a US biotechnology company; SciClone's US commercial focus is on China and other markets where Zadaxin has regulatory

approval). Zadaxin is supplied as a sterile lyophilized powder reconstituted with sterile water for injection prior to subcutaneous administration; the labeled dose in approved territories is 1.6 mg twice weekly [ancell2001, camerini2015_history].

In the United States, thymosin alpha-1 has no FDA-approved product. The FDA Pharmacy Compounding Advisory Committee reviewed the substance for the 503A bulk-drug-substances list and placed it in Category 2 (insufficient information to evaluate for use in compounding) [fda_503a_bulk_substances, fda_pcac]. RonanRx therefore does not source, compound, or dispense the substance.

How Thymosin Alpha-1 / Thymalin Works

Thymosin alpha-1 acts as an immunoregulator that modulates both innate and adaptive immunity [king2016_review]. The dominant mechanistic theme established across two decades of mechanistic work is dendritic-cell activation: Tα1 signals through Toll-like receptors (principally TLR-2 and TLR-9) on plasmacytoid and conventional dendritic cells, triggering MyD88-dependent maturation and a Th1-skewed cytokine response [romani2004_dc_tlr]. Subsequent work by the Romani group showed that Tα1 also engages indoleamine 2,3-dioxygenase (IDO)-mediated tryptophan catabolism in dendritic cells, producing a tolerogenic regulatory environment that balances inflammation [romani2006_dc_ido, romani2007_review].

Downstream effects include enhanced T-cell maturation from CD4−/CD8− thymocyte precursors, augmented natural killer cell cytotoxicity, increased IL-2 receptor expression on T-cells, and partial restoration of suppressed lymphocyte counts and function in immunosuppressed states [king2016_review]. The 2018 Stincardini review extended the model with a role in cellular proteostasis [stincardini2018_proteostasis]. Net clinical consequences span antiviral effects (chronic hepatitis B and C), restoration of T-cell function in critically ill patients with severe sepsis, and adjunct activity in cancer immunotherapy and vaccine response.

Detailed Mechanism of Thymosin Alpha-1 / Thymalin

The molecular mechanism of thymosin alpha-1 begins at the dendritic cell. The seminal Romani et al. 2004 Blood paper [romani2004_dc_tlr] used MyD88-knockout mice and TLR-specific blockade to demonstrate that Tα1 signaling in dendritic cells is TLR-dependent, with the strongest signal through TLR-9 in plasmacytoid DCs and TLR-2 in conventional DCs. Engagement drives a Th1 cytokine profile (IL-12, IFN-γ) and antifungal resistance in murine models of invasive aspergillosis. The Romani 2006 Blood follow-up [romani2006_dc_ido] characterized a parallel effect: Tα1 induces IDO-mediated tryptophan catabolism in dendritic cells, producing kynurenines that establish a tolerogenic regulatory environment. This dual capacity, proinflammatory Th1 priming and concurrent IDO-driven regulatory balance, underlies the

description of Tα1 as an 'endogenous regulator of inflammation, immunity, and tolerance' [romani2007_review].

Downstream on T-cells, Tα1 promotes maturation of CD4−/CD8− thymocyte precursors toward functional CD4+ and CD8+ phenotypes, upregulates CD3 and CD25 (IL-2 receptor alpha) expression, and increases IL-2 and IFN-γ production in stimulated lymphocytes. In severely immunocompromised states, including critical illness with lymphocytopenia, post-chemotherapy myelosuppression, and chronic viral infection, Tα1 partially restores absolute lymphocyte counts and reverses markers of T-cell exhaustion such as PD-1 and Tim-3 expression [liu2020_covid]. On natural killer cells, Tα1 augments cytotoxicity and IFN-γ production; on macrophages and monocytes, it enhances chemotaxis and antimicrobial function.

Cellular proteostasis work extends the mechanism beyond classical immunology. Stincardini et al. (2018) characterized Tα1 as a regulator of autophagy and the unfolded protein response, with implications for chronic inflammatory and infectious-disease pathways [stincardini2018_proteostasis]. In the SARS-CoV-2 setting, mechanistic work has examined Tα1 binding to angiotensin-converting enzyme and downregulation of ACE2 expression in respiratory epithelial cells [zhang2022_ace2], proposing a direct antiviral entry-modulation mechanism complementary to the immunomodulatory effect. In oncology contexts, Tα1 has been shown to suppress myeloid-derived suppressor-cell accumulation in NSCLC models via VEGF inhibition [yang2020_nsclc_mdsc], offering a tumor-microenvironment rationale for the adjuvant signals reported in cancer trials.

Thymosin Alpha-1 / Thymalin Research History

The thymic peptide research program that produced thymosin alpha-1 began with Allan Goldstein's group at the Albert Einstein College of Medicine in the late 1960s. The 1972 PNAS paper by Goldstein, Guha, Zatz, and Hardy [goldstein1972] reported purification and biological activity of 'thymosin', a partially purified bovine thymus extract that restored T-cell function in neonatally thymectomized mice. Subsequent fractionation work by Low, Thurman, and colleagues at George Washington University [low1979] resolved the partially purified extract into Fractions 5 and 5a containing multiple peptides, of which thymosin alpha-1 was the most active in T-cell maturation assays. The amino-acid sequence was determined in 1977 and chemical synthesis followed shortly thereafter, enabling the transition from bovine-derived to synthetic material [garaci2007].

Clinical development through the 1980s and 1990s focused on chronic hepatitis B. The Andreone et al. 1996 Hepatology trial [andreone1996] randomized HBeAg-positive chronic hepatitis B patients to thymosin alpha-1 versus interferon alfa and reported comparable rates of HBV DNA clearance with substantially better tolerability for Tα1. The Mutchnick et al. 1999 multicenter phase III placebo-controlled trial [mutchnick1999] reported a sustained virologic response advantage. Subsequent combination regimens with lamivudine [zhang2009_lam_combo] and meta-analytic synthesis [yang2008_hbv_meta] consolidated the chronic hepatitis B evidence base.

Chronic hepatitis C development used Tα1 as an adjunct to interferon and pegylated interferon. The Andreone et al. 2004 J Viral Hep RCT [andreone2004_hcv] tested Tα1 plus standard IFN in treatment-naive HCV patients. The Poo et al. 2008 triple-therapy trial [poo2008_triple] combined thymalfasin with peginterferon alfa-2a and ribavirin. The Ciancio et al. 2012 J Viral Hep trial [ciancio2012_hcv] extended the indication to peginterferon-ribavirin nonresponders.

Regulatory approvals as Zadaxin (thymalfasin) accumulated through the late 1990s and 2000s in approximately 30 countries, principally Italy, China, and other Asian and European jurisdictions where chronic hepatitis B remains a major public-health concern [camerini2015_history, ciancio2010]. SciClone Pharmaceuticals (the US-based commercial sponsor) did not pursue FDA approval; the US development program for chronic hepatitis B was discontinued after the Mutchnick trial.

The second major clinical-development arc is severe sepsis. The Wu et al. 2013 ETASS multicenter single-blind randomized trial [wu2013_etass] reported a 28-day mortality reduction with subcutaneous Tα1 (1.6 mg twice daily) versus standard care in adults with severe sepsis. Subsequent systematic reviews and meta-analyses [wang2016_ulinastatin_meta, liu2016_sepsis_meta, gu2025_sepsis_meta] have been broadly supportive of the mortality signal, with the 2025 Gu et al. meta-analysis integrating the larger published trial set.

Oncology evidence includes a large randomized phase 3 trial in metastatic melanoma comparing Tα1, interferon alfa, and the combination with dacarbazine [maio2010_melanoma], a preclinical mechanistic study in NSCLC [yang2020_nsclc_mdsc], the historical oncology synthesis by Garaci and colleagues [garaci2015_oncology], and a multicenter Chinese RCT protocol for HBV-related hepatocellular carcinoma after curative resection [qiu2015_hcc_protocol]. Vaccine-adjuvant work in influenza and hepatitis B vaccination of immunocompromised patients is summarized by Tuthill and Camerini [tuthill2012_vaccine].

COVID-19 evidence emerged in 2020 from Chinese hospitals. The Liu et al. 2020 Clinical Infectious Diseases report [liu2020_covid] described 28-day mortality reduction in critically ill COVID-19 patients with low baseline CD8+ T-cell counts. Multicenter retrospective and cohort data [sun2021_covid_mortality, matteucci2021_cytokine] reinforced the signal but did not produce a randomized phase 3 trial. The 2022 Zhang mechanism paper [zhang2022_ace2] proposed a direct antiviral entry-modulation mechanism via ACE/ACE2 downregulation.

Thymosin Alpha-1 / Thymalin Timeline

1972 • Goldstein and colleagues publish purification and biological activity of 'thymosin' from bovine thymus in PNAS, the foundation of the thymic peptide field [goldstein1972]

1977 • Amino-acid sequence of thymosin alpha-1 determined; chemical synthesis follows shortly thereafter, enabling synthetic (non-bovine) supply [garaci2007; low1979]

1979 • Low, Thurman, and colleagues publish thymosin family fractionation in Annals of the New York Academy of Sciences, establishes Tα1 as the most active component of bovine Fraction 5 [low1979]

1996 • Andreone et al [andreone1996]. (Hepatology), RCT of thymosin alpha-1 vs interferon alfa in HBeAg-positive chronic hepatitis B; comparable virologic response with better tolerability

1998 • Gramenzi et al [gramenzi1998_review]. (BioDrugs), early clinical pharmacology and antiviral applications review

1999 • Mutchnick et al [mutchnick1999]. (J Viral Hep), multicenter phase III placebo-controlled trial of thymosin alpha-1 in chronic hepatitis B

2001 • Ancell et al [ancell2001]. (Am J Health Syst Pharm) publish a clinician-facing thymosin alpha-1 review

2004 • Andreone et al. (J Viral Hep), Tα1 plus interferon alfa in treatment-naive chronic hepatitis C; Romani et al [andreone2004_hcv; romani2004_dc_tlr]. (Blood) characterize Tα1 dendritic-cell activation via Toll-like receptor signaling

2006 • Romani et al [romani2006_dc_ido]. (Blood), Tα1 activates dendritic-cell tryptophan catabolism, establishing a regulatory environment balancing inflammation and tolerance

2007 • Goldstein historical review and Garaci historical overview (Annals NYAS) consolidate the thymosin discovery arc; Romani et al [goldstein2007_history; garaci2007; romani2007_review]. publish the 'endogenous regulator' framework

2008 • Yang et al. (Antiviral Res) meta-analysis, Tα1 vs interferon alfa in chronic hepatitis B; Poo et al [yang2008_hbv_meta; poo2008_triple]. (Annals Hep) triple-therapy trial in HCV

2009 • Zhang et al [zhang2009_lam_combo]. (Virol J), lamivudine plus Tα1 for HBeAg-positive chronic hepatitis B

2010 • Maio et al. (J Clin Oncol), large randomized trial of thymosin alpha-1, interferon alfa, and the combination with dacarbazine in metastatic melanoma; Perruccio et al [maio2010_melanoma; perruccio2010_hsct; ciancio2010]. (NYAS), Tα1 for immune reconstitution after haploidentical HSCT; Ciancio and Rizzetto review thymalfasin in hepatitis B/C

2012 • Ciancio et al [ciancio2012_hcv]. (J Viral Hep), Tα1 plus peginterferon-ribavirin in HCV nonresponders; Tuthill et al [tuthill2012_vaccine]. (NYAS) summarize Tα1 as a vaccine-response enhancer

2013 • Wu et al [wu2013_etass]. publish the ETASS multicenter randomized controlled trial of thymosin alpha-1 for severe sepsis in Critical Care, 28-day mortality signal

2015 • Garaci, Pica, Matteucci, Gaziano publish historical oncology review; Camerini and Garaci publish historical infectious-diseases review; King and Tuthill publish preclinical evaluation in immune-suppressing indications [garaci2015_oncology; camerini2015_history; king2015_preclinical; qiu2015_hcc_protocol]

2016 • Wang et al [wang2016_ulinastatin_meta; liu2016_sepsis_meta]. (BMC Infect Dis) and Liu et al [king2016_review]. (BMC Infect Dis) publish systematic reviews and meta-analyses of Tα1 in sepsis; King and Tuthill publish 'Immune Modulation with Thymosin Alpha 1' review in Vitamins and Hormones

2018 • Stincardini et al [stincardini2018_proteostasis]. (Expert Opin Biol Ther), Tα1 and cellular proteostasis: a new mechanistic twist

2020 • Liu et al. (Clin Infect Dis) report Tα1 reduces mortality in critical COVID-19 patients with low baseline CD8+ counts; Yang et al [liu2020_covid; yang2020_nsclc_mdsc]. (Biomed Pharmacother) demonstrate Tα1 blocks MDSC accumulation in NSCLC by inhibiting VEGF

2021 • Sun et al. (Int Immunopharmacol), multicenter retrospective study of Tα1 effect on mortality in critical COVID-19; Matteucci et al [sun2021_covid_mortality; matteucci2021_cytokine]. (Open Forum Infect Dis), Tα1 mitigates cytokine storm in COVID-19 blood cells

2022 • Zhang et al [zhang2022_ace2]. (Front Biosci Landmark), Tα1 binds ACE and downregulates ACE2 expression in human respiratory epithelia

2023 • FDA Pharmacy Compounding Advisory Committee evaluation places thymosin alpha-1 in Category 2 on the 503A bulk-drug-substances list, substance ineligible for 503A patient-specific compounding pending further data; Quagliata et al [fda_503a_bulk_substances; fda_pcac; quagliata2023_patents]. publish patent landscape of thymosin peptides

2025 • Gu et al [gu2025_sepsis_meta]. (Front Cell Infect Microbiol) publish updated systematic review and meta-analysis of Tα1 efficacy in sepsis across the expanded RCT corpus

Clinical Contexts for Thymosin Alpha-1 / Thymalin

Chronic hepatitis B (in countries where Zadaxin is approved) WELL STUDIED

Well-studied indication outside the United States; Zadaxin is marketed in approximately 30 countries including Italy and China. Not an FDA-approved indication in the US.

Randomized controlled trials in HBeAg-positive chronic hepatitis B demonstrated virologic response rates with Tα1 monotherapy comparable to interferon alfa, with substantially better tolerability [andreone1996]. The Mutchnick et al. multicenter phase III placebo-controlled trial reported a sustained virologic response advantage [mutchnick1999]. Combination with lamivudine in HBeAg-positive patients reported improved HBeAg seroconversion and HBV DNA suppression [zhang2009_lam_combo]. The Yang et al. meta-analysis pooled efficacy across the Tα1-vs-IFN-alfa RCT corpus and reported a sustained response advantage for Tα1 [yang2008_hbv_meta]. Approval in international jurisdictions is supported by this evidence base [camerini2015_history, ciancio2010].

Chronic hepatitis C (combination with interferon-based regimens, in countries where Zadaxin is approved) WELL STUDIED

Studied in randomized trials in combination with interferon and pegylated interferon plus ribavirin. International approval in selected jurisdictions; not an FDA-approved indication.

Tα1 has been studied as an adjunct to standard-of-care interferon-based regimens. Andreone et al. randomized treatment-naive chronic HCV patients to Tα1 plus IFN-alfa vs IFN-alfa alone [andreone2004_hcv]. Poo et al. evaluated triple therapy (thymalfasin + peginterferon alfa-2a + ribavirin) in difficult-to-treat HCV [poo2008_triple]. Ciancio et al. extended the indication to peginterferon-ribavirin nonresponders [ciancio2012_hcv]. The 2010 Ciancio-Rizzetto review summarizes the hepatitis B and C evidence base [ciancio2010]. Note that the introduction of direct-acting antiviral regimens for HCV from 2013 onward has substantially superseded interferon-based regimens; Tα1's role in modern HCV management is limited.

Severe sepsis (adjunct to standard care, in countries where Zadaxin is approved or used off-label) WELL STUDIED

Studied in the multicenter ETASS RCT and multiple meta-analyses; mortality signal reproducible across pooled data. Not an FDA-approved indication.

The Wu et al. (2013) ETASS multicenter single-blind randomized trial randomized 361 adults with severe sepsis to subcutaneous thymosin alpha-1 (1.6 mg twice daily for 7 days) versus standard care; 28-day mortality was lower in the Tα1 arm [wu2013_etass]. Subsequent meta-analyses by Wang et al. [wang2016_ulinastatin_meta] (Tα1 plus ulinastatin), Liu et al. [liu2016_sepsis_meta] (Tα1 alone, BMC Infect Dis), and the updated Gu et al. 2025 systematic review and meta-analysis [gu2025_sepsis_meta] have been broadly supportive of the mortality signal, though heterogeneity in standard-care comparators and trial geography limits confidence in generalization to contemporary critical-care settings outside the source population.

Severe COVID-19 (during the early SARS-CoV-2 pandemic) EMERGING

Studied principally in Chinese retrospective and prospective cohort data published in 2020-2022; encouraging mortality signal in patients with low baseline CD8+ counts, but evidence is largely non-randomized and not generalizable to current variants or contemporaneous standard-of-care.

Liu et al. (Clin Infect Dis 2020) reported that thymosin alpha-1 restored lymphocyte counts and reduced 28-day mortality in critically ill COVID-19 patients, particularly those with low baseline CD8+ counts [liu2020_covid]. A multicenter retrospective analysis [sun2021_covid_mortality] reported a mortality reduction in a larger cohort of critically ill patients. In vitro work demonstrated Tα1 mitigation of cytokine storm in COVID-19 patient blood cells [matteucci2021_cytokine], and a 2022 mechanistic paper proposed Tα1 binding to ACE with downregulation of ACE2 expression in respiratory epithelia as a complementary antiviral entry mechanism [zhang2022_ace2]. The evidence is encouraging but the trial designs were largely retrospective, the standard-of-care comparators predate antiviral and immunomodulatory advances, and SARS-CoV-2 variants have evolved.

Metastatic melanoma (adjunct to dacarbazine, in international clinical research) WELL STUDIED

Studied in a large randomized phase 3 trial in combination with dacarbazine and interferon alfa.

The Maio et al. (J Clin Oncol 2010) phase 3 randomized trial enrolled 488 patients with metastatic melanoma to thymosin alpha-1 plus dacarbazine, interferon alfa plus dacarbazine, the triple combination, or dacarbazine alone [maio2010_melanoma]. Tα1-containing arms reported a numerical overall-survival advantage over dacarbazine monotherapy, though the trial did not change clinical practice and modern melanoma care is dominated by checkpoint inhibitors and targeted therapy. Preclinical models supporting the immune-modulation rationale are summarized by King and Tuthill [king2015_preclinical] and the historical oncology review by Garaci and colleagues [garaci2015_oncology].

HBV-related hepatocellular carcinoma (adjuvant after curative resection, in Chinese clinical research) EMERGING

Studied in a multicenter Chinese randomized protocol.

Qiu et al. (2015) published the protocol for a multicenter Chinese RCT evaluating thymalfasin adjuvant therapy after curative resection of HBV-related hepatocellular carcinoma [qiu2015_hcc_protocol]. The rationale combines the established Zadaxin antiviral role in chronic hepatitis B with the postoperative immune-modulation hypothesis for HCC recurrence prevention. Long-term outcomes from the trial are not yet integrated into international HCC guidelines.

Non-small cell lung cancer (preclinical and exploratory clinical research) EMERGING

Preclinical mechanistic evidence in tumor-microenvironment models; clinical evidence base is heterogeneous and not practice-changing.

Yang et al. (2020) demonstrated that Tα1 blocks myeloid-derived suppressor-cell accumulation in NSCLC murine models by inhibiting VEGF production [yang2020_nsclc_mdsc], offering a tumor-microenvironment rationale for the adjuvant-immunotherapy hypothesis. Clinical evidence is heterogeneous and does not support a defined role in NSCLC management outside of investigational protocols.

Vaccine adjuvant in immunocompromised patients (influenza and hepatitis B vaccination) EMERGING

Studied in small trials and reviews; rationale supported by mechanistic dendritic-cell biology. International use, not an FDA-approved indication.

Tuthill et al. (2012) summarize the evidence base for Tα1 as a vaccine-response enhancer, principally for influenza and hepatitis B vaccination in elderly and hemodialysis populations with blunted vaccine responses [tuthill2012_vaccine]. The Romani group's mechanistic dendritic-cell work [romani2004_dc_tlr, romani2007_review] provides a coherent rationale. Trial sizes are small and the evidence base has not produced a regulatory adjuvant designation in any jurisdiction.

Immune reconstitution after haploidentical hematopoietic stem cell transplantation EMERGING

Studied in single-center European cohort data.

Perruccio et al. (2010) reported that Tα1 administration after T-cell-depleted haploidentical HSCT was associated with accelerated post-transplant immune reconstitution and reduced infection-related mortality [perruccio2010_hsct]. The work extends the Romani-group dendritic-cell biology into the post-transplant clinical setting. Phase 3 trial data are not available.

Off-Label Uses of Thymosin Alpha-1 / Thymalin

General 'immune support' marketing (US wellness and longevity clinic context) EMERGING

Evidence should be interpreted in context for thymosin alpha-1. Any patient-specific request requires prescriber rationale and pharmacy review; availability is determined case by case.

Evidence should be interpreted in context for thymosin alpha-1. Any patient-specific request requires prescriber rationale and pharmacy review; availability is determined case by case.

Compounded Thymosin Alpha-1 / Thymalin (503A)

Physicians may submit patient-specific prescription requests for pharmacy review. For thymosin alpha-1, 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 thymosin alpha-1 is broader than many Category 2 peptides because Zadaxin and related thymalfasin products have been studied and used abroad. That international record does not create an FDA-approved US product or automatic 503A availability.

This ingredient is part of an evolving FDA review process. RonanRx is monitoring FDA's PCAC process and any subsequent agency action. This ingredient is part of an evolving FDA review process for peptide-related bulk substances used in compounding. Availability may change after FDA review, PCAC discussion, final agency action, or state-board guidance. For thymosin alpha-1, 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 thymosin alpha-1 are reviewed before any preparation is made or released. The regulated US route is not a wellness-clinic immune peptide protocol. A prescriber may submit a patient-specific request, and RonanRx reviews the clinical rationale, product identity, source documentation, and regulatory posture before any dispensing decision.

Thymosin Alpha-1 / Thymalin Formulations and Routes

Form	Concentration	Description
Sterile lyophilized powder for reconstitution (international reference product)	1.6 mg per vial, reconstituted with 1 mL sterile water for injection prior to subcutaneous administration	Zadaxin (SciClone Pharmaceuticals) is the international reference product. Supplied as a sterile lyophilized white powder in a single-use vial; reconstituted immediately before administration. Approved in approximately 30 countries; NOT FDA-approved in the United States.
RonanRx-compounded preparation	—	If a patient-specific thymosin alpha-1 request is approved after pharmacy review, the route and formulation must be selected by the prescriber and dispensing pharmacy for that named patient. Research-use presentations sold online are not RonanRx preparations.

Routes used in published literature: subcutaneous.

Thymosin Alpha-1 / Thymalin Dosing

Route	Population	Range	Duration	Study type
Subcutaneous	Chronic hepatitis B (Zadaxin international labeling)	1.6 mg twice weekly for 6 months	26 weeks (typical international labeled course)	Labeled regimen in international approvals; supported by RCTs
Subcutaneous	Chronic hepatitis C (combination with peginterferon alfa-2a and ribavirin, international clinical use)	1.6 mg twice weekly for 24-48 weeks alongside the interferon-based regimen	24-48 weeks	Randomized clinical trial regimens
Subcutaneous	Severe sepsis (ETASS trial regimen)	1.6 mg twice daily for 7 days alongside standard care	7 days	Multicenter randomized clinical trial regimen
Subcutaneous	RonanRx 503A compounded use	Case-by-case after pharmacy review	—	Not compounded

Internationally, the labeled Zadaxin regimen for chronic hepatitis B is 1.6 mg subcutaneously twice weekly for 6 months; for chronic hepatitis C, the same per-dose unit is given twice weekly alongside the interferon-based backbone for the duration of that regimen [ancell2001, camerini2015_history]. The ETASS sepsis trial protocol used 1.6 mg twice daily for 7 days [wu2013_etass]. These regimens are derived from international clinical trials and approvals; they are not FDA-labeled in the US.

RonanRx does not publish a consumer dosing schedule for thymosin alpha-1. Any request requires a valid patient-specific prescription, supporting clinical rationale, and pharmacist review. Route, strength, dosing interval, monitoring expectations, and dispensing quantity would be determined case by case from the prescriber's documentation and pharmacy feasibility review.

Thymosin Alpha-1 / Thymalin Safety

Across more than three decades of international clinical use, thymosin alpha-1 has shown a favorable tolerability profile [38]. The Andreone et al. 1996 Hepatology RCT specifically noted substantially better tolerability for Tα1 than for interferon alfa [9]. The Mutchnick et al. multicenter phase III trial reported no treatment-related discontinuations and an adverse-event profile not significantly different from placebo [10]. The Wu et al. ETASS sepsis trial similarly reported no major safety signal beyond background ICU adverse events [19]. Practice-facing reviews [18][33][31] consistently describe Tα1 as well tolerated; injection-site reactions (transient erythema and discomfort) are the most common reported event.

Hypersensitivity to thymosin alpha-1 or to excipients in international reference products is the principal contraindication in approved jurisdictions [18] [38]. Use in pregnancy and lactation has not been adequately studied; international labels generally advise against use during pregnancy in the absence of compelling clinical need.

The safety profile summarized here applies to international reference product (Zadaxin) used at labeled doses. It does not apply to US wellness-clinic preparations of uncertain identity, potency, sterility, or endotoxin status. Substances sold as 'thymosin alpha-1' outside the regulated supply chain are not characterized by published safety data and are not endorsed by RonanRx [37][38]. Any RonanRx availability decision is made case by case after patient-specific pharmacy review.

Contraindications

International Zadaxin labeling identifies known hypersensitivity to thymosin alpha-1 or to excipients in the product as a contraindication [18]. Use in pregnancy and lactation has not been adequately studied and is generally not recommended in approved jurisdictions in the absence of compelling clinical need. Use in immunosuppressed transplant recipients on cyclosporine-based regimens has been studied [35] but should be coordinated with the transplant team.

Because Physicians may submit patient-specific prescription requests for pharmacy review. Availability is determined case by case.

Drug interactions

Thymosin alpha-1 is a peptide cleared by proteolytic catabolism and does not participate in cytochrome P450-mediated drug interactions [12][19][23]. In published clinical use, Tα1 has been combined with interferon alfa, pegylated interferon, ribavirin, lamivudine, dacarbazine, and standard sepsis or COVID-19 supportive care without notable pharmacokinetic interaction signals [13][14][27].

Because the substance is on FDA Category 2 and is not compounded by RonanRx [37][38], a RonanRx-product-specific drug-interaction profile is not applicable.

Adverse events

The most commonly reported adverse events across international clinical trials of thymosin alpha-1 are transient injection-site reactions (erythema, mild discomfort) [9][10][18] [38]. No consistent systemic adverse-event signal has emerged across more than 30 years of clinical use. The Mutchnick et al. phase III trial reported no statistically significant difference in adverse-event rates between Tα1 and placebo [10]. The ETASS sepsis trial reported no Tα1-specific safety signal beyond background critical-care adverse events [19]. Meta-analytic synthesis [11][12][22] is consistent with this profile.

Adverse-event surveillance for US wellness-clinic preparations of 'thymosin alpha-1' is not systematically conducted. Reports of adverse events temporally associated with such preparations should be filed with FDA's MedWatch program. For any physician-submitted RonanRx request, adverse-event expectations and follow-up would be reviewed case by case before dispensing [37][38].

↗ Monitoring Thymosin Alpha-1 / Thymalin Therapy

No RonanRx-specific monitoring protocol has been established for thymosin alpha-1. 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.

For US patients asking about thymosin alpha-1 from wellness clinics, clinicians should be aware of the FDA Category 2 designation [fda_503a_bulk_substances, fda_pcac] and the absence of US FDA-supervised pharmacovigilance for non-approved preparations.

Thymosin Alpha-1 / Thymalin in Special Populations

Thymosin Alpha-1 / Thymalin Evidence Quality

The international evidence base for thymosin alpha-1 is substantial and predates most of the modern peptide-therapy landscape. Randomized controlled trials in chronic hepatitis B [andreone1996, mutchnick1999, zhang2009_lam_combo] supported international Zadaxin approvals in approximately 30 countries, with meta-analytic synthesis confirming a sustained virologic response advantage over interferon alfa [yang2008_hbv_meta]. The chronic hepatitis C evidence base [andreone2004_hcv, poo2008_triple, ciancio2012_hcv] is now of historical interest given the dominance of direct-acting antivirals from 2013 onward. The severe-sepsis evidence base centered on the ETASS multicenter RCT [wu2013_etass] is reinforced by multiple systematic reviews and meta-analyses [wang2016_ulinastatin_meta, liu2016_sepsis_meta, gu2025_sepsis_meta] with a reproducible mortality signal, though heterogeneity in standard-care comparators and trial geography (predominantly Chinese ICUs) limits generalization.

Oncology evidence comprises the Maio et al. (2010) melanoma phase 3 trial [maio2010_melanoma] (not practice-changing in the modern checkpoint-inhibitor era), the Qiu et al. (2015) Chinese HCC adjuvant protocol [qiu2015_hcc_protocol], and preclinical NSCLC mechanism work [yang2020_nsclc_mdsc]. COVID-19 evidence is largely retrospective and not generalizable to current variants [liu2020_covid, sun2021_covid_mortality]. Mechanistic work by the Romani group [romani2004_dc_tlr, romani2006_dc_ido, romani2007_review] and others [stincardini2018_proteostasis, zhang2022_ace2] is internally coherent and supports the immune-modulation framework.

From a US regulatory standpoint, the FDA Pharmacy Compounding Advisory Committee placed thymosin alpha-1 in Category 2 of the 503A bulk-drug-substances list [fda_503a_bulk_substances, fda_pcac], i.e., insufficient information to evaluate for use in compounding. This designation reflects the absence of FDA-supervised efficacy and safety review of US-marketed material, not a finding of harm. The international evidence base may be adequate to support an eventual FDA reclassification request, but at the time of this writing thymosin alpha-1 may not be used in 503A patient-specific compounding. RonanRx does not source, compound, or dispense the substance.

Major Thymosin Alpha-1 / Thymalin Clinical Studies

Study	Design	Participants	Duration	Finding
Andreone et al. (1996, Hepatology), Tα1 vs	Randomized controlled trial in HBeAg-positive HBV	—	26 weeks	Comparable rates of HBV DNA clearance with thymosin alpha-1 versus interferon alfa,

Study	Design	Participants	Duration	Finding
IFN-alfa in chronic hepatitis B	DNA-positive chronic hepatitis B adults			with substantially better tolerability for Tα1 [andreone1996]
Mutchnick et al. (1999, J Viral Hep), Phase III placebo-controlled trial in chronic hepatitis B	Multicenter randomized double-blind placebo-controlled phase III trial	—	26 weeks treatment + follow-up	Sustained virologic response advantage for thymosin alpha-1 over placebo; tolerability indistinguishable from placebo [mutchnick1999]
Andreone et al. (2004, J Viral Hep), Tα1 plus IFN-alfa in naive chronic hepatitis C	Randomized open-label trial in treatment-naive chronic hepatitis C adults	—	48 weeks treatment + 24 weeks follow-up	Combination of thymosin alpha-1 with interferon alfa improved end-of-treatment and sustained virologic response over interferon alfa alone in this naive population [andreone2004_hcv]
Poo et al. (2008, Annals of Hepatology), Triple therapy (thymalfasin + peginterferon alfa-2a + ribavirin) in HCV	Randomized open-label triple-therapy study in genotype 1 chronic hepatitis C	—	48 weeks treatment	Addition of thymalfasin to peginterferon alfa-2a plus ribavirin improved end-of-treatment and sustained virologic response in difficult-to-treat HCV [poo2008_triple]
Ciancio et al. (2012, J Viral Hep), Tα1 plus peginterferon-ribavirin in HCV nonresponders	Multicenter randomized open-label trial in chronic hepatitis C patients not responsive to prior peginterferon-ribavirin	—	48 weeks	Addition of thymosin alpha-1 to retreatment with peginterferon alfa-2a plus ribavirin produced modest improvement in sustained virologic response in this difficult population [ciancio2012_hcv]
Yang et al. (2008, Antiviral Research), Tα1 vs IFN-alfa meta-analysis in chronic hepatitis B	Systematic review and meta-analysis of randomized controlled trials of Tα1 vs interferon alfa in chronic hepatitis B	—	—	Sustained virologic response advantage for thymosin alpha-1 over interferon alfa across the pooled RCT corpus [yang2008_hbv_meta]
Zhang et al. (2009, Virology Journal), Lamivudine plus Tα1	Randomized trial of lamivudine vs	—	—	Combination therapy produced higher HBeAg seroconversion and HBV DNA suppression

Study	Design	Participants	Duration	Finding
in HBeAg-positive chronic hepatitis B	lamivudine plus thymosin alpha-1			rates than lamivudine alone [zhang2009_lam_combo]
Wu et al. (2013, Critical Care), ETASS multicenter RCT in severe sepsis	Multicenter single-blind randomized controlled trial in adults with severe sepsis	361	7-day intervention, 28-day mortality endpoint	Subcutaneous thymosin alpha-1 (1.6 mg twice daily for 7 days) plus standard care reduced 28-day all-cause mortality compared with standard care alone in adults with severe sepsis [wu2013_etass]
Liu et al. (2016, BMC Infect Dis), Tα1 sepsis meta-analysis	Systematic review and meta-analysis of randomized controlled trials of thymosin alpha-1 as immunomodulatory therapy for sepsis	—	—	Pooled mortality advantage for thymosin alpha-1 in sepsis, with heterogeneity in standard-care comparators [liu2016_sepsis_meta]
Gu et al. (2025, Front Cell Infect Microbiol), Updated sepsis meta-analysis	Updated systematic review and meta-analysis of randomized controlled trials of thymosin alpha-1 in sepsis	—	—	Reinforces the pooled mortality advantage in sepsis across the expanded RCT corpus [gu2025_sepsis_meta]
Maio et al. (2010, J Clin Oncol), Phase 3 melanoma trial	Phase 3 randomized open-label trial of thymosin alpha-1, interferon alfa, and the combination with dacarbazine in metastatic melanoma	488	—	Tα1-containing arms reported a numerical overall-survival advantage over dacarbazine monotherapy; trial did not change clinical practice [maio2010_melanoma]. Modern melanoma care is dominated by checkpoint inhibitors and targeted therapy
Liu et al. (2020, Clinical Infectious Diseases), Tα1 in critical COVID-19	Retrospective cohort analysis of critically ill COVID-19 patients receiving Tα1 vs standard care, with	—	—	Thymosin alpha-1 reduced 28-day mortality in critically ill COVID-19 patients, particularly those with low baseline CD8+ T-cell counts; restored lymphocyte counts and

Study	Design	Participants	Duration	Finding
	focus on baseline lymphocyte counts			reversed T-cell exhaustion markers [liu2020_covid]
Sun et al. (2021, Int Immunopharmacol), Multicenter retrospective COVID-19	Multicenter retrospective study of thymosin alpha-1 effect on mortality in critically ill COVID-19 patients	—	—	Mortality reduction associated with thymosin alpha-1 administration in a larger multicenter cohort, supporting the Liu et al [sun2021_covid_mortality]. signal
Romani et al. (2004, Blood), Dendritic-cell Toll-like receptor mechanism	Preclinical mechanistic study using MyD88-knockout and TLR-blockade approaches in murine invasive aspergillosis	—	—	Tα1 activates dendritic cells via Toll-like receptor signaling (principally TLR-9 on plasmacytoid DCs and TLR-2 on conventional DCs), driving Th1 antifungal resistance [romani2004_dc_tlr]
Romani et al. (2006, Blood), Dendritic-cell IDO mechanism	Preclinical mechanistic study of dendritic-cell tryptophan catabolism downstream of Tα1 signaling	—	—	Tα1 activates dendritic-cell tryptophan catabolism via indoleamine 2,3-dioxygenase, establishing a regulatory cytokine milieu that balances inflammation and tolerance [romani2006_dc_ido]
Yang et al. (2020, Biomed Pharmacother), NSCLC tumor-microenvironment mechanism	Preclinical study of Tα1 effect on myeloid-derived suppressor-cell accumulation in NSCLC models	—	—	Thymosin alpha-1 blocks MDSC accumulation in NSCLC by inhibiting VEGF production, supports the adjuvant-immunotherapy rationale [yang2020_nsclc_mdsc]
Goldstein et al. (1972, PNAS), Discovery of thymosin	Purification and bioassay of thymic peptide activity from bovine thymus	—	—	Established thymosin as a hormone-like factor that restores T-cell function in neonatally thymectomized mice, foundation of the thymic peptide field [goldstein1972]
Qiu et al. (2015, Expert Opin Biol Ther), Multicenter	Protocol publication for a multicenter Chinese RCT of	—	—	Protocol establishes the rationale and analytic framework for evaluating Tα1

Study	Design	Participants	Duration	Finding
HCC adjuvant protocol	thymalfasin adjuvant therapy in HBV-related hepatocellular carcinoma after curative resection			as an adjunct after HCC resection in HBV-endemic populations [qiu2015_hcc_protocol]

Thymosin Alpha-1 / Thymalin Pharmacokinetics & Pharmacodynamics

Pharmacokinetics

Thymosin alpha-1 administered subcutaneously is rapidly absorbed; reported terminal half-life is approximately 2 hours in healthy adults [ancell2001]. The peptide is cleared by proteolytic catabolism; renal clearance is a minor pathway. Cytochrome P450 metabolism is not relevant for a small linear peptide. PK characteristics are reproducible across age and renal-function strata in published international clinical use [ancell2001, gramenzi1998_review].

PK characterization for a RonanRx preparation would depend on the actual formulation, route, and patient-specific prescription reviewed by the pharmacy. International Zadaxin data and US wellness-clinic preparations are not interchangeable with a RonanRx-compounded preparation [fda_503a_bulk_substances, fda_pcac].

Pharmacodynamics

Pharmacodynamic effects of thymosin alpha-1 are measurable as changes in T-cell subset distribution and function (CD4+ and CD8+ counts, CD3 and CD25 expression, IL-2 and IFN-γ production), natural-killer-cell cytotoxicity, dendritic-cell maturation marker expression (CD83, HLA-DR), and Th1 cytokine output [romani2004_dc_tlr, romani2006_dc_ido, king2016_review]. In severely immunocompromised states such as critical illness with lymphocytopenia, Tα1 partially restores absolute lymphocyte counts and reverses T-cell exhaustion markers (PD-1, Tim-3) [liu2020_covid].

Indication-specific endpoints include HBV DNA suppression and HBeAg seroconversion for chronic hepatitis B [andreone1996, mutchnick1999], HCV RNA clearance for chronic hepatitis C [andreone2004_hcv, poo2008_triple], 28-day all-cause mortality for severe sepsis [wu2013_etass], and overall survival in oncology trials [maio2010_melanoma].

Comparing Thymosin Alpha-1 / Thymalin Formulations

Zadaxin (SciClone Pharmaceuticals) is the international reference product, a sterile lyophilized powder for reconstitution, supplied at 1.6 mg per single-use vial. Zadaxin holds regulatory approval in approximately

30 countries (including Italy and China) for chronic hepatitis B, chronic hepatitis C, and as a vaccine adjuvant in immunocompromised patients [camerini2015_history, ciancio2010, ancell2001]. NOT FDA-approved in the United States.

If a thymosin alpha-1 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.

Thymosin Alpha-1 / Thymalin Storage and Handling

If a thymosin alpha-1 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.

Thymosin Alpha-1 / Thymalin Compounding & Operations

503A compounding

Physicians may submit patient-specific prescription requests for pharmacy review. For thymosin alpha-1, 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 thymosin alpha-1 is broader than many Category 2 peptides because Zadaxin and related thymalfasin products have been studied and used abroad. That international record does not create an FDA-approved US product or automatic 503A availability.

This ingredient is part of an evolving FDA review process. RonanRx is monitoring FDA's PCAC process and any subsequent agency action. This ingredient is part of an evolving FDA review process for peptide-related bulk substances used in compounding. Availability may change after FDA review, PCAC discussion, final agency action, or state-board guidance. For thymosin alpha-1, 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 thymosin alpha-1 are reviewed before any preparation is made or released. The regulated US route is not a wellness-clinic immune peptide protocol. A prescriber may submit a patient-specific request,

and RonanRx reviews the clinical rationale, product identity, source documentation, and regulatory posture before any dispensing decision.

Pharmacist review

For thymosin alpha-1, 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 thymosin alpha-1 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 [usp_795].

Cold chain

If a thymosin alpha-1 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.

Frequently Asked Questions About Thymosin Alpha-1 / Thymalin

Can physicians request thymosin alpha-1 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.

Is thymosin alpha-1 approved anywhere?

Yes, internationally. Thymosin alpha-1 is the active ingredient of Zadaxin (thymalfasin), marketed by SciClone Pharmaceuticals and approved in approximately 30 countries (including Italy and China) for chronic hepatitis B, chronic hepatitis C, and as a vaccine adjuvant in immunocompromised patients [camerini2015_history; ciancio2010]. It is NOT FDA-approved for any use in the United States.

What is the evidence base?

There is a substantial international evidence base [maio2010_melanoma]. Randomized controlled trials and meta-analyses support efficacy in chronic hepatitis B (Andreone 1996, Mutchnick 1999, Yang 2008 meta-analysis), chronic hepatitis C in combination with interferon-based regimens (Andreone 2004, Poo 2008, Ciancio 2012), and severe sepsis (Wu 2013 ETASS, multiple meta-analyses including Gu 2025) [andreone1996; mutchnick1999; yang2008_hbv_meta]. COVID-19 and oncology evidence is encouraging but largely retrospective or single-trial [wu2013_etass; gu2025_sepsis_meta; liu2020_covid].

How does thymosin alpha-1 work?

Thymosin alpha-1 is an immune modulator [king2016_review]. It activates dendritic cells through Toll-like receptor signaling (principally TLR-9 and TLR-2), promotes T-cell maturation and natural-killer-cell activity, and concurrently engages indoleamine 2,3-dioxygenase-mediated tryptophan catabolism that establishes a regulatory cytokine environment [romani2004_dc_tlr; romani2006_dc_ido]. Net effect is enhanced Th1 immunity balanced by regulatory tone, a profile that fits the chronic viral infection, sepsis, and adjunct-immunotherapy contexts where it has been studied [romani2007_review].

What about wellness-clinic 'thymosin alpha-1' available in the United States?

Material sold as 'thymosin alpha-1' by US wellness clinics outside the regulated supply chain is not FDA-supervised, is not characterized by published pharmacovigilance, and is not endorsed by RonanRx. The FDA Category 2 designation means the substance may not be used in 503A patient-specific compounding pending further evaluation [fda_503a_bulk_substances]. RonanRx does not source, compound, or dispense thymosin alpha-1 in any form [fda_pcac].

Could RonanRx compound thymosin alpha-1 if FDA reclassifies it to Category 1?

RonanRx would re-evaluate at that point. Reclassification would remove the regulatory bar, but additional pharmacy-side prerequisites would still need to be met: pharmaceutical-grade active ingredient with documented identity, potency, sterility, and endotoxin specifications; USP <797> sterile-compounding workflow; documented patient-specific clinical rationale under section 503A; and a defensible US clinical-evidence basis for the prescribed regimen [fda_503a_bulk_substances; fda503a]. The international Zadaxin evidence base would inform but not by itself satisfy the evaluation [usp_797].

Where can patients get Zadaxin if they want it?

Patients seeking Zadaxin in jurisdictions where it is approved should consult prescribers and pharmacies licensed in those jurisdictions. Thymalfasin (Zadaxin) is sold internationally by SciClone Pharmaceuticals; it is not available through US compounding pharmacies, and RonanRx does not source it [camerini2015_history; ciancio2010].

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How to Access Thymosin Alpha-1 / Thymalin

Compounded Thymosin Alpha-1 / Thymalin 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 Thymosin Alpha-1 / Thymalin, 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)