Thymosin Alpha-1 — Research Summary

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1. What It Is

Thymosin Alpha-1 (thymalfasin, Tα1) is a 28-amino-acid synthetic peptide identical to the natural Tα1 produced by the thymus gland. It is a biological response modifier that activates various cells of the immune system, and is studied for benefit in conditions where immune response is impaired or ineffective — chronic viral/bacterial infection, certain cancers, sepsis, and vaccine non-responsiveness.

Regulatory status: Thymosin Alpha-1 is approved in 35+ countries under the brand name Zadaxin (originally SciClone Pharmaceuticals) for chronic hepatitis B, hepatitis C (with interferon), and as an immune-enhancing agent — most notably in China. It has never received FDA or EMA approval and remains available in the US only through compounding pharmacies; it was subject to additional FDA compounding restrictions in 2023.

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2. Reported Effects in Research Literature

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Thymosin Alpha-1 has an unusually large clinical evidence base for a research peptide — a 2024 comprehensive review documented evidence from over 30 clinical trials involving more than 11,000 human subjects.

- **Hepatitis B/C:** Foundational human trials beginning in the 1980s investigated Tα1 in chronic active hepatitis B, supporting its regulatory approval pathway in Asia.
- **Sepsis:** The TESTS trial (BMJ, 2025) — the largest randomized controlled trial of Tα1 to date, 1,106 sepsis patients across multiple Chinese hospitals — is the strongest controlled human evidence available. A separate systematic review/meta-analysis of RCTs reported Tα1 therapy significantly reduced 28-day sepsis mortality versus controls.
- **COVID-19:** Multiple studies examined Tα1 in hospitalized COVID-19 patients, including a Wuhan cohort study reporting a trend toward reduced mortality in severe cases, and a published clinical study (Liu et al., *Clin Infect Dis* 2020) reporting reduced mortality via restoration of lymphocytopenia and reversion of exhausted T cells.
- **Cancer immunotherapy:** Studied as an adjunct in melanoma, hepatocellular carcinoma, and lung cancer; mechanistic work reports effects on tumor cell signaling pathways (e.g., STAT3-MMP2 suppression in lung cancer cells).
- **Vaccine response:** Reported to improve vaccine response in elderly and immunocompromised (e.g., renal disease) populations.
- **Safety:** Across trials, no significant organ toxicity (liver, kidney, cardiac) has been reported; the compound has a favorable safety record spanning decades of use.

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3. Clinical & Preclinical Study References

- Naylor PH, et al. “Thymosin alpha 1 in chronic active hepatitis B.” (1987). PMID: 3545119
- Liu Y, Pan Y, Hu Z, et al. “Thymosin Alpha 1 Reduces the Mortality of Severe Coronavirus Disease 2019 by Restoration of Lymphocytopenia and Reversion of Exhausted T Cells.” *Clin Infect Dis.* 2020;71(16):2150-2157. PMID: 32442287
- Shehadeh F, et al. “A Pilot Trial of Thymalfasin (Thymosin-alpha-1) to Treat Hospitalized Patients

With Hypoxemia and Lymphocytopenia Due to COVID-19." *J Infect Dis.* 2023;227(2):226-235.
- Wu J, et al. "The efficacy and safety of thymosin α1 for sepsis (TESTS): multicentre, double blinded, randomised, placebo controlled, phase 3 trial." *BMJ.* 2025.
- Systematic review: Efficacy of thymosin α1 for sepsis — meta-analysis of RCTs (Frontiers)
- Systematic review: Thymosin alpha1 use in adult COVID-19 patients — meta-analysis (PMC)

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4. Reconstitution Process

For research/laboratory handling purposes only.

Keep out of reach of children. Not for use by pregnant or nursing individuals. For laboratory research use by qualified personnel only.

1. **Materials needed:** lyophilized (freeze-dried) Thymosin Alpha-1 powder, bacteriostatic water, alcohol swabs, syringe with needle.
2. **Bring the vial to room temperature** before reconstitution.
3. **Sanitize** the rubber stopper of both vials with an alcohol swab.
4. **Draw the bacteriostatic water** into the syringe.
5. **Add the water slowly** down the *inside wall* of the vial, to reduce shear/foaming.
6. **Do not shake.** Gently swirl or roll between palms until fully dissolved.
7. **Inspect the solution** — should be clear and free of particulates.
8. **Label the vial** with reconstitution date and concentration.
9. **Storage:** refrigerate (2–8°C); avoid freeze-thaw cycles.

Reference: Bacteriostatic Water Volume by Vial Size

Vial Size	BAC Water Added	Resulting Concentration
5 mg	1 mL	5 mg/mL
5 mg	2 mL	2.5 mg/mL
5 mg	5 mL	1 mg/mL
10 mg	1 mL	10 mg/mL
10 mg	2 mL	5 mg/mL
10 mg	4 mL	2.5 mg/mL
10 mg	5 mL	2 mg/mL
10 mg	10 mL	1 mg/mL

Notes: Higher water volume = more dilute solution; lower volume = more concentrated. Always use bacteriostatic water (0.9% benzyl alcohol) for multi-draw vials; sterile water without preservative should be discarded within 24 hours.

Document created: July 16, 2026. **Revision 1:** July 29, 2026. Regulatory status (FDA compounding lists, WADA lists) is actively shifting; re-verify against current sources before any customer-facing use.
