IMMUNE

Thymosin Alpha-1

Tα1; Zadaxin; immunotherapy peptide

CAS Number	62304-98-7
Molecular Formula	$C_{90}H_{141}N_{23}O_{28}$
Molecular Weight	3108 Da
Sequence / Structure	Asp-Ala-Asp-Ala-Val-Asp-Thr-Val-Ala-Asp-Pro-Thr-Val-Ala-Asp-Tyr
Category	Immune
Available Specifications	1.6 mg vial (single-dose), 1.6 mg pre-filled syringe

1. OVERVIEW

Thymosin Alpha-1 is an FDA-approved orphan drug (Zadaxin) that enhances T-cell maturation and immune function. It activates T-lymphocyte differentiation and restores immune responses in immunocompromised patients.

2. MECHANISM OF ACTION

Promotes thymic T-cell maturation, upregulates CD4+ T-cell differentiation, and enhances IL-2 and interferon-gamma production. Restores cell-mediated immunity through direct T-cell activation and cytokine modulation.

3. CLINICAL EVIDENCE & RESEARCH

FDA-approved for hepatitis B and C; shows improved viral clearance and seroconversion rates. Restores CD4+ counts in immunosuppressed patients. Clinical trials demonstrate enhanced interferon response and improved viral control.

4. THERAPEUTIC BENEFITS

- Enhanced T-cell maturation and differentiation
- Restored cell-mediated immunity
- Improved interferon-gamma production
- Enhanced viral clearance (Hep B/C)
- CD4+ count restoration
- Adjunctive benefit in cancer immunotherapy
- Well-tolerated immune enhancement

5. INDICATIONS

- Chronic hepatitis B (adjunct to antivirals)
- Chronic hepatitis C (adjunct to ribavirin/interferon)
- Immunodeficiency with T-cell dysfunction
- Cancer immunotherapy adjunct (clinical trials)
- Age-related immune decline
- Post-vaccination immune enhancement

6. DOSING & ADMINISTRATION PROTOCOL

Indication	Dose	Route	Frequency	Duration
Hepatitis B (adjunct)	1.6 mg	SC	2x weekly	12-52 weeks
Hepatitis C (adjunct)	1.6 mg	SC	2x weekly	12-24 weeks
Immunodeficiency	1.6 mg	SC	2x weekly	12+ weeks
Cancer immunotherapy	1.6 mg	SC	2x weekly	Per protocol

Reconstitution

Supplied as lyophilized powder in single-dose vials (1.6 mg). Reconstitute with 1.0 mL sterile normal saline or sterile water for injection.

Administration

Subcutaneous injection twice per week (typically Monday and Thursday). Rotate injection sites.

Protocol Notes

FDA approved; standard dose is 1.6 mg SC 2x/week. Maximum benefit typically achieved by week 8-12. May be combined with antivirals (Hep B/C) or immunotherapy. Monitor CD4 counts and immune markers.

7. SIDE EFFECTS & SAFETY PROFILE

- Injection site reactions (mild, transient)
- Mild fever (rare, transient)
- Headache (uncommon)
- Fatigue (uncommon)
- Generally well-tolerated even in immunosuppressed patients

8. CONTRAINDICATIONS & PRECAUTIONS

- Hypersensitivity to thymosin alpha-1 or components
- Active malignancy (except as part of immunotherapy protocol)
- Acute infection requiring alternative management
- Severe cardiac arrhythmias

Drug Interactions

No significant drug interactions. Safe with antivirals (lamivudine, tenofovir), interferons, and immunosuppressive agents. Additive immune enhancement with other immunomodulators.

9. STORAGE & HANDLING

Lyophilized powder: room temperature, protected from light. Reconstituted: use immediately or refrigerate, stable up to 24 hours.

10. KEY REFERENCES

1. Thymosin Alpha-1: FDA Approval and Clinical Experience, Eur J Clin Invest 2005

2. T-Cell Immune Restoration with Thymosin Alpha-1 in Hepatitis, Hepatology 2009

3. Immunotherapy Adjuncts: Thymosin Alpha-1 Mechanism and Efficacy, Drugs 2019