COMPOUND GUIDE

Thymosin Alpha-1 (TA1) — Thymalfasin / Zadaxin

28-AA thymic peptide · Approved in 35+ countries for HBV/HCV · Twice-weekly SubQ

Quick Start

APPROVED IN 35+ COUNTRIES — NOT FDA APPROVED

Thymosin Alpha-1 (synthetic form: thymalfasin; brand name Zadaxin) is approved in more than 35 countries including China, Italy, and various Asia-Pacific nations for Hepatitis B and C treatment, and as an adjunct in cancer therapy and sepsis. It is NOT FDA-approved in the US. FDA placed it in Category 2 (September 2023), then removed it (September 2024), with PCAC review December 2024.

WHAT IT IS

Thymosin Alpha-1 is a 28-amino acid peptide naturally produced by the thymus gland. It is the first thymosin fraction described to have significant immunomodulatory activity. The synthetic form (thymalfasin) is identical to the naturally occurring peptide and is the active ingredient in Zadaxin. It acts as a biological response modifier — enhancing immune function rather than suppressing it.

RESEARCH DOSING

1.6 mg SubQ twice weekly (e.g. Monday and Thursday). The standard 6-month HBV protocol uses this dose continuously. For immune support research, some protocols use 1.6 mg 2–3× per week for 4–12 weeks. No ramp-up required.

REGULATORY STATUS

Approved in 35+ countries for HBV, HCV, and cancer adjunct. NOT FDA-approved. FDA removed from Category 2 September 2024; PCAC reviewed December 2024. TESTS BMJ 2025 trial showed negative primary endpoint for sepsis. Not on WADA prohibited list. For research purposes only in the US and SA context.

Dosing Protocol

PROTOCOL	DOSE	FREQUENCY	DURATION	CONTEXT
HBV Standard (Zadaxin)	1.6 mg	Twice weekly (Mon + Thu)	6 months	Approved clinical protocol for hepatitis B
Immune research	1.6 mg	2–3× weekly	4–12 weeks	General immune-modulation research
Adjunctive	1.6 mg	Twice weekly	With active protocol	Used alongside other treatments in international approved contexts

Supplies & Reconstitution

Reconstitution Math — 5 mg Vial (3 mL BAC)

TARGET DOSE	UNITS (U-100)	DOSES / VIAL
0.5 mg	**30.0 units**	10
1 mg	**60.0 units**	5
1.6 mg	**96.0 units**	3.1

Reconstitute the 5 mg vial with **3.0 mL bacteriostatic water** → 1.67 mg/mL. U-100 syringe = 100 units per mL. Swirl gently — do not shake. Refrigerate 2–8°C.

Reconstitution Steps

01 **Warm the vial**
Remove from freezer 10–15 minutes before reconstitution. Allow to reach room temperature.

02 **Swab both stoppers**
Wipe the tops of both vials with fresh alcohol swabs. Air-dry.

03 **Draw and inject BAC water**
Draw BAC water and let it run slowly down the inside wall of the peptide vial. Do not jet onto the powder cake.

04 **Swirl gently**
Swirl until clear. Solution should be colourless to faint yellow. Do not shake.

05 **Refrigerate**
Store at 2–8°C for up to 30 days. Do not freeze after reconstitution. Protect from light.

Mechanism of Action

TLR SIGNALLING

Activates Toll-like receptor 2 (TLR2) and TLR9 signalling on dendritic cells and plasmacytoid DCs. This triggers innate immune activation, type-I interferon production, and bridges innate to adaptive immunity.

T-CELL ACTIVATION (TH1 SHIFT)

Promotes differentiation and maturation of T-helper 1 (Th1) cells, and augments cytotoxic T-lymphocyte (CTL) activity. Key mechanism for its antiviral effects in HBV and HCV research. Shifts immune response toward cellular immunity.

DENDRITIC CELL MATURATION

Promotes dendritic cell maturation and antigen-presenting function. Mature DCs are required for effective T-cell priming, relevant to both viral clearance and adjuvant cancer therapy research contexts.

NO IMMUNOSUPPRESSION

Unlike corticosteroids or calcineurin inhibitors, TA1 does not suppress immune function. It is a biological response modifier — it enhances responses that are deficient rather than globally suppressing inflammation.

Key Research

STUDY / TRIAL	DESIGN	FINDING
Multiple RCTs (Zadaxin era)	HBV and HCV; 26–52 weeks	HBeAg seroconversion and HBV DNA suppression in multiple trials; approved basis in 35+ countries
Cancer adjunct studies	Lung, colon, breast cancer + chemo	Improved immune recovery post-chemotherapy in multiple open-label and controlled studies
TESTS trial (BMJ 2025)	RCT; n=1,100+; sepsis; 28-day mortality	Primary endpoint not met — no significant mortality difference vs placebo in sepsis
COVID-19 research	Observational; China 2020	Suggested reduced mortality in severe COVID-19; not confirmed in RCTs

Storage

STATE	TEMPERATURE	DURATION	NOTES
Lyophilised (powder)	−20°C (freezer)	Up to 24 months	Protect from light and moisture
Reconstituted (liquid)	2–8°C (refrigerator)	Up to 30 days	Do not freeze after reconstitution
Short-term (travel)	<25°C	Up to 72 hours	Avoid heat and direct sunlight