Safety Profiles of BPC-157 and TB-500 for Sports-Related Musculoskeletal Pain: A Review of the Human Evidence

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Introduction

Interventional pain physicians routinely encounter patients requesting or self-administering BPC-157 and TB-500 for sports-related musculoskeletal pain, often alongside procedures like PRP and prolotherapy. Both peptides remain unapproved for clinical use, yet patients obtain them from unregulated sources without physician oversight. Because pain physicians coordinate care around these injections and field safety questions, this review compares the available human safety data for BPC-157 and TB-500 to support informed patient counseling.

Methods

We searched MEDLINE, EMBASE, the Cochrane Library and PubMed using "BPC-157" OR "TB-500" OR "thymosin beta-4" AND "safety" OR "adverse events" OR "toxicity" OR "phase 1," combined with pain-related terms (musculoskeletal pain, knee pain, joint pain). All published human studies were included; animal and in vitro studies were excluded.

Preclinical vs. Human Evidence

BPC-157 studies of musculoskeletal healing



35 preclinical studies

1 human study

Tendon, ligament, muscle and bone healing models vs. one retrospective knee case series. Systematic review of 36 studies, Vasireddi 2025.

No conflicts of interest. IRB-exempt per One Brooklyn Health policy (no patient-identifiable information). No off-label drug use; no IND approval applicable.

Results

About 30 people have received BPC-157 in peer-reviewed studies, and no one has studied the TB-500 fragment patients actually inject.

BPC-157 · 3 peer-reviewed human studies

IV safety pilot *Lee 2025* ●○○

DESIGN	Uncontrolled pilot in 2 healthy adults
DOSE	Intravenous infusion, escalating to 20 mg
MONITORED	Heart, liver, kidney and thyroid markers and blood glucose
ADVERSE EVENTS	None reported; no change in any measured marker
CAVEAT	Two people cannot reveal uncommon or delayed harm

Knee pain case series *Lee 2021* ●○○

DESIGN	Retrospective chart review; 16 of 17 patients reached by phone
DOSE	One knee injection; 4 of 16 also received thymosin β4
OUTCOME	14 of 16 reported relief; no validated pain scores
ADVERSE EVENTS	None reported; how they were screened is not described
CAVEAT	No control group; the treating physician collected outcomes

Interstitial cystitis pilot *Lee 2024* ●○○

DESIGN	Uncontrolled pilot in 12 women with refractory disease
DOSE	Single 10 mg dose into the bladder wall at cystoscopy
MONITORED	Fever, rash, nausea, vomiting, urinary symptoms, dyspareunia
ADVERSE EVENTS	None reported over 6 weeks
OUTCOME	10 of 12 symptom-free; not a musculoskeletal use

Also reported, but only as conference abstracts: enema trials of BPC-157 in healthy volunteers and ulcerative colitis (2003, 2005). FDA staff judged these data inadequate to establish safety.

TB-500 and its parent molecule, thymosin β4

TB-500 fragment *FDA briefing 2026* ○○○

WHAT IT IS	Synthetic 7-amino-acid piece (residues 17–23) of thymosin β4
HUMAN DATA	None: FDA found no human studies, dosing or exposure data
PRODUCT	FDA flagged aggregation and characterization concerns
ADVERSE EVENTS	Unknown
CLOSEST DATA	4 knee-series patients also received thymosin β4 (Lee 2021)

Thymosin β4 Phase I trial *Wang 2021* ●●○

DESIGN	Randomized, double-blind, placebo-controlled; healthy adults
DOSE	Single IV dose 0.05–25 µg/kg (54 people), or daily for 10 days at 0.5–5 µg/kg (30 people), followed 28 days
MONITORED	Adverse events, pharmacokinetics, anti-drug antibodies
ADVERSE EVENTS	All mild or moderate, at the same rate and severity as placebo; none serious or dose-limiting
EVENT COUNT	45 after one dose, 39 after 10 days (incl. placebo arms)
CAVEAT	Full-length recombinant IV drug, not the injected fragment

Safety at a glance	BPC-157	TB-500	Thymosin β4
People studied	~30	0	84
Controlled data	No	None	Yes
Serious adverse events	None reported	Unknown	None
Strength of evidence	●○○	○○○	●●○

Strength of evidence: ●●● strong (multiple high-quality RCTs) · ●●○ moderate (an RCT or a meta-analysis of few RCTs) · ●○○ low (small or uncontrolled study) · ○○○ none (no human data)

The gap: no human study exists for the injectable TB-500 fragment, and no study has tested either peptide alongside PRP, prolotherapy or other procedures.

Discussion and Conclusions

Summary of evidence. BPC-157 human data total about 30 people across three small, uncontrolled pilot studies from one research group, with no adverse events reported. Full-length thymosin beta-4 has a placebo-controlled Phase I trial showing good tolerability, but the injectable TB-500 fragment has no human data.

Counseling points. Ask about peptide use before procedures and document it. Tell patients that neither peptide is FDA-approved, that product content and sterility are unverified, and that both are prohibited at all times in WADA-tested sport. Existing studies are too small to detect rare harms or interactions with procedures.

Limitations. Very few human studies, no randomized trials of BPC-157, short follow-up, and reliance on published reports only.

Conclusion. Neither peptide has established safety or efficacy for musculoskeletal pain. Pain physicians should counsel patients accordingly, and controlled trials are needed before either can be recommended.

Regulatory Timeline

2022 — WADA prohibits BPC-157 in sport

2023 — FDA flags BPC-157 as a significant safety risk

Apr 2026 — BPC-157 removed from that list

Jul 2026 — **Advisers vote 8–6 for compounding, against FDA staff advice. MSK use not reviewed.**

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