EDUCATIONAL CLINICAL OVERVIEW

BPC-157

Body Protection Compound-157 · Investigational Compounded Peptide · Subcutaneous Injection · Available in the state of Texas

Drug Class	Investigational compounded peptide (BPC-157); not an FDA-approved drug product
Compounded Form	Subcutaneous injection (compounded); 5 mL vial, 3 mg per mL
Investigational Area	Regenerative Medicine / Tissue Repair / Sports Medicine / Gastrointestinal Health / Post-Surgical Recovery
Revision Date	June 2025

IMPORTANT — NOT FDA-APPROVED FOR ANY INDICATION

BPC-157 is not FDA-approved for tissue repair, injury recovery, pain, sports performance, post-surgical recovery, wound healing, gastrointestinal disease, or any regenerative-medicine indication. This is an investigational compounded preparation. Human clinical-trial data are limited and the majority of supportive evidence derives from preclinical animal models. Any clinical use is at the prescriber's discretion based on individual patient assessment, current literature, and applicable federal and state law.

1 · Investigational Interest & Proposed Mechanisms

BPC-157 (Body Protection Compound-157) is a synthetic pentadecapeptide derived from a protective protein found in human gastric juice. The peptide has been studied in preclinical models across a range of tissue types. The following represent areas of investigational interest derived from in vitro studies, animal models, and mechanistic reviews. None of the effects described constitute established clinical outcomes in humans.

- **Tendon & Ligament Repair —** Preclinical (largely rodent) data describe associations between BPC-157 and changes in fibroblast activity and collagen type I expression in tendon and ligament tissue. Efficacy in human tendon/ligament injury has not been established in controlled trials.
- **Musculoskeletal Injury Recovery —** Animal models have reported associations between BPC-157 and accelerated healing of muscle, bone, and connective tissue injuries. Human data are limited and no controlled clinical trials support routine use for musculoskeletal indications.
- **Gastrointestinal Mucosal Protection —** BPC-157 is derived from a gastric protective protein and has demonstrated cytoprotective effects in rodent models of GI mucosal injury, including gastric ulcers, inflammatory bowel conditions, and intestinal anastomosis healing. Human clinical data are absent for injectable GI applications.
- **Nitric Oxide & Vascular Signaling —** BPC-157 has been reported in preclinical models to interact with the NO-cGMP signaling pathway, which may influence local blood flow and nutrient delivery to injured tissue. Human data are limited.
- **Angiogenesis & Wound Healing —** Animal studies report associations between BPC-157 and upregulation of VEGF, EGF, and other growth factors, promoting angiogenesis and wound closure. Comparable effects have not been demonstrated in adequately powered human trials.
- **Chronic Pain & Persistent Inflammation —** Investigational only; not a substitute for evidence-based pain management. Preclinical anti-inflammatory signaling data exist; clinical relevance in humans is not established.
- **Corneal & Ocular Injury —** Described in preclinical models only. No controlled human data.
- **Cardiac Ischemia/Reperfusion —** Described in preclinical models only. No controlled human data.

2 · Mechanism of Action

The mechanisms below summarize proposed biological activity based on preclinical in vitro and animal data. None of the mechanisms described have been validated as establishing clinical efficacy in adequately powered human clinical trials.

- **Growth Factor Upregulation —** In preclinical studies, BPC-157 has been associated with changes in VEGF, EGF, and other growth factor signaling pathways related to angiogenesis and collagen synthesis in damaged tissues. These effects are reported in animal and cell-culture models; human translation has not been established.
- **Nitric Oxide (NO) Pathway —** BPC-157 has been reported in preclinical models to interact with the NO-cGMP signaling pathway. This mechanism is proposed to increase blood flow and nutrient delivery to injured tissue by promoting vasodilation. Human data are limited.
- **Tendon & Ligament Healing —** Animal studies report associations between BPC-157 and enhanced fibroblast activity and increased collagen type I expression. These changes in connective tissue markers are proposed to accelerate repair of tendons, ligaments, and other structural tissues; efficacy in human tendon/ligament injury has not been established in controlled trials.
- **Cytoprotective Effects —** Derived from gastric juice proteins, BPC-157 has demonstrated cytoprotective activity in preclinical gastrointestinal and tissue models, proposed to protect mucosal and systemic tissue from injury. Clinical relevance in humans has not been established.
- **Inflammatory Signaling Modulation —** BPC-157 is hypothesized, based on animal data, to modulate pro-inflammatory signaling pathways. The clinical relevance of this proposed anti-inflammatory activity in humans is not established.
- **Fibroblast Activity & Collagen Synthesis —** BPC-157 has been reported in preclinical studies to be associated with changes in fibroblast proliferation and collagen synthesis markers. Comparable effects have not been demonstrated in adequately powered human trials.

3 · Areas of Investigational Interest

The categories below reflect investigational or anecdotal use discussions only and do not represent approved or evidence-based indications. Limitations apply to each.

Investigational Categories (Not Approved Indications)

- Recurrent or overuse musculoskeletal injury — investigational only; no controlled human trials support routine use
- Recovery following surgery — investigational only; not an FDA-approved indication and no controlled human data support efficacy or safety in the postoperative setting
- Chronic pain or persistent inflammation — investigational only; not a substitute for evidence-based pain management
- Reduced mobility — investigational only; functional outcomes have not been demonstrated in controlled human studies
- Inadequate response to conventional therapy — investigational only; no comparative-effectiveness data exist
- Athletes should be screened for WADA-prohibited substances; see Contraindications

Additional Areas Described in Preclinical Literature Only (Not Approved Indications)

- Gastrointestinal mucosal injury (rodent models only)
- Cutaneous wound healing (rodent models only)
- Corneal and ocular injury (preclinical models only)
- Cardiac ischemia/reperfusion (preclinical models only)
- Tendon, ligament, and connective-tissue injury (preclinical models only)

Note: BPC-157 is investigational. Prescribing decisions should be made based on individual patient assessment, current literature, and clinical judgment.

4 · Dosing & Administration

DOSING DISCLAIMER

No validated dosing regimen exists for BPC-157. The values shown below reflect internal practice examples and published preclinical literature conventions only and are not evidence-based dosing guidance. Dosing has not been standardized or validated in controlled human studies. All dosing decisions remain with the prescribing clinician.

4.1 Investigational Subcutaneous Dosing (Clinical Practice Conventions)

Parameter	Common Practice (Non-Validated)
Weekly Dose Range	1.25–7 mg
Common Dose	0.5 mg daily
Combination Stack Example (internal use only)	0.75 mg (0.25 mL / 25 units) once daily Mon–Fri
Weekly Dose (Standalone)	~2.5–3.5 mg (individualized)
Frequency	Daily or 5 days on / 2 days off (weekends off)
Injection Sites	Abdomen, glute, upper arm, thigh — rotate sites with each injection

No dose-finding, pharmacokinetic, or exposure-response studies have been published for subcutaneous BPC-157 in humans. The values above reflect clinical practice convention only.

4.2 Compounded Vial Specifications

Parameter	Detail
Vial Size	5 mL
Concentration	3 mg BPC-157 per mL
Beyond-Use Date (BUD)	45 days from compounding date; refer to lot-specific labeling
Maximum Day Supply	30 days
Storage	Refrigerate at 2–8°C; protect from light
Distribution	Texas only

4.3 Route & Technique

- Route: Subcutaneous injection
- Sites: Abdomen, glute, upper arm, thigh — rotate injection sites with every administration
- Inspect vial before use: discard if cloudy, discolored, or particulate matter is present
- Use strict aseptic technique to minimize infection risk

5 · Contraindications & Warnings

Contraindications

- Pregnancy and breastfeeding — avoid use; safety not established
- Competitive athletes subject to anti-doping rules — BPC-157 is prohibited under WADA regulations; screen all patients for competitive athletic status prior to prescribing
- Active or suspected malignancy, or history of malignancy — avoid use given theoretical concerns regarding angiogenic signaling (VEGF upregulation)
- Unknown long-term safety — long-term human safety data are not established; risks of cumulative or delayed adverse effects cannot be excluded
- Injection-related infection and sterility risk — inherent risk of local infection, abscess, or systemic infection with any subcutaneous injection; strict aseptic technique is required
- Lack of controlled human safety data — no controlled human trials have evaluated BPC-157 by subcutaneous injection; safety profile, dose-response, and incidence rates are not established

WADA ANTI-DOPING NOTICE

BPC-157 is a prohibited substance under the World Anti-Doping Agency (WADA) Prohibited List. Prescribers should screen patients for competitive athletic status and relevant anti-doping obligations prior to prescribing. Prescribing BPC-157 to a competitive athlete subject to WADA regulations may result in a regulatory violation for the athlete.

Precautions

- **Potential Immune Response —** Antibody formation has been reported with peptide therapies. Monitor for signs of immune reaction, particularly with repeated courses.
- **Immune Reaction Management —** Hold therapy and evaluate if immune reaction is suspected. Manage per clinician judgment; antihistamines may be considered for mild hypersensitivity if clinically appropriate. Discontinue and evaluate for suspected immune response.
- **Angiogenic Activity —** BPC-157 is proposed to upregulate VEGF and promote angiogenesis in preclinical models. Theoretical concern exists regarding promotion of growth in undetected or occult malignancy. Screen patients for malignancy risk factors before prescribing.
- **Combination Use —** Combination ("stacking") use with other investigational peptides has not been evaluated in controlled trials. Additive or unpredictable interactions may occur. Use clinical judgment when prescribing alongside other investigational agents.

6 · Adverse Effects

Frequency descriptors reflect limited internal observational, uncontrolled prescribing experience and published preclinical/case literature, not validated incidence rates from controlled clinical trials. The true frequency, severity profile, and causality of adverse events with BPC-157 subcutaneous injection are not established.

Adverse Effect	Frequency / Severity	Management
Injection site irritation (erythema, pain, induration)	Reported / Mild	Rotate sites; cool compress if needed; use proper injection technique
Fatigue	Reported / Mild	Monitor; typically transient; assess dose
Nausea	Reported / Mild	Reduce dose if persistent; administer at night
Headache	Reported / Mild	Monitor; assess hydration
Antibody / immune response	Uncertain incidence / Variable	Hold therapy and evaluate. Antihistamines may be considered for mild hypersensitivity if clinically appropriate. Discontinue for suspected immune response.
WADA violation risk	If competitive athlete / Regulatory	Screen all patients prior to prescribing; confirm anti-doping obligations

7 · Drug Interactions

No controlled human drug interaction studies have been conducted for BPC-157. The following theoretical interactions are based on proposed preclinical mechanisms only.

Interacting Drug / Class	Theoretical Effect & Clinical Recommendation
Anticoagulants / antiplatelet agents	Theoretical additive bleeding risk based on hypothesized angiogenic and NO-pathway activity; not clinically established. No controlled human interaction data exist; use clinical judgment.
NSAIDs	Theoretical pharmacodynamic interaction with inflammatory pathways; not clinically established. Effect on efficacy and safety is unknown; use caution.
Immunosuppressants	Theoretical interaction based on preclinical immune-modulation data; not clinically established. No human interaction data; use caution and monitor as clinically indicated.
Other investigational peptides	Additive or unpredictable interactions; not evaluated in humans. Not recommended unless clinically justified and benefits outweigh unknown risks.

8 · Storage & Handling

Parameter	Detail
Temperature	Refrigerate at 2–8°C

Parameter	Detail
Light Sensitivity	Protect from light; store in original packaging
Appearance / Inspection	Discard if cloudy, discolored, or particulate matter present
Beyond-Use Date (BUD)	45 days from compounding date; refer to lot-specific labeling
Maximum Day Supply	30 days
Distribution	Texas only
Disposal	Follow applicable federal/state guidelines for disposal of compounded medications

9 · Limitations of Evidence

BPC-157 has primarily preclinical data. No controlled human clinical trial has evaluated subcutaneous BPC-157 for any indication. The limitations below are critical for accurate clinical interpretation and must be communicated to patients during informed consent.

- **No Controlled Human Clinical Trials by Subcutaneous Route:** No randomized, controlled human trial has evaluated subcutaneous BPC-157 for any indication. Internal ReviveRX prescribing observations are observational, uncontrolled, and not sufficient to establish safety, efficacy, incidence rates, or causality; they should not be cited as clinical evidence.
- **Preclinical Evidence Base:** The majority of mechanistic and efficacy data for BPC-157 derive from rodent and in vitro models. Human-to-animal translation has not been confirmed in powered RCTs. Positive findings in animal models do not establish clinical efficacy or safety in humans.
- **Long-Term Safety Data Not Established:** Long-term human safety data for subcutaneous BPC-157 are not available. Risks of cumulative or delayed adverse effects — including effects related to angiogenic signaling, immune response, or other proposed mechanisms — cannot be excluded.
- **FDA Regulatory Status:** BPC-157 is not an FDA-approved drug product. The FDA has reviewed, and continues to review, the bulk-substance status of BPC-157 for compounding under sections 503A/503B of the FD&C Act. Prescribers should confirm the current FDA bulk-substance status before prescribing or dispensing. Compounding and prescribing of this substance may carry enforcement risk depending on current FDA and applicable state-board positions, which can change. This document does not constitute legal or regulatory advice; prescribers and pharmacies are responsible for verifying compliance with all applicable federal and state requirements.
- **WADA Prohibition:** BPC-157 is prohibited under WADA. All patients must be screened for competitive athletic status prior to prescribing.
- **Pharmacokinetics Uncharacterized in Humans:** No published pharmacokinetic study has characterized the absorption, distribution, metabolism, or excretion of subcutaneous BPC-157 in humans. Bioavailability, tissue distribution, and optimal dosing are unknown.
- **Combination Use Not Evaluated:** BPC-157 is sometimes prescribed in combination with other investigational peptides (e.g., Thymosin Beta-4). Such combination use has not been evaluated in controlled trials; additive or unpredictable risks are unknown.

10 · Special Populations

Population	Guidance
Pregnancy	Avoid use; safety not established in humans or animals for this route and indication
Lactation	Avoid use; unknown excretion and potential effects on nursing infants
Pediatrics	Not established; no safety or efficacy data in pediatric populations
Active malignancy	Contraindicated; theoretical angiogenic signaling (VEGF upregulation) may support tumor vascularity
History of malignancy	Use with extreme caution; assess benefit vs. theoretical risk; oncology consultation recommended

Population	Guidance
Competitive athletes (WADA)	Contraindicated; BPC-157 is a WADA-prohibited substance. Screen all patients before prescribing.
Renal impairment	No data; pharmacokinetics are uncharacterized; exercise caution
Hepatic impairment	No data; monitor as clinically indicated
Immunocompromised patients	Theoretical immune-modulation concerns; use caution; monitor for immune reactions

11 · References & Disclaimer

Key References

Sikiric P, et al. Brain-gut Axis and Pentadecapeptide BPC 157. Curr Neuropharmacol. 2016;14(8):857–865.

Chang CH, et al. The promoting effect of pentadecapeptide BPC 157 on tendon healing. J Appl Physiol. 2011;110(3):774–780.

Sikiric P, et al. Stable Gastric Pentadecapeptide BPC 157 and the Central and Peripheral Nervous System. Neural Regen Res. 2016;11(12):1938–1940.

Gwyer D, Bhatt DL, Bhatt N. BPC 157 and Standard NSAID Treatment on Tendon Healing: an Animal Study. J Orthop Surg Res. 2019;14:123.

Sikiric P, et al. Toxicity by NSAIDs. Counteraction by Stable Gastric Pentadecapeptide BPC 157. Curr Pharm Des. 2013;19(1):76–83.

World Anti-Doping Agency (WADA). Prohibited List. Current edition. https://www.wada-ama.org/en/prohibited-list

ReviveRX internal prescribing data (observational). Data on file.

DISCLAIMER

This Educational Clinical Overview is intended exclusively for licensed healthcare professionals and is not intended as patient-directed information. The information contained herein is for educational purposes only and does not constitute medical advice.

BPC-157 is not an FDA-approved drug product for any indication. All injectable use is investigational. Compounded medications are not FDA-approved drug products. The FDA bulk-substance status of BPC-157 for compounding under sections 503A/503B may be subject to change; prescribers and pharmacies are responsible for verifying compliance with all applicable federal and state requirements. Prescribers are solely responsible for all clinical decisions, patient counseling, informed consent, and documentation. This document is subject to revision.