Semax — Research Summary

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1. What It Is

Semax is a synthetic heptapeptide derived from the ACTH(4-10) fragment — the melanocyte-stimulating portion of adrenocorticotropic hormone — modified with a Pro-Gly-Pro extension for stability and central nervous system penetrance. It was developed at the Institute of Molecular Genetics in collaboration with Moscow State University. Despite its ACTH-fragment origin, Semax lacks ACTH's hormonal (adrenal-stimulating) activity and instead targets neurotrophic signaling pathways.

- **Regulatory status:** Semax has been used clinically in Russia as a nasal spray (Semax® and Semax 1%) for stroke recovery, cognitive decline, and optic nerve disease. It has never been approved by the FDA or EMA. The FDA has noted concerns for compounded Semax around limited human safety information, immunogenicity risk, and peptide-related impurities.
- **PCAC update (July 24, 2026):** The FDA's Pharmacy Compounding Advisory Committee voted 8–5 to recommend Semax for inclusion on the 503A Bulk Drug Substances List for cerebral ischemia, migraine, and trigeminal neuralgia, overriding FDA staff's recommendation against inclusion. This is a non-binding advisory recommendation only — it does not add Semax to the list, does not authorize compounding, and does not change RUO sale status. A formal rulemaking process, expected to take 8–12 months, would be required before any actual change takes effect.

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2. Reported Effects in Research Literature

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- **Neurotrophic mechanism:** Animal research reports Semax upregulates brain-derived neurotrophic factor (BDNF) and its receptor TrkB in the hippocampus and prefrontal cortex, supporting neuroplasticity and learning. Also reported to modulate dopaminergic and serotonergic/noradrenergic transmission and increase nerve growth factor (NGF) expression.
- **Human evidence — strongest in stroke recovery:** The most substantial human clinical data comes from neurological disease settings, particularly ischemic stroke recovery, where Semax's role in BDNF elevation and motor function improvement has been documented in controlled clinical trials conducted in Russia.
- **Cognitive research in healthy adults:** Older publications from Russian pharmacology groups report improvements in memory and attention in healthy men under cognitively demanding conditions. Neuroimaging studies in healthy subjects have documented measurable changes in brain network activity following intranasal administration.
- **Other studied contexts (varying evidentiary strength):** anxiety, ADHD, opioid withdrawal, and neurodegenerative disease (ALS, Parkinson's, Alzheimer's) — these applications are discussed in the literature but with less robust controlled trial support than the stroke-recovery indication.

Research limitation to note: Translating Semax's stroke-recovery and cognitively-demanding-task findings to general cognitive enhancement in healthy adults is not directly supported by the same evidence tier — the strongest data is disease-specific (stroke), not a general nootropic-use dataset.

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3. Clinical & Preclinical Study References

- BDNF upregulation research (hippocampus/prefrontal cortex). PMID: 14556513

- Dopaminergic transmission modulation research. PMID: 16996037
- Serotonin/norepinephrine modulation research. PMID: 16362768
- Overview: Semax vs Selank: Nootropic Peptide Comparison (Peptpedia)
- Overview: Semax and Selank: The Cognitive Peptides Now Legal for Compounding — What the Evidence Says (Meto)

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4. Reconstitution Process

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1. **Materials needed:** lyophilized (freeze-dried) Semax 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. **Add the water slowly** down the *inside wall* of the vial, to reduce shear/foaming.
5. **Do not shake.** Gently swirl or roll between palms until fully dissolved.
6. **Inspect the solution** — should be clear and free of particulates.
7. **Label the vial** with reconstitution date and concentration.
8. **Storage:** refrigerate (2–8°C); avoid freeze-thaw cycles. Note: Semax is also commonly formulated as an intranasal solution in the research literature (its historical Russian clinical use); if reconstituting for that context, follow supplier-specific concentration guidance since nasal-spray formulations differ from injectable reconstitution.

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.

This document is intended for research and internal reference use only. It does not constitute medical advice, dosing guidance, or an endorsement of human use. Semax is not FDA-approved; it has clinical use history in Russia only.