Semax Research Summary

Research Library Summary — PHX Performance Research

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What the Research Suggests, in Plain Language

Semax is a lab-made peptide based on a fragment of a natural hormone. It is a registered prescription medicine in Russia, but it is not approved in the U.S. or Europe. Most of the research comes from Russian labs.

• In animal studies, mostly in rats, results suggest Semax may be linked to higher levels of brain proteins that support nerve cells, and to protective effects in experiments that model stroke and other brain injuries. Some animal experiments also reported effects on learning.

• In people, the evidence comes from small Russian clinical reports, mostly without a comparison group, in stroke, optic nerve disease and other brain conditions. One small controlled study in 27 people with motor neuron disease found no change in the course of the disease, but reported better quality-of-life scores.

• No large, well-controlled trials of the kind required in the U.S. or Europe have been published.

In short: these studies point to possibilities for further research. They do not show that Semax is safe or effective in people outside the settings studied.

Overview

Semax is a synthetic heptapeptide (seven amino acids) based on a fragment of adrenocorticotropic hormone, ACTH(4-10). It is a registered prescription drug in Russia (as a nasal preparation). It is not FDA- or EMA-approved.

What the Research Actually Presents

Animal studies (~155 records, mostly Russian):

• Ischemia and neurotrophic models: Researchers observed changes in brain-derived neurotrophic factor (BDNF) and nerve growth factor (NGF) expression and reported neuroprotective observations in the brain injury models tested. A 2006 rat study (PMID 16996037) reported increased hippocampal BDNF protein and mRNA after Semax administration.

• Route comparisons: A 2010 rat study (PMID 21268834) compared intranasal and intraperitoneal administration and reported that learning effects were stronger after intranasal administration, while effects on pain sensitivity were seen only after intraperitoneal administration.

Human series (mostly non-randomized Russian clinical reports): Studies report changes in BDNF levels and clinical observations in stroke patients (for example, 43 patients, PMID 29798983), optic nerve disease, and encephalopathy. These used the intranasal route.

Administration routes reported in the literature (descriptive only): The published human clinical series used the intranasal route. Animal studies used intranasal, subcutaneous, and intraperitoneal administration and reported model-specific behavioral and neurotrophic findings. No published human pharmacokinetic or efficacy studies of subcutaneous Semax were identified.

One small controlled study in motor neuron disease (27 patients; PMID 18379501) is listed. It reported no effect on disease course and improved quality-of-life scores. No ClinicalTrials.gov registrations.

What the Research Suggests

In animal ischemia and neurotrophic models, Semax administration was associated with increased BDNF/NGF expression and neuroprotective observations. Route-dependent differences in learning and pain-sensitivity effects have been reported in rats.

Small Russian human series report clinical observations in the conditions studied using the intranasal route. No large Western-standard randomized controlled trials are identified.

Mechanism and Signaling Pathways (as described in the literature)

Russian literature describes Semax in the context of BDNF and NGF expression, activation of the BDNF receptor TrkB, and gene-expression changes in animal models.

Research Landscape

Catalog: 211 records — 1 human randomized controlled trial (RCT), 20 other human, 155 animal, 6 in-vitro, 12 reviews, 0 systematic reviews/meta-analyses, 17 other. Many records are in Russian (89 with English abstracts only). Russian databases such as eLIBRARY and CyberLeninka were not searched, so more Russian clinical papers likely exist.

Key Studies

• Dolotov OV et al. 2006 (Brain Research): animal study (rats), BDNF and TrkB in the hippocampus (PMID 16996037).

• Manchenko DM et al. 2010: animal study (rats) comparing intranasal and intraperitoneal routes (PMID 21268834).

• Serdiuk AV et al. 2007: small controlled human study in motor neuron disease; 27 patients (PMID 18379501).

• Gusev EI et al. 2018: human clinical series in ischemic stroke; 43 patients (PMID 29798983).

Safety Findings Reported in the Studies

Safety data limited to small Russian clinical series.

Limitations and Evidence Gaps

No large Western-standard RCTs. Many full texts are Russian-only. Human subcutaneous data are absent.

Regulatory Status

Registered prescription drug in Russia (first registered 1994; current registration LS-002553, 2011) and on Russia's essential-drugs list. Not FDA- or EMA-approved. Included in the Department of Health and Human Services (HHS) draft/interim 503A compounding enforcement-discretion policy (October 2026).

References

Dolotov OV et al. 2006 (PMID 16996037, BDNF study). Manchenko DM et al. 2010 (PMID 21268834, route comparison). Serdiuk AV et al. 2007 (PMID 18379501). Gusev EI et al. 2018 (PMID 29798983). Additional Russian sources in the catalog.

Evidence reviewed through November 2026 (PHX research catalog snapshot of PubMed, ClinicalTrials.gov and Europe PMC).

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