

Epitalon (Epithalon) — Research Summary

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1. What Is Epitalon

Epitalon (also spelled Epithalon or Epithalone) is a synthetic tetrapeptide composed of four amino acids: alanine, glutamic acid, aspartic acid, and glycine (sequence: Ala-Glu-Asp-Gly, abbreviated AEDG).

- **CAS Number:** 307297-39-8
 - **Origin:** Developed in the 1980s by a research team led by Prof. Vladimir Khavinson at the St. Petersburg Institute of Bioregulation and Gerontology, based on the amino acid composition of Epithalamin — a crude polypeptide extract derived from bovine pineal glands.
 - **Distinction from Epithalamin:** Epithalamin is a heterogeneous mixture of multiple pineal polypeptides with variable composition between extraction batches. Epitalon is the single, purified, standardized synthetic peptide isolated from that mixture. Because Epitalon is synthetic and standardized, it offers consistent, reproducible composition from batch to batch, unlike crude extract preparations.
 - **Research focus areas:** telomere biology and telomerase activity, melatonin secretion and circadian rhythm regulation, pineal gland function, and broader markers of cellular aging.
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2. Reported Effects in Research Literature

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The following are effects reported in published preclinical and clinical research. These are findings from the literature — not verified therapeutic claims, and not evidence of safety or efficacy for human use.

- **Telomerase activity / telomere length:** Research has reported that Epitalon can induce telomerase activity and telomere elongation in human somatic cell lines, extending proliferative capacity in fibroblast cultures.
- **Antioxidant activity:** Comparative studies report Epitalon functions as a more potent antioxidant than crude Epithalamin extract, with Epithalamin requiring substantially higher doses to produce comparable antioxidant effects in the same assays.
- **Melatonin / circadian regulation:** Related research on Epithalamin (not always isolated to pure Epitalon) reports effects on restoring or modulating melatonin secretion patterns, particularly in aged subjects with pineal dysfunction.
- **Oncogene/tumor-related findings:** Rodent studies report reduced tumor incidence and reduced expression of the HER-2/neu oncogene in genetically tumor-prone mouse models, along with antimetastatic effects in spontaneous tumor models.
- **Retinal function:** In the one controlled human clinical trial (detailed below), Epitalon was associated with statistically significant improvement in retinal neuron amplitude activity in retinitis pigmentosa patients, with no reported adverse effects.
- **Lifespan studies (animal models):** Research in rodents and in *Drosophila melanogaster* reports lifespan-extension effects under certain experimental conditions.
- **Neurogenesis / gene expression:** Some studies report Epitalon stimulates gene expression and protein synthesis during neurogenesis, proposed to occur through epigenetic mechanisms.

Important research limitations to note: - The large majority of the evidence base consists of animal, rodent, and in vitro/cell-culture studies conducted by a single Russian research group (Khavinson et al.), without independent replication by outside laboratories. - Only one substantive controlled human clinical trial exists for Epitalon specifically (retinitis pigmentosa, below); other cited “human studies” often

involve Epithalamin (the crude extract), not the isolated synthetic peptide. - Approximately half of the ~110 published papers on Epithalamin/Epitalon are published only in Russian and have not been independently translated or verified in English-language literature. - Epitalon has not undergone the clinical trial process required for pharmaceutical regulatory approval in the United States or European Union, and has no FDA-approved medical use. - **PCAC update (July 24, 2026):** The FDA's Pharmacy Compounding Advisory Committee voted 7-4 (some reports: 7-5 with one abstention) to recommend epitalon for inclusion on the 503A Bulk Drug Substances List for insomnia, overriding FDA staff's recommendation against inclusion. One dissenting committee member specifically cited insufficient data characterizing epitalon as a substance. This is a non-binding advisory recommendation only — it does not add epitalon 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.

3. Clinical & Preclinical Study References

Primary human clinical trial (Epitalon, retinitis pigmentosa): - Study conducted at the St. Petersburg Institute of Bioregulation and Gerontology; 162 patients (ages 18-72) received parabolbar Epitalon injections over 10 consecutive days, compared against a conventional-treatment control group. No adverse effects reported; significant improvement in retinal neuron amplitude activity. - Full overview article: [Overview of Epitalon—Highly Bioactive Pineal Tetrapeptide with Promising Properties \(PMC\)](#)

Key peer-reviewed studies (PubMed): - Anisimov VN, et al. "Epithalon inhibits tumor growth and expression of HER-2/neu oncogene in breast tumors in transgenic mice." *Bull Exp Biol Med*. 2002. PMID: [12428286](#) - Kossoy G, Anisimov VN, et al. "Effect of the synthetic pineal peptide epitalon on spontaneous carcinogenesis in female C3H/He mice." *In Vivo*. 2006. PMID: [16634527](#) - Vinogradova IA, et al. "Effect of Ala-Glu-Asp-Gly peptide on life span and development of spontaneous tumors in female rats exposed to different illumination regimes." *Bull Exp Biol Med*. 2007. PMID: [18856211](#) - Khavinson VK, Bondarev IE, Butyugov AA. "Epithalon peptide induces telomerase activity and telomere elongation in human somatic cells." *Bull Exp Biol Med*. 2003. DOI: 10.1023/A:1025493705728 - Khavinson VK, Zemchikhina VN, Trofimova SV, Malinin VV. "Effects of peptides on proliferative activity of retinal and pigmented epithelial cells." *Bull Exp Biol Med*. 2003. - Sibarov DA, et al. "Effects of intranasal administration of epitalon on neuron activity in the rat neocortex." *Neurosci Behav Physiol*. 2007. PMID: [17955380](#) - Recent telomerase mechanism study: "Epitalon increases telomere length in human cell lines through telomerase upregulation or ALT activity." [PMC12411320](#)

Related Epithalamin (crude extract) human studies, referenced for context — not equivalent to isolated Epitalon: - Khavinson VKh, et al. (2003) — elderly subjects treated with Epithalamin over 2-3 years; reported reduced mortality rate ratio and lower rates of coronary artery disease, hypertension, and osteoarthritis vs. control. - Korkushko OV, Khavinson VKh, Shatilo VB, Magdich LV. "Effect of peptide preparation epithalamin on circadian rhythm of epiphyseal melatonin-producing function in elderly people." *Bull Exp Biol Med*. 2004. PMID: [15452611](#)

Independent third-party review (non-Khavinson group): - Cognitive Vitality Report, Alzheimer's Drug Discovery Foundation: [Epithalamin/Epithalon research summary \(PDF\)](#) — notes lack of independent replication outside the original Russian research group.

4. Reconstitution Process

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1. **Materials needed:** lyophilized (freeze-dried) Epitalon powder, bacteriostatic water (preferred over sterile water for multi-use vials, due to the antimicrobial preservative), alcohol swabs, syringe with needle.
2. **Bring vials to room temperature** before reconstitution to reduce peptide degradation from condensation/temperature shock.
3. **Sanitize** the rubber stopper of both the peptide vial and the bacteriostatic water vial with an alcohol

swab.

4. **Draw the bacteriostatic water** into the syringe.
5. **Add the water slowly**, directing the needle stream down the *inside wall* of the peptide vial rather than injecting it directly onto the lyophilized powder — this reduces mechanical shear/foaming that can degrade the peptide.
6. **Do not shake the vial**. Instead, gently swirl or roll it between your palms until the powder is fully dissolved into a clear solution.
7. **Inspect the solution** — it should be clear and free of particulates. Discard and do not use if cloudy or discolored.
8. **Label the vial** with the reconstitution date and concentration for tracking.
9. **Storage:** refrigerate the reconstituted solution (typically 2–8°C); avoid freeze-thaw cycles, which degrade peptide integrity. Use within the timeframe indicated by your quality/stability documentation.

Reference: Bacteriostatic Water Volume by Vial Size

The table below shows commonly referenced bacteriostatic water (BAC water) volumes for reconstituting standard vial sizes, and the resulting solution concentration. Researchers select the water volume based on the concentration needed for their assay or measurement method (e.g., syringe graduation precision) — no single “correct” volume applies universally.

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 on selecting a volume: - A higher BAC water volume produces a more dilute solution, which allows for finer-grained volume adjustments when using a 1 mL (100-unit) insulin syringe for measurement, at the cost of requiring more storage volume per vial. - A lower BAC water volume produces a more concentrated solution, useful when minimizing solution volume per use is preferred. - Some suppliers pre-mark vials with a fill line; if provided, follow the vial-specific instructions from that supplier’s Certificate of Analysis (COA) or product insert over generic guidance. - Always use bacteriostatic water (containing 0.9% benzyl alcohol) rather than plain sterile water for multi-draw vials, as it inhibits bacterial growth across repeated punctures. Sterile water without a preservative should be used within 24 hours of reconstitution and discarded thereafter.

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.

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