

Epitalon (Epithalon) — Research Summary

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1. What It Is

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.

Developed in the 1980s by Prof. Vladimir Khavinson's team 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. Epitalon is the single, purified, standardized synthetic peptide isolated from that mixture, offering consistent composition unlike the crude extract.

Research focus areas: telomere biology and telomerase activity, melatonin secretion and circadian rhythm regulation, pineal gland function, and broader markers of cellular aging.

2. Reported Effects in Research Literature

The following are findings from the literature — not verified therapeutic claims, and not evidence of safety or efficacy for human use.

- **Telomerase activity / telomere length:** Research reports 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.
- **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.
- **Human/in-vitro immune data:** A 2022 Italy-Russia collaboration (Avolio, Martinotti, Khavinson, et al., published in the International Journal of Molecular Sciences) examined Epitalon in LPS-stimulated THP-1 human monocytes, finding reduced TNF and IL-6 secretion and decreased monocyte adhesion to activated endothelium — a mechanistic anti-inflammatory signal in human immune cells, and a collaborative study extending beyond purely in-house Khavinson-group output.
- **Human circadian data:** A small study (Ivko et al., 2021) in night-shift workers given the peptide found 1.7 times greater excretion of the melatonin metabolite 6-sulfatoxymelatonin, with shifts in circadian-gene expression in blood cells; the study was short, small, and blinding was not clearly specified.
- **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 with a clinical outcome measure, 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.
- **Important limitations:** The large majority of the evidence base consists of animal, rodent, and in vitro/cell-culture studies conducted by a single Russian research group, without independent replication by outside laboratories. Only one substantive controlled human clinical trial with a clinical outcome exists for Epitalon specifically (retinitis pigmentosa); 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.
- **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.

3. Clinical & Preclinical Study References

Primary human clinical trial (retinitis pigmentosa): St. Petersburg Institute of Bioregulation and Gerontology; 162 patients (ages 18–72) received parabulbar Epitalon injections over 10 consecutive days vs. conventional-treatment control. No adverse effects; significant improvement in retinal neuron amplitude activity.

Khavinson VK, Bondarev IE, Butyugov AA. "Epithalon peptide induces telomerase activity and telomere elongation in human somatic cells." Bull Exp Biol Med. 2003.

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." Bull Exp Biol Med. 2007. PMID: 18856211

Avolio F, Martinotti S, Khavinson VK, et al. Epitalon anti-inflammatory effects in LPS-stimulated human THP-1 monocytes. Int J Mol Sci. 2022.

Ivko OM, et al. Epithalamin/epitalon effects on melatonin metabolite excretion in night-shift workers. 2021. PMID: 33280326

Sibarov DA, et al. "Effects of intranasal administration of epitalon on neuron activity in the rat neocortex." Neurosci Behav Physiol. 2007. PMID: 17955380

Regulatory/Safety Note: 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.

Verification Update: Two additional citations were identified and added: a 2022 human-monocyte in-vitro study (Avolio et al., IJMS) and a 2021 human circadian/melatonin-metabolite study in night-shift workers (Ivko et al., PMID 33280326). Both are small studies from research groups connected to the original Khavinson network and do not change the overall conclusion that independent, large-scale human replication remains absent.

This compound has not been evaluated by the FDA and is not intended to diagnose, treat, cure, or prevent any disease in humans or animals.

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