

Ashwagandha

Withania somnifera — Indian winter cherry; sold as KSM-66, Sensoril, Shoden and generic root extracts

Ashwagandha carries the best efficacy evidence of any adaptogen sold at retail, and simultaneously the most serious active safety question in this class. Two 2025 meta-analyses confirm a reliable cortisol-lowering effect and a probable benefit for stress and anxiety over eight weeks. In the same period, regulators in at least six countries — most recently Australia, which issued a medicine safety advisory in September 2026 — have restricted or warned against it, and NIH LiverTox now classes it a likely cause of clinically apparent liver injury.

SUMMARY TABLE

Attribute	Summary
Primary uses	Lowering cortisol and perceived stress; easing anxiety; improving sleep onset; supporting exercise recovery; modest testosterone support.
Evidence strength	Moderate for cortisol reduction (consistent across 2025–26 trials). Moderate for stress/anxiety scales at 8 weeks. Weak for testosterone, fertility, cognition.
Effective dose	300–600 mg/day of KSM-66-type root extract (≥5% withanolides), or 125–250 mg/day of Sensoril-type (10%+ withanolides). 600 mg/day for 8 weeks is the most-replicated protocol.
How to take	With food, in capsule form; splitting 600 mg into two 300 mg doses reduces nausea and loose stool. Evening favors sleep; morning or split dosing favors daytime stress.
Time to effect	Subjective calm within 1–2 weeks; cortisol and validated stress/anxiety scales show clearest separation from placebo at 8 weeks.
Serious risks	NIH LiverTox likelihood B (likely cause of drug-induced liver injury; ~23 published cases, onset 2–12 weeks, cholestatic/mixed pattern). Fatal outcomes reported in pre-existing liver disease. Can raise T3/T4.
Who should avoid it	Anyone with liver disease, pregnancy, hyperthyroidism or thyroid replacement therapy, immunosuppressant use, hormone-sensitive prostate cancer, or in childhood.
Quality markers	Named clinical extract with stated withanolide %; root-only sourcing disclosed; third-party heavy-metal testing; USP/NSF certification; certificate of analysis available.

MECHANISM AND THE 2025–26 EVIDENCE

Withanolides, steroidal lactones concentrated in the root, are the presumed active constituents, with the dominant hypothesis being modulation of the hypothalamic-pituitary-adrenal axis rather than direct sedation or stimulation. That mechanism predicts exactly the pattern seen in the trial literature: a reliable hormonal change and a less reliable subjective one.

A 2025 meta-analysis in BJPsych Open (15 RCTs, 873 patients) found cortisol fell 2.36 units, Perceived Stress Scale scores fell 4.88 points, and Hamilton Anxiety scores fell 3.52 points at 8 weeks (all $p<0.01$). A narrower 2025 analysis (Albalawi et al., Nutrition and Health; 488 participants) reproduced the cortisol effect but found no significant change in perceived stress, underscoring that the biochemical effect is more robust than the subjective one.

A September 2026 60-day Indian trial (published in *Stress*) extended this to a mixed-risk population — adults with mild stress, anxiety and hypertension — reporting reductions in cortisol, daytime sleepiness, fatigue, triglycerides and blood-pressure parameters at 600 mg/day, suggesting a possible role alongside standard cardiovascular risk management.

THE LIVER QUESTION AND REGULATORY RESPONSE

NIH LiverTox assigns ashwagandha a likelihood score of B on the basis of roughly 23 published cases, typically presenting 2–12 weeks after starting with a cholestatic or mixed injury pattern; most resolve within 1–4 months of stopping, but fatal acute-on-chronic liver failure has occurred in patients with pre-existing liver disease.

Denmark banned ashwagandha in food and supplements in 2023; the Netherlands, France and Germany have issued cautions for vulnerable groups; the UK opened a formal risk-assessment review in 2024. Australia's Therapeutic Goods Administration added a fresh medicine safety advisory in September 2026, extending this international pattern. A 12-month observational safety study in healthy adults found no major safety signal, but such designs are poorly suited to detecting rare, idiosyncratic liver injury.

BOTTOM LINE

For a healthy adult with no liver disease, no thyroid condition, no immunosuppressant prescription and no pregnancy, a named clinical extract at 300–600 mg daily for 8–12 weeks remains a reasonable, evidence-backed trial. Take it with food, buy a product with a stated withanolide percentage and heavy-metal testing, and stop immediately for jaundice, dark urine, persistent itching or unexplained fatigue. A liver panel is a sensible precaution if use continues past three months.

SOURCES

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3. NIDDK. "Ashwagandha." LiverTox, NCBI Bookshelf, updated 2024.
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