

Ashwagandha SAP

Science-based nutraceutical for optimal health

Commonly known as ashwagandha, 'Indian ginseng', or winter cherry, *Withania somnifera* has been used as a staple ingredient in Ayurvedic preparations due to its numerous therapeutic properties for over 3000 years. This plant has been used in the treatment of asthma, bronchitis, ulcers, insomnia and inflammation. Ashwagandha is a unique herb with adaptogenic benefits, which helps modulate stress and anxiety responses to external and internal stimuli. In recent years, clinical trials have supported the use of ashwagandha for weight management, muscle strength, sexual health in men and women, and various neurological disorders.

Ashwagandha SAP may help alleviate chronic stress, and improve overall quality of life and can be used to relieve general debility, especially during convalescence or old age. **Ashwagandha SAP** may help support testosterone production in males, improve sexual function in females. **Ashwagandha SAP** may help improve muscle strength and is an ideal workout/exercise supplement.

ACTIVE INGREDIENTS

Each vegetable capsule contains:

Ashwagandha (Withania somnifera) root extract (5% withanolides). 500 mg

Other ingredients: Vegetable magnesium stearate and a vegetable capsule composed of vegetable hypromellose and purified water.

Contains no: Gluten, soy, wheat, corn, eggs, dairy, yeast, citrus, preservatives, artificial flavour or colour, starch, or sugar.

This product is non-GMO and vegan friendly.

Ashwagandha SAP contains 60 and 120 capsules per bottle.

DIRECTIONS FOR USE

Adults: See indication specific dosages below outlined in the table.

Ashwagandha SAP can be taken with or without food. Some people may experience mild stomach discomfort, while taking on an empty stomach and can be taken after a small snack.

INDICATIONS

Ashwagandha SAP can help:

- Increase resistance to chronic stress and improve overall quality of life.
- Improve fatigue and anxiety and improve sleep.
- Support physical aspects of sexual health in females and improve testosterone production in males.
- Promote nerve health and enhance memory.
- Relieve general debility, especially during convalescence or old age.

CAUTIONS AND WARNINGS

Consult a healthcare practitioner prior to use if you are pregnant or breast feeding. Consult a healthcare practitioner prior to use if you have benign prostate hypertrophy and/or prostate cancer. If you have been diagnosed with hypoactive sexual disorder, sexual dysfunction, or erectile dysfunction, consult a health care practitioner prior to use. Consumption with alcohol, other drugs or natural health products with sedative properties is not recommended.

PURITY, CLEANLINESS, AND STABILITY

All ingredients listed for each **Ashwagandha SAP** lot number have been tested by an ISO 17025 accredited third-party laboratory for identity, potency, and purity.



Scientific Advisory Panel (SAP):
adding nutraceutical research
to achieve optimum health



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ASHWAGANDHA

Withania somnifera is a well-recognized herb worldwide due to its wide distribution and its use in traditional medicine. This small shrub herb belongs to the family Solanaceae, and grows up to a height of 0.5-2m. Geographically, ashwagandha grows in India, Sri Lanka, China, Canary Islands, Middle east, and South Africa, it has however been found in Australia and warmer regions of Europe as well ^(1,2). The unique phytochemical composition of ashwagandha consists of more than 40 withanolides, sitoindosides and over 12 alkaloids, which give the plant its unique therapeutic properties ⁽³⁾. Ashwagandha has been used in traditional medicine for the treatment of stress, inflammation, ulcers, acne, rheumatism, senile debility, nervous breakdowns; and has even been prescribed for snake venom and scorpion stings ⁽⁴⁾. In recent times, clinical trials have been conducted to support these claims. Ashwagandha has been found to not only have specific therapeutic properties, but also improve overall health and quality of life.

BENEFITS IN NEUROLOGICAL DISORDERS

Ashwagandha has long been used in the traditional medicinal system as a nerve tonic. In recent years, several clinical trials have further elucidated the benefits of ashwagandha in the treatment of neurological disorders. In a randomized double blind placebo-controlled trial conducted with 30 obsessive compulsive disorder (OCD) patients, a dose of 120mg per day for 6 weeks significantly improved OCD symptoms compared to placebo ⁽⁵⁾. Administration of 500 mg of ashwagandha extract for 8 weeks to 53 patients suffering from bipolar disorder showed significant changes in cognitive responses, such as improved reaction time and social cognition ⁽⁶⁾. Thirty schizophrenic patients suffering from dyslipidemia, a side effect of anti-psychotics, showed remarkable decrease of serum triglycerides and fasting blood glucose after consumption of 400 mg ashwagandha extract thrice a day for one month ⁽⁷⁾. A preliminary study in ten patients suffering from degenerative cerebellar ataxia showed improved anteroposterior balance in these patients after administration of 500 mg ashwagandha thrice a day for one month ⁽⁸⁾. These benefits could potentially be attributed to the ability of withanolides to modulate cholinergic pathways, and their modulation of opioid receptors ^(9,10).

STRESS RELIEF AND REJUVENATION

In addition to psychological disorders, ashwagandha has the unique quality of being an adaptogenic herb, and shows capacity to attenuate immunosuppression, increased plasma corticosterone, gastric ulcerations and mental depression, which are hallmarks of chronic stress ⁽¹¹⁾. Several clinical trials have been conducted to observe the effects of ashwagandha on stress, anxiety and fatigue. In a non-randomized trial of 100 breast cancer patients undergoing chemotherapy, 2 g of ashwagandha extract was administered every 8 hours throughout the course of chemotherapy. Compared with the control group, patients administered ashwagandha extract showed significantly less fatigue and significant changes in symptoms, indicative of an improved quality of life ⁽¹²⁾. In one study conducted with 52 participants suffering from chronic stress found that administration of 300 mg of ashwagandha extract twice a day for 8 weeks showed a significant improvement in perceived stress, food cravings as well as serum cortisol, body weight and body mass index ⁽¹³⁾. Another study conducted with 41 employees with moderate to severe anxiety exhibited reduced anxiety levels, better concentration, less fatigue and an improved quality of life after being administered 300 mg of ashwagandha extract twice a day for 12 weeks ⁽¹⁴⁾.

DIABETES AND CARDIOVASCULAR BENEFITS

Apart from mental disorders and ailments, ashwagandha has other numerous physiological benefits. In a cohort of six participants diagnosed with non-insulin dependent diabetes mellitus and hypercholesterolemia, a dose of 3 g per day for 30 days brought about a reduction in blood glucose comparable to the effect of an oral hypoglycemic drug. Subjects also showed reduction in levels of serum triglycerides, low density lipoproteins (LDL) and very low density lipoproteins (VLDL) ⁽¹⁵⁾. In a randomized, double blinded placebo controlled study conducted with 57 participants, consuming 300 mg of ashwagandha extract twice a day for 8 weeks significantly increased muscle strength and mass, and reduced muscle damage and body fat percentage ⁽¹⁶⁾.

PAIN AND IMMUNE SUPPORT

In a pilot study that evaluated the administration of 5 g of ashwagandha extract twice a day for 3 weeks to 78 participants, a remarkable reduction in intensity of tender joints, swollen joints and pain were observed ⁽¹⁷⁾. In another study, the effect of ashwagandha extract on immune cells was investigated in five participants who were administered 6 ml of ashwagandha root extract twice a day for 96 hours. The researchers found that the expression of all immune cell receptors such as CD4 and CD56 receptors was increased, indicating the immune response modulating properties of ashwagandha ⁽¹⁸⁾.

REPRODUCTIVE HEALTH

Given the overall health benefits of ashwagandha, its uses in improvement of reproductive health have been studied, and beneficial effects in male and female sexual health have been observed. In a pilot study conducted with 50 subjects, 300 mg of high-concentration ashwagandha root twice daily for 8 weeks improved Female Sexual Function Index (FSFI), Female Sexual Distress Scale (FSDS) in participants compared to placebo treatment ⁽¹⁹⁾. Ashwagandha was found to improve levels of lactate, alanine, citrate, histidine, phenylalanine in seminal plasma, and improve serum biochemistry in 50 infertile men administered 5 g ashwagandha daily for 3 months ⁽²⁰⁾. Administration of 5 g daily for 3 months showed improved sperm count and motility, inhibited lipid peroxidation and restored seminal plasma levels of antioxidant enzymes and vitamins A, C and E, in a study conducted with 75 male participants diagnosed with infertility. Hormone imbalances of testosterone, luteinizing hormone, follicle stimulating hormone also appeared reversed in these subjects compared to control treatment ⁽²¹⁾.

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INDICATION SPECIFIC DOSAGE SUMMARY BASED ON HUMAN CLINICAL RESEARCH#

#Please note these suggestions are guidelines based on the clinical studies. Evidence for efficacy and safety has been qualitatively (study quality in terms of study design, sample size, appropriate methods of analysis, use of appropriate placebo/control, bias etc) assessed and has been rated using a 5 star ★ rating classification.

Indication	Suggested dosage	Supporting evidence and study outcomes	Study design	Outcome measures/ selection criteria for studies	Safety	Evidence quality rating
Neurological Disorders						
OCD ¹	1 capsule/day	Reduction in Obsessive Compulsive Disorder scores	Randomized, double-blind, placebo controlled (n=30, 6 weeks); 120 mg/day	Yale-Brown Obsessive-Compulsive Scale (Y-BOCS). SPSS Kruskal-Wallis and Mann-Whitney U tests	No adverse events reported	★★★★
DSM-IV bipolar disorder ²	2 capsules/day	Improvement in cognition and markers of bipolar disorder	Randomized, double-blind, placebo controlled (n=53, 8 weeks); 500 mg/day (8% withanolides)	Cognition-Digit span backward, Flanker neutral response time, Penn Emotional Acuity Test, ANCOVA	No adverse events reported	★★★★
Schizophrenia (and anti-psychotics induced dyslipidemia) ³	3 capsules/day	Reduction in serum triglycerides, fasting blood glucose	Randomized, double-blind, placebo controlled (n=30, 1 month); 1200 mg/day	Fasting blood glucose, serum triglycerides, high-density cholesterol. Paired t-test and unpaired t-test	No adverse events reported	★★★★
Memory and cognition ⁴	2 capsules/day	Improved immediate and general memory, executive function, sustained attention, information processing speed	Randomized, double-blind, placebo-controlled (n=50, 8 weeks); 600 mg/day	Wechsler Memory Scale III, Erikson Flanker task, Wisconsin Card Sort test, Trial-Making test part A, Mackworth Clock test	No adverse events reported	★★★★
Depression and anxiety (schizophrenia patients) ⁵	2 capsules/day	Improvement of depression single item, depression-anxiety cluster scores	Randomized, double-blind, placebo-controlled (n=66, 12 weeks); 1000 mg/day	Positive and negative syndrome scale (examination of cluster subscores)	Mild and transient adverse effects	★★★★
Progressive degenerative cerebellar ataxia ⁶	3 capsules/day	Improvement in walking, overall and anteroposterior balance- indicators of dynamic stability	Preliminary open labelled study (n=10, 1 month); 1500 mg/day	Biodex balance system, Paired samples t-test	No adverse events reported	★
Stress Management						
Weight management in chronic stress ⁷	2 capsules/day	Improvement in perceived stress, food cravings and serum cortisol, body weight, body mass index	Randomized, double-blind, placebo controlled (n=52, 8 weeks); 600 mg/day	Perceived Stress Scale (PSS), Food Cravings Questionnaire Trait (FCQ-T), Oxford Happiness Questionnaire (OHQ), Three-Factor Eating Questionnaire (TFEQ), serum cortisol, body weight, body mass index	No adverse events reported	★★★★
Anxiety ⁸	1 capsule/day	Reduced anxiety scores, improved mental health, concentration, social functioning, vitality, overall quality of life, reduced fatigue	Randomized, double-blind, placebo controlled (n=75, 12 weeks); 600 mg/day- 1.5% withanolides	Neck Anxiety Inventory (BAI), Short Form 36 (SF-36), Fatigue Symptom Inventory (FSI), Measure Yourself Medical Outcomes Profile (MY-MOP)	No adverse events reported	★★★★
Stress relief ⁹	4 capsules/day	Reduction in anxiety, depression and stress scores, reduced cortisol and DHEA-S levels	Randomized, double-blind, placebo-controlled trial (n=60, 60 days); 240 mg/day- 35% withanolides, 84 mg withanolide glycosides/capsule	Hamilton Anxiety Rating Scale (HAM-A), Depression, Anxiety, Stress Scale-21 (DASS-21), dehydroepiandrosterone-sulphate (DHEA-S), cortisol and testosterone	No adverse events reported	★★★★
Sleep ¹⁰	2 capsules/day	Improvement of sleep parameters, more in insomnia patients, improvement in anxiety scores	Randomized, double-blind, placebo-controlled parallel trial (n=80, 8 weeks); 600 mg/day	Sleep parameters - onset latency, total sleep time, wake after sleep onset, total time in bed, Hamilton Anxiety Rating Scale (HAM-A), Pittsburgh sleep quality index	No adverse events reported	★★★★
Sleep ¹¹	1 capsule/day	Improvement in sleep quality and efficiency, improved quality of life parameters	Randomized, double-blind, placebo-controlled trial (n=150, 6 weeks); 120 mg/day, 21mg withanolide glycosides/capsule	Restorative Sleep Questionnaire, World Health Organization Quality of Life Bref (WHOQOL), sleep parameters - onset, latency, total, wake up time	No adverse events reported	★★★★

Reproductive Health

Male sexual health ¹²	1 capsule/day	Increased levels of DHEA-S and testosterone	Randomized, double-blind, placebo-controlled crossover trial (n=57, 8 weeks); 300 mg/day (21mg of withanolides daily)	Profile of Mood States Short Form (POMS-SF), Aging Males Symptoms (AMS), salivary levels of DHEA-S, testosterone, cortisol and estradiol	No adverse events reported	★★★★★
Sexual function in women ¹³	2 capsules/day	Improvement in sexual function score and female sexual distress scale	Randomized, placebo controlled, double-blind (n=50, 8 weeks)- pilot; 600 mg/day, 5% withanolides	Female sexual function index (FSFI) Questionnaire, Female sexual distress scale (FSDS)	No adverse events reported	★★★★
Male infertility ¹⁴	2 capsules/day	Improved semen quality and levels of amino acids in seminal plasma, improved enzymatic activity and reproductive hormonal balance	Prospective study (n=180, 3 months); 5000 mg/day (Withanolide potency assumed at 1%)	Proton NMR spectroscopy to measure seminal plasma amino acids, sperm concentration, motility, lipid peroxide, hormonal balance	No adverse events reported	★★
Male infertility ¹⁵	2 capsules/day	Improved sperm count and motility, reduced lipid peroxidation and protein carbonyl content, increase in serum testosterone, leutinizing hormone, reduced levels of follicle-stimulating hormone and prolactin	Prospective study (n=75, 3 months); 5000 mg/day (Withanolide potency assumed at 1%)	Seminal plasma biochemical parameters, antioxidant vitamins, serum testosterone, leutinizing hormone, follicle-stimulating hormone, prolactin levels	No adverse events reported	★★

Muscle Strength

Muscle mass and strength ¹⁶	2 capsules/day	Increased muscle strength and size, reduced exercise-induced muscle damage, increased testosterone, decreased body fat percentage	Randomized, placebo controlled, double-blind (n=57, 8 weeks); 600 mg/day, 5% withanolides	Muscle strength (1 repetition maximum), testosterone serum levels, muscle size, body fat percentage, muscle recovery. ANOVA	No adverse events reported	★★★★
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Hypothyroidism

Subclinical hypothyroidism ¹⁷	2 capsules/day	Improvement in serum TSH, T3, T4	Randomized, double-blind, placebo-controlled trial (n=50, 8 weeks); 600 mg/day	Serum TSH, serum triiodothyronine (T3), and thyroxine (T4) levels	4/50 subjects reported fever, asthenia, cough and headache (milk and temporary)	★★★★
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