VitalAshwagandha





Clinical Applications

- Supports a Healthy Stress Response*
- Supports Restful Sleep*

VitalAshwagandha features Shoden®, a purified extract of the leaves and roots of the ashwagandha plant that has been standardized to an industry-leading concentration of 35% withanolide glycosides. Shoden has been researched for its effects in helping the body adapt to physical and mental stressors and supporting the restoration of sleep quality.*

All Rise Direct Primary Care Formulas Meet or Exceed cGMP Quality Standards

Discussion

Ashwagandha (*Withania somnifera*) is classified as an "adaptogenic" herb, indicating an ability to support how the body physiologically adapts.^[1,2] In the Ayurvedic tradition, ashwagandha is considered a *rasayana*,^[3] meaning it is used as a rejuvenator to achieve homeostasis, build vitality, and slow degenerative- and senescence-related processes. For thousands of years, ashwagandha has been used to help support ailments ranging from musculoskeletal conditions to sleep issues.^[4,5] It is widely used today for restoring physical and mental energy while balancing the effects of daily stress.*^[4,6]

Ashwagandha contains a wide range of biologically active chemical constituents collectively known as withanolides. [7,8] Although the exact mechanism of action for a projected effect on stress response has yet to be elicited, ashwagandha extract appears to ease stress-induced increases of plasma corticosterone, lactic acid in the blood, and blood urea nitrogen. [4,8] Due to the positive association of steroid hormones with general well-being and quality of life and the fact that cortisol is associated with stress, the influence of ashwagandha on these hormones has also been studied.*[2]

A systematic review assessing the effects of ashwagandha for anxiety and stress response included five randomized controlled human trials. An analysis of results indicated that ashwagandha intervention resulted in greater score improvements than placebo in outcomes shown on anxiety or stress scales, with no observed adverse events.*[1]

Shoden® Ashwagandha Extract

Shoden is an extract derived from the leaves and roots of the ashwagandha plant. This multi-patented ashwagandha extract is distinguished by its industry-leading concentration of 35% withanolide glycosides. Shoden has been clinically studied for its adaptogenic role in the stress response^[2,7] and for support of a more restful night sleep.^[9] Additionally, studies designed specifically to assess the safety of Shoden resulted in no adverse or toxic effects.^[3] Rise Direct Primary Care's VitalAshwagandha contains 240 mg of Shoden per the two-capsule daily dose.*

A randomized, double-blind, placebo-controlled trial in adults (N=60) was designed to assess the stress-balancing effects and the potential mechanism of action of Shoden. Test subjects given 240 mg of Shoden daily for 60 days demonstrated reduced levels of the stress hormone cortisol and the steroidal hormone DHEA-S. There was also an increase of testosterone in male participants. Although other potential mechanisms of action were not investigated, the results of this study suggested ashwagandha has an attenuating effect on the hypothalamic-pituitary-adrenal axis activity in stressed individuals.*[7]

Results from a randomized, controlled trial in adult males (N = 57) with moderate fatigue who were given Shoden daily for 16 weeks indicated significant improvements in salivary levels of the steroid hormones DHEA-S and testosterone, which typically decline with age. Additionally, although insignificant, self-reported improvements in fatigue, vigor, and sexual and psychological well-being were documented via questionnaire. No significant difference was recorded for salivary cortisol levels; however, it should be noted that in previous findings serum rather than salivary cortisol was assessed.*[2]

To ascertain the effect of Shoden on restorative sleep, healthy subjects (N = 150) were given 120 mg of Shoden daily for 6 weeks in a double-blind, placebo-controlled study. The overall quality of sleep was evaluated using a weekly questionnaire and an assessment of parameters such as sleep latency, sleep efficiency, and total sleep time as measured by a wearable sleep actigraphy diagnostic monitoring device. A significant improvement of sleep measures that define non-restorative sleep were noted in the treatment group when compared to placebo, demonstrating the positive effect of Shoden on encouraging restful sleep.*[9]

*These statements have not been evaluated by the Food and Drug Administration.
This product is not intended to diagnose, treat, cure, or prevent any disease.

Distributed By: Rise Direct Primary Care 814 E Jackson St Ste A, Medford, OR US 97504-6011 541-827-8603



Supplement Facts Serving Size: 2 Capsules Servings Per Container: 30 Amount Per Serving %Daily Value Ashwagandha Extract 240 mg ** (Withania somnifera) (roots and leaves) (35% withanolide glycosides) ** ** Daily Value not established. Other Ingredients: Dicalcium phosphate capsule (hypromellose and

Other Ingredients: Dicalcium phosphate, capsule (hypromellose and water), ascorbyl palmitate, and silica.

S1. Shoden® is a registered trademark of Arjuna Natural Pvt. Ltd.

Directions

Take one to two capsules daily, or as directed by your healthcare professional.

Consult your healthcare professional before use. Individuals taking medication should discuss potential interactions with their healthcare professional. Do not use if tamper seal is damaged.

References

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- 3. Antony BE, Benny ME, Kuruvilla BT, et al. Int J Pharm Pharmaceut Sci. 2018;10(12):41-46. doi:10.22159/ijpps.2018v10i12.29493
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Formulated To Exclude

Wheat, gluten, corn, yeast, soy, animal and dairy products, fish, shellfish, peanuts, tree nuts, egg, sesame, ingredients derived from genetically modified organisms (GMOs), artificial colors, and artificial sweeteners.

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