

Pure Sleep

PROMOTES RESTFUL SLEEP[‡]

Pure Sleep helps patients fall asleep, stay asleep and experience the restorative, restful sleep they need without morning grogginess. Unlike melatonin, this formula works with the body via the hypothalamic-pituitary-adrenal axis and various neurotransmitter systems to support restorative sleep over time with continued use.[‡]

This formula combines clinically studied **ashwagandha (KSM-66®)**, **saffron (affron®)** and **valerian root (Sleeproot)** to support sleep onset, quality and duration.¹⁻¹¹ KSM-66® supports sleep onset, helping individuals fall asleep faster, while enhancing sleep quality and efficiency when taken continuously over several weeks.²⁻⁴ Saffron extract (affron®) promotes multiple aspects of restful sleep, supporting both sleep onset and duration with continued use.⁵⁻⁷ Sleeproot, a valerian root extract standardized to a higher potency of active constituents (2% total valerenic acids) than typical extracts, promotes sleep quality, efficiency and duration.^{8,11†}



Helps your patients fall asleep, stay asleep and wake up refreshed without morning grogginess[‡]



Improves sleep quality, efficiency and duration with continued use[‡]



Helps relieve occasional stress and anxiety[‡]



Supports a calm, relaxed mood[‡]



Supports a healthy cortisol response[‡]

WHO IS THIS SUPPLEMENT FOR?†

- Patients seeking support for sleep onset and/or duration with continued use
- Patients requesting a melatonin-free product



MECHANISMS OF ACTION†

Ashwagandha. KSM-66® ashwagandha (*Withania somnifera*) root extract helps relieve occasional stress and anxiety, which interfere with restful sleep.^{1,2} Its calming and sleep-promoting effects are attributed to GABAergic pathways and adaptogenic activity. Importantly, ashwagandha supports a healthy cortisol response, moderating HPA-axis activity that may disrupt sleep-wake cycles.¹

Saffron. Preclinical evidence shows that crocin and other active constituents of saffron extract act on multiple neurotransmitter and stress-regulation pathways, including GABAergic and serotonergic signaling, which are implicated in sleep latency and sleep architecture.^{9,10}

Valerian root. Preclinical and mechanistic data indicate that valerian (*Valeriana officinalis*) enhances sleep by supporting inhibitory neurotransmission, including GABAergic signaling. Whole-root extracts and major actives (notably valerenic acid) act as positive allosteric modulators at GABA_A receptors in vitro.¹²



[‡]This statement has not been evaluated by the Food & Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

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CLINICAL RESEARCH HIGHLIGHTS[‡]

Saffron (affron®) supported sleep onset, duration and global sleep quality ratings. In a randomized, double-blind clinical trial involving 66 adults, saffron (affron®, 15.5 mg per day) for 6 weeks led to significant improvements in ease of getting to sleep, sleep quality, sleep duration and global Pittsburgh Sleep Quality Index (PSQI) scores.⁵

Saffron extract (affron®) supports sleep quality in adults. In a double-blind clinical trial, 63 healthy adults aged 18-70 with self-reported sleep concerns were randomized to receive either saffron extract (affron; 14 mg twice daily) or placebo for 28 days. Saffron significantly improved total sleep scores, reducing sleeplessness (ISI score), Restorative Sleep Questionnaire (RSQ) and Pittsburgh Sleep Diary (PSD) scores also significantly improved compared to placebo.⁶

Saffron extract (affron®) supported sleep quality and mood ratings upon awakening in adults with self-reported unsatisfactory sleep. In a double-blind clinical trial, 120 subjects were randomized to receive placebo, 14 mg or 28 mg of standardized saffron extract (affron®), 1 hour before bed for 28 days. Both doses of saffron produced comparable and significant improvements in mean sleep quality ratings (Figure 1) and mood ratings after awakening, compared to placebo.⁷

Ashwagandha (KSM-66®) supported sleep onset and prolonged total time asleep. In a randomized, double-blind clinical trial involving 80 adults, ashwagandha supplementation (KSM-66®, 300 mg twice daily) for 8 weeks led to a significant mean reduction in sleep onset latency (the time it takes to fall asleep after going to bed), sleep quality and total sleep time.³

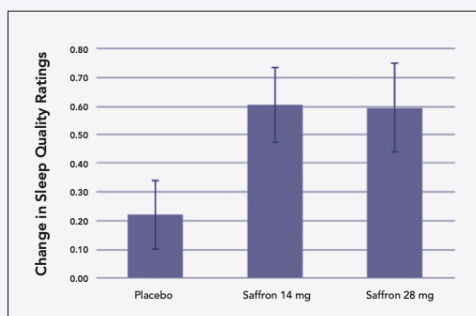


Image created with BioRender.com

Figure 1. Improvement in mean sleep quality ratings from baseline in subjects receiving saffron extract (affron®) after 28 days ($p=0.023$ vs. placebo, error bars depict SE).⁷



Ashwagandha (KSM-66®) supported morning mental alertness in healthy elderly subjects. In a 12-week randomized, double-blind clinical trial, ashwagandha (KSM-66®, 300 mg twice daily) improved subjective sleep parameters and mental alertness on rising in healthy elderly subjects.⁴

Ashwagandha (KSM-66®) supported a healthy cortisol response by 33% in adults experiencing stress. In a double-blind trial, 60 participants were randomized to receive KSM-66® Ashwagandha extract (125 mg or 300 mg) or placebo twice daily for 8 weeks. A significant reduction in perceived stress scale (PSS) scores was observed with both doses of ashwagandha compared to the placebo group. Mean cortisol response decreased by 17% and 33% in the groups receiving 125 mg and 300 mg twice daily, respectively, after 8 weeks. Subjects receiving ashwagandha also exhibited significant improvements in sleep quality.¹

Valerian (Sleeproot) supported sleep onset and sleep quality with continued use in healthy adults. In a randomized, double-blind clinical trial involving 72 adults, Sleeproot (200 mg/day) for 8 weeks improved overall sleep quality, reduced sleep latency, enhanced sleep efficiency and prolonged total sleep time. Sleeproot resulted in significant improvements in mean total PSQI sleep scores and reduced sleep latency, assessed by wrist actigraphy, compared to placebo.⁸

Valerian (Sleeproot) improved actual sleep time. In a randomized, double-blind, placebo-controlled, parallel, 8-week trial involving 80 subjects with sleep-related complaints, the group receiving Sleeproot exhibited a significant increase in actual sleep time, assessed by wrist actigraphy, compared to the placebo group on day 1.¹¹

POTENTIAL INTERACTIONS

Valerian root may have mild sedative effects.¹³ This may cause an additive sedative effect when combined with benzodiazepines or other CNS depressants. Be watchful for drowsiness, dizziness, confusion and difficulty concentrating, which are side effects of sedatives that may increase when given with herbs with CNS relaxant properties

To check whether a medication may have clinically significant interactions with [nutrients and] ingredients based on doses commonly used in dietary supplements, visit our [Drug-Nutrient Interaction Checker](#).

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Supplement Facts

2 capsules, 30-60 minutes before bedtime.

Two (size 00) capsules contain:

KSM-66 Ashwagandha® (Withania somnifera) extract (root)	600 mg
Sleeproot valerian (<i>Valeriana officinalis</i>) extract (root) (standardized to contain 2% valerenic acid)	200 mg
Suntheanine® (L-Theanine)	100 mg
Affron® saffron (<i>Crocus sativus</i>) extract (stigma) (standardized to contain 3.5% Lepticrosalides®)	28 mg

Other ingredients: vegetarian capsule (cellulose, water), hypoallergenic plant fiber (cellulose), ascorbyl palmitate, tri-magnesium citrate

WARNING: Not to be taken if you are pregnant or lactating. Consult your healthcare practitioner before use if on any medication or have any health condition. Discontinue use and seek medical advice if adverse reactions occur. Product may impair ability to drive a motor vehicle or operate machinery.

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Sleeproot is a trademark of OmniActive Health Technologies Ltd.

Suntheanine® is a registered trademark of Taiyo International, Inc.

Affron® & Lepticrosalides® are trademarks owned by Pharmactive Biotech Products S.L.U.



Pure Sleep	Quantity	Order Code
	60	PSL6

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