

Ashwagandha Advantage

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Case Study

At the Root of a Unique Adaptogen



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shwagandha (Withania somnifera Dunal) is a popular Indian botanical that has been in use in Ayurveda, the 5,000-year-old Indian system of medicine, as a rejuvenative and a daily tonic for many centuries. Ashwagandha embodies the very essence of the preventative and curative approach to health in Ayurveda. The name Ashwagandha is from the Sanskrit language and is a combination of the word ashva, meaning horse, and gandha, meaning smell; the root has a strong aroma that is described as "horse-like."

Ashwagandha is a small, woody shrub that is part of the nightshade (*Solanaceae*) family, the same family as the tomato. This perennial plant grows to about two feet in height, with branches extending radically from a central stem. It generally has dull green leaves and bell-shaped flowers; the ripe fruit is orange-red. *Withania somnifera* is cultivated in many of the drier regions of India, and is also found in some areas of Asia, Africa and the Mediterranean. As a result of this wide-ranging habitat, there are considerable morphological and chemo-typical variations in local species. However, the root phytoactives of the wild and cultivated species appear to be the same.

Ashwagandha is referred to as the "Prince of Herbs" in Ayurveda because it has an impressively broad range of therapeutic effects. Such a broad range of effects arises perhaps because ashwagandha is one of the more complex herbs with many phytochemical constituents in it.



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Ashwagandha contains many useful medicinal chemicals, including withanolides (steroidal lactones), alkaloids, flavonoids, choline, fatty acids, amino acids and a variety of sugars. While the leaves and fruit have been occasionally used, the root of the Ashwagandha plant is the part most commonly used in Western herbal remedies. Indeed, the significant majority of the clinical studies use the root; in contrast, there is much less published evidence in support of using leaf components of ashwagandha. Withanolides are an important (though by no means the sole critical) set of the major bioactive constituents of the ashwagandha root. At present, more than 140 withanolides from this plant have been isolated and are being studied. Not all withanolides are beneficial. Withaferin A is one withanolide that is cytotoxic, making it undesirable to have in an ashwagandha extract when the intended use is for adaptogenic applications or support of cognitive and immune health. Withaferin A has a considerably stronger presence in the leaf of the ashwagandha plant than the root.





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—Kartikeya Baldwa, Ixoreal Biomed Inc.



While in the nutraceutical industry, much of the discussion on ashwagandha is centered around the withanolides constituents or alkaloid constituents, Ayurvedic experts and doctors emphasize there is much more to ashwagandha than just the withanolides. The synergistic effect from this diverse set of active constituents is believed to be responsible for the multiple therapeutic properties of ashwagandha. This is often delivered in a "full spectrum," which maintains the balance of the various constituents as in the original herb.

The Science Behind the Botanical

Ashwagandha operates at the level of the overall body system by helping maintain balance in the substances and processes running in the human body. "Historically, most ashwagandha use in North America, Europe and Australia has been toward stress relief, largely emphasizing only the 'mind' benefits of ashwagandha," said Kartikeya Baldwa, CEO of Ixoreal Biomed Inc., referencing proven effects like enhanced sleep, memory, cognition, stress management and focus. "However, in the last five years, ashwagandha has started to be recognized by formulators for the 'body' benefits, with respect to sports and active life."

Stress & Brain Health

Ashwagandha root extract (as KSM-66 Ashwagandha by Ixoreal Biomed Inc.) significantly reduced cortisol levels and stress on all measures in a randomised, placebo-controlled study. Healthy adults (n=64) with a history of chronic stress took 600 mg/d of root extract or placebo, and were assessed with a battery of psychometric scales. The study concluded ashwagandha can be used to increase resistance to stress and improve the quality of life through enhancing sleep quality, productivity and mental calmness and relaxation.

Similarly, ashwagandha (300 mg) was also included as part of a naturopathic care regimen (NC) used in a study evaluating the effectiveness of NC versus standardized psychotherapy intervention (PT) on anxiety.² For the study, 81 participants were randomised to NC or PT treatments, where participants in the NC group received dietary counseling, deep breathing relaxation techniques, a standard multivitamin and 300 mg ashwagandha, while the PT intervention participants received psychotherapy, matched deep breathing relaxation techniques and placebo. The primary outcome measure was the Beck Anxiety Inventory (BAI); final BAI scores decreased by 56.5 percent in the NC group and 30.5 percent in the PT group. Significant differences between groups were also observed in mental health, concentration, fatigue, social functioning, vitality and overall quality of life, with the NC group exhibiting greater clinical benefit.

Two recent studies on KSM-66 focused on the ability of ashwagandha (600 mg/d) to enhance sleep and support mental alertness. The first, a 10-week study in 60 healthy adults with insomnia and anxiety, focused on sleep onset latency (SOL), total sleep time and efficiency, and wake after sleep onset.³ SOL was significantly shorter after 10 weeks compared with

placebo, and sleep efficiency and quality was significantly improved. In addition, anxiety scores were also significantly improved, leading researchers to conclude supplementation with ashwagandha root extract at 300 mg twice daily is well tolerated and improves SOL and sleep quality. A second placebo-controlled, double-blind, randomised study, conducted in 50 elderly adults (aged 65 to 80 years), explored whether 600 mg/d of ashwagandha root extract could improve general health and sleep.⁴ Again, intervention significantly increased quality of sleep and mental alertness upon rising.

Ashwagandha may suppress the acute effects of sleep loss on learning and memory impairments, according to results of a study conducted in rats and published in 2016,⁵ and may inhibit neurological abnormalities due to oxidative stress in rodent brains.⁶ Ashwagandha (as KSM-66) may even benefit memory and cognitive function, as a study in healthy

Ashwagandha root extract was found in one clinical trial to improve muscle building while decreasing muscle damage in adult males who lifted weights for eight weeks, compared to placebo.

Source: Ayu.

adults found supplementation at 600 mg/d improved immediate and general memory, as well as executive function, attention and information processing speed.⁷

Sports Nutrition

Ashwagandha root extract was found in one clinical trial to improve muscle building while decreasing muscle damage in adult males who lifted weights for eight weeks, compared to placebo. The randomised, prospective, double-blind, placebo-controlled clinical study involved 57 males aged 18 to 50 years who had little experience with resistance training. They were randomised to take either 300 mg capsules of ashwagandha root extract (as KSM-66) or 300 mg/d of starch twice daily. Researchers determined those taking ashwagandha had significantly more muscle strength for both the upper (75 percent more) and lower body (50 percent more) compared to those taking placebo, had greater muscle size increases and also experienced greater decreases in body fat (nearly doubling fat loss relative to muscle gain in the treatment group), higher testosterone levels and improved recovery—lower creatine kinase levels—after eight weeks in subjects taking ashwagandha.







KSM-66 also enhanced the cardiorespiratory endurance and improved the quality of life in a prospective, double-blind, randomised and placebo-controlled study conducted in 50 healthy athletic adults.⁹

Sexual Function, Reproduction Health

A double-blind, randomised, placebo-controlled trial, published in 2015 in BioMed Research International, examined the effect of supplementation with ashwagandha (as KSM-66) in 50 women between the ages of 21 and 50 years. ¹⁰ Compared to the placebo subjects, the group consuming ashwagandha had significantly greater improvement in sexual interest, arousal, lubrication and in achieving orgasm. Importantly, those receiving ashwagandha also had significantly greater improvement in sexual satisfaction and emotional closeness during sexual activity. Moreover, ashwagandha supplementation caused a marked reduction in sexually related distress in women during the study.

Supplementation with ashwagandha (as KSM-66) in adult males demonstrated significant improvement in testosterone level and other metrics related to male sexual function in a clinical study published in 2014. The study found KSM-66 supplementation increased testosterone levels by 17 percent, semen volume by 53 percent, sperm concentration by 167 percent, luteinizing hormone by 34 percent and sperm motility by 57 percent. The double-blind, randomised, placebo-controlled trial looked at 46 males between the ages of 22 and 44. All participants were healthy, but had oligospermia, a condition that causes low sperm count. Based on the study, Health Canada approved KSM-66 for the claim "helps promote healthy testosterone production in males."

Delivering the Goods

In Europe for a long time, ashwagandha was largely unknown outside of the Ayurvedic communities, and was primarily found only in capsules, tablets and powders from Ayurvedic practitioners. There were some small supplement makers offering ashwagandha in a supplement format, but it was not well-known due to both a lack of education as well as challenges associated with the use of hydro-alcoholic-extracted ashwagandha, which can retain the bitter notes of the plant. Concerted education around full-spectrum, water-based KSM-66 extract, have raised awareness and allowed ashwagandha to be included in many types of more mainstream products from food supplements to alternative delivery formats.













Ixoreal Biomed
Inc. has supported
companies in developing
products ranging from
confectionery (i.e.,
chocolates, gummies)
to beverages (such as
energy drinks or protein
drinks) and much more.



"Delivery forms are driven to a large extent by consumer preferences," Baldwa said. "Consumers are increasingly averse to taking pills or capsules, preferring instead foods that are more functional, which in turn makes manufacturers try these alternative deliveries."

Baldwa noted while other ashwagandha extracts use a hydro-alcoholic extraction processes, yielding a rather bitter extract and detracting from its whole-herb character, KSM-66 high-potency ashwagandha has a neutral, bitterless taste sought after by food and beverage manufacturers.

Delivering ashwagandha in foods and beverages opens the market to new consumers who are interested in products with functional or "wellness" benefits. KSM-66 can be included in functional foods and beverages in many countries. Ixoreal Biomed Inc. has supported companies in developing products ranging from confectionery (i.e., chocolates, gummies) to beverages (such as energy drinks or protein drinks) and much more.

In addition, ashwagandha's ability to bolster energy, muscle recovery and cognitive focus, while improving the capacity for handling stress make it an ideal ingredient for sports nutrition applications. It can be used not only in food supplements, but also in meal replacements, nutrition bars and protein mixes. The Sports Authority of India accepts that ashwagandha is a non-dope ingredient and an energy booster par excellence.

The market potential is only expected to grow as more studies elucidate the mechanisms of action of this botanical, adding evidence to millennia of use supporting its safety and efficacy.

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