

Ashwagandha Advantage

October 2020

Return to natural plant medicine with ashwagandha

As E.U. consumers take an increasingly proactive approach to health and wellness, this ancient adaptogen is more relevant than ever before.



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Novel and new. Those words used to refer to technologies, products, and even ways of thinking. In 2020, the novel coronavirus has led us to a “new normal.” We’re only beginning to see what that looks like in the wake of the pandemic.

In this new age of uncertainty, one thing is certain: People are paying more attention to their health and playing a more active role in staying healthy.

“Across Europe, consumers continue to become more health conscious, buoyed by concerns about their immunity in the wake of COVID-19,” noted Mike Hughes, director of insights for FMCG Gurus, a U.K.-based consumer market research firm for the food, beverage and supplement markets.

Nearly 60% of consumers are now more concerned about their health, especially immunity, based on three separate surveys conducted by FMCG Gurus across Europe between April and July 2020. More importantly, about 77% of Europeans say they are attempting to improve their health because of COVID-19.

Consumers are ready not just for novel and new. They want a better way to take control of their health in a personal way. Ayurveda is the millennia-old holistic health care system that emphasizes botanical formulations and a personalized wellness approach—well before ideas like “precision medicine” became a thing. The Prince of Herbs among all Ayurvedic plants is ashwagandha.

In the United States, ashwagandha (*Withania somnifera*) has become the go-to adaptogen; adaptogens are a class of botanicals that support the body’s stress response and help it return to homeostasis. It’s the central ingredient in cookies and smoothies, a star player in sports and brain health supplements. In Europe, adaptogens like ashwagandha are just gaining momentum, pointing to huge market opportunity.

Building awareness around efficacy

That’s not to say Europe doesn’t boast a strong herbs and botanicals market.

Nutrition Business Journal (NBJ) estimated total sales in this category across the region at about US\$6 billion, which places it just behind both the U.S. (\$9.5 billion) and China (\$9.1 billion) in global market size.¹ Countries like Germany, France, and Switzerland are leading the way, with herbs and botanicals making up more than a third of each market’s total supplement sales.²



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Annual growth, however, is slow across all those countries at less than 3%.³ European consumers are ready for something better to sustain their health naturally—but they don't know where to look.

“Consumer awareness on adaptogens is still low, with a very small group of consumers—usually lifestyle and early adopters—having heard about it and experimenting with such products,” said Joana Maricato, market research manager at New Nutrition Business, a research and consultancy company focused on the business of food and health.

Yet the science is clear: Ashwagandha has a real and measurable effect on human health. A case in point: Ixoreal Biomed, the company behind the leading KSM-66 ashwagandha brand, has invested considerable resources into clinical research across a range of potential applications.

There are more than 20 human clinical trials—published in peer-reviewed journals—on KSM-66 full-spectrum ashwagandha root extract. For instance, a 2012 study demonstrated that ashwagandha can decrease cortisol levels in people under chronic stress, restore healthy adrenal function, and normalize the nervous system.⁴ That ground-breaking research has been cited more than 200 times in other research papers.

A newer double-blind, randomized, placebo-controlled study published in 2019 further confirmed those results. It was also the first clinical trial to investigate the efficacy of different dosages of ashwagandha, with 60 participants receiving either 250 mg or 600 mg of ashwagandha, or a placebo, for eight weeks.⁵ Both ashwagandha groups felt the effects, with improvements in the perceived stress scale and sleep quality, along with measurable drops in cortisol, the stress hormone.⁶

Results from a second study in 2019 designed to look specifically at the effects of ashwagandha on insomnia and associated anxiety suggest the adaptogen can help people get to sleep faster and improve sleep quality, based on a 10-week double-blind, randomized, placebo-controlled clinical trial.⁷ Both studies were published by *Cureus*, a medical journal co-founded by John Adler, MD, a former professor of neurosurgery at Stanford, who instituted an innovative peer-review process with a focus on accepting papers based on small-scale trials and case studies.

“We're moving towards a world of precision medicine with the basic premise that we're all unique and don't all have the same response to a treatment,” Adler said. “So I argue that the ultimate kernel of truth is at the individual patient level and therefore we need to be documenting the stories of individuals even more.”⁸





A silver lining in the regulatory sky

While the E.U. botanicals market has thrived for years, many feel its potential has been stifled by a complex set of rules governing these food supplements from both the E.U. and member states.

In a nutshell: The European Food Safety Authority (EFSA) influences how the E.U. designs and applies the various laws, rules and policies that affect the supplements market, including botanicals like ashwagandha. Each member state adds another regulatory layer. The intricacies ensure full-time employment of an army of attorneys to keep it all straight.

But one of the ongoing chokepoints is EFSA's restrictive stance on health claims, exemplified by the fact it even prohibits companies from using the word "probiotics" in the labeling and marketing of probiotic formulations. Since 2012, there's been a hiatus on even reviewing applications on botanicals, leaving many doing the regulatory limbo.

Luca Bucchini believes there is "a glimmer of hope that some of those barriers may be coming down, in the interest of quality, safety, efficacy, and product diversity."

Bucchini is a food risk scientist and an expert in food and food supplement regulation who runs a consultancy in Italy called Hylobates. He explained how an E.U. initiative called REFIT, intended to assess the regulatory fitness of the bloc's laws and policies, re-examined the issue of claims on botanicals. Currently, the rules stipulate that health effect claims in relation to a nutrient or substance must absolutely be based on scientific evidence.

One way forward, if the E.U. Commission restarts the process, could allow applicants to include traditional use as a source of evidence, not only human intervention trials, according to Bucchini.

While health claims can be used if an application was pending prior to the hiatus, the regulatory uncertainty combined with individual E.U. member laws make for a difficult environment for food supplement manufacturers and suppliers to operate within.

"There is a lot of confusion about which claims can be used and how they will be assessed in different countries," Bucchini said. "In the present state, it is important to have strong scientific files to support pending claims. This is where the scientific support of individual suppliers comes into play."

Not only does KSM-66 have more than 20 peer-reviewed papers for scientific support, it has filed some 15 pending health claims with EFSA, giving the branded ashwagandha a distinct advantage over other functional ingredients that have yet to start the health claims process. It is market ready and already used in more than 700 finished products across the world, with a major audience in the U.S.

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— Luca Bucchini, Hylobates



Growth in the U.S. market paving the way for Europe

On the other side of the Atlantic, there's an ocean of difference in how the U.S. market has embraced ashwagandha and other adaptogens out of the Ayurvedic tradition in recent years thanks to—and sometimes in spite of—the U.S. Food and Drug Administration (FDA), the chief agency that oversees dietary supplements.

Ashwagandha has been a best-selling botanical in the U.S. natural channel since 2015 when it first cracked the top 40 list. In 2019, it hit \$13.6 million in sales, a jump of 7.2% from the previous year, strong enough to place it in the No. 5 slot, according to the “2019 Herb Market Report” from the American Botanical Council's *HerbalGram* journal.¹⁰

The ancient herb is also on a meteoric rise in the mainstream retail channel, notching more than \$10.8 million in total sales, a leap of more than 45% from 2018 sales.¹¹ That was the same year ashwagandha broke into the top-40 mainstream herbal market after sales skyrocketed by 166%. It now sits at No. 33 list.¹²

Those numbers aren't too surprising given recent market numbers and trends.

Ayurvedic botanicals, in general, are grabbing consumers' attention for functional ingredients that combine modern twists on health with age-old wisdom.¹³ It really started with turmeric, another important herb in the Eastern medical cannon that's promoted as a potent antioxidant thought to support healthy inflammatory response. Today it's a top-five seller in both the natural and mainstream channels, per the numbers from *HerbalGram*, which compiles its report from NBJ and SPINS, a wellness-focused data company.

But here's the most interesting math: In 2018, from the latest data available from NBJ, sales of Ayurvedic herbs grew 23% to \$222 million.¹⁴ Ashwagandha sales in the natural and mainstream channels that same year (and the same data sources) reached roughly \$20 million. Ashwagandha accounts for about 10% of the total botanical market in the United States.

Green is one clean way to unlock the E.U. market

It's certainly possible to unlock that same potential in the E.U. market: No matter what language they speak, consumers are after many of the same benefits from functional ingredients like ashwagandha as their American counterparts. Increasingly, they're also expressing a desire for green and clean products that are produced sustainably and ethically, according to Hughes at FMCG Gurus.

“This is due to consumers wanting reassurance about the safety of products and the transparency around ingredient content,” he said.

For instance, a total of 21% of consumers from last year's three rounds of surveys say they want more information about the safe distribution of products and 33% on the country of origin of products. Moreover, 54% of consumers say they are being more attentive toward natural claims, while 37% say this in relation to sustainability claims.



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—*HerbalGram*



“In many instances, consumers believe that natural formulation and sustainability claims are interlinked, **driving demand for products that are deemed good for the individual and good for the environment.**”

—Mike Hughes, director of insights, FMGG Gurus



“In many instances, consumers believe that natural formulation and sustainability claims are interlinked, driving demand for products that are deemed good for the individual and good for the environment,” Hughes said.

That’s where a brand like KSM-66 can appeal to the growing segment of woke consumers. Planted on 1,600 acres of E.U.-certified organic farmland operated by Ixoreal Biomed, KSM-66 is planted, harvested, cleaned, and prepared by hand. During the off-season, a nitrogen-fixing crop is rotated in to replenish the soil, as part of the company’s regenerative farming practices. Ixoreal invested 14 years of R&D to perfect a green chemistry methodology to produce its full-spectrum extract without alcohol or other chemicals.

Ixoreal Biomed also practices social sustainability in the communities around its farms and facilities in Ramganj Mandi, a municipality in the Kota district of Rajasthan, which has become the epicenter of ashwagandha cultivation in India. Ixoreal Biomed provides funding to schools and for community medicine and job creation. The ashwagandha crop is harvested mostly by local women, offering economic opportunity that supports better nutrition and quality of life for families.

Finding success in the E.U. market

Entrepreneurs like Tom and Maibritt Johnsson are finding success with ashwagandha. In 2017, they founded MedicineGarden with one aim: to increase awareness around KSM-66 ashwagandha in Sweden.

“What thrilled us besides the result of the studies was the mechanism of action. KSM-66 Ashwagandha worked deeper and more effectively on stress resistance than anything we had seen before,” said Tom Johnsson. “We believed 100% in the product and in Ixoreal; therefore, the aim was clear: to be number one in the adaptogen/stress segment.”

The story and science behind the brand helped them reach that goal in a short amount of time. In three months, MedicineGarden became the category leader of stress, adaptogens, and herbal-based supplements.

“Our communications focused on stress, explaining how high cortisol levels influence sleep, mood, energy level, and sexual desire and function. This is one of the very strong aspects of KSM-66—stress control,” he said. “This is very important and deserves to be repeated. KSM-66 helps the body cope with stress better than any other product.”

Ashwagandha’s mechanism of action to help modulate the body’s fight-or-flight response also helps explain why researchers have found other health benefits, from improving libido in both men¹⁵ and women¹⁶ to enhancing cardiorespiratory health¹⁷ and muscle mass and stamina for athletes.¹⁸

For David Neeley, managing director of Weider Germany at Weider Global Nutrition, ashwagandha hits the spot in terms of satisfying consumer demands for natural sports supplements.

Four years ago, the company developed Weider Prime, a co-branded ashwagandha product for the U.S. market. A combination of ingredients

enabled Weider to make claims on the health symptoms it sought to address. The formula has since been adapted for the E.U. market. The company is also marketing Testo Xtreme, a more sports endurance-driven product targeting the fitness and bodybuilding sector.

“We put ashwagandha in capsules, liquids, and powders,” Neeley said. “Ashwagandha is a plant extract, so there is that to think about, but from a product development point of view it is not a difficult ingredient to work with.”

Another thing that makes KSM-66 an appealing ingredient from a product development point of view is that it is a fully traceable organic ingredient with a very good safety profile, noted Dr. Ciska Wyns, head of R&D at KeyPharm. A Belgium-based manufacturer of premium food supplements, aromatherapy, and superfoods, KeyPharm uses KSM-66 ashwagandha in its adaptogenic formulations for stress relief and as an organic energy complex. The ingredient has even been incorporated into the company’s student formula — to cope with stressful periods like exams — because of its safety profile.

“Ingredients like ashwagandha, which already have a long history of use, are being rediscovered,” Wyns said. “Certainly, when they are backed by science and produced with state-of-the-art modern technologies [and] methods, this makes them highly attractive.”

No one can predict if what’s novel and new will eventually be good or bad. We do know that better ways of achieving a healthier lifestyle through Ayurveda have been around since the late dawn of human history. While these traditions have always pointed the way to ashwagandha as an important healing herb, science is teaching us why this shrubby little plant can help both people and the planet achieve better health naturally.

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