hfff 건강기능식품미래포럼
Health Functional Food Future Forum

글로벌에서 로컬로:
해외 기능성 원료의 국내 활용 확대 방안

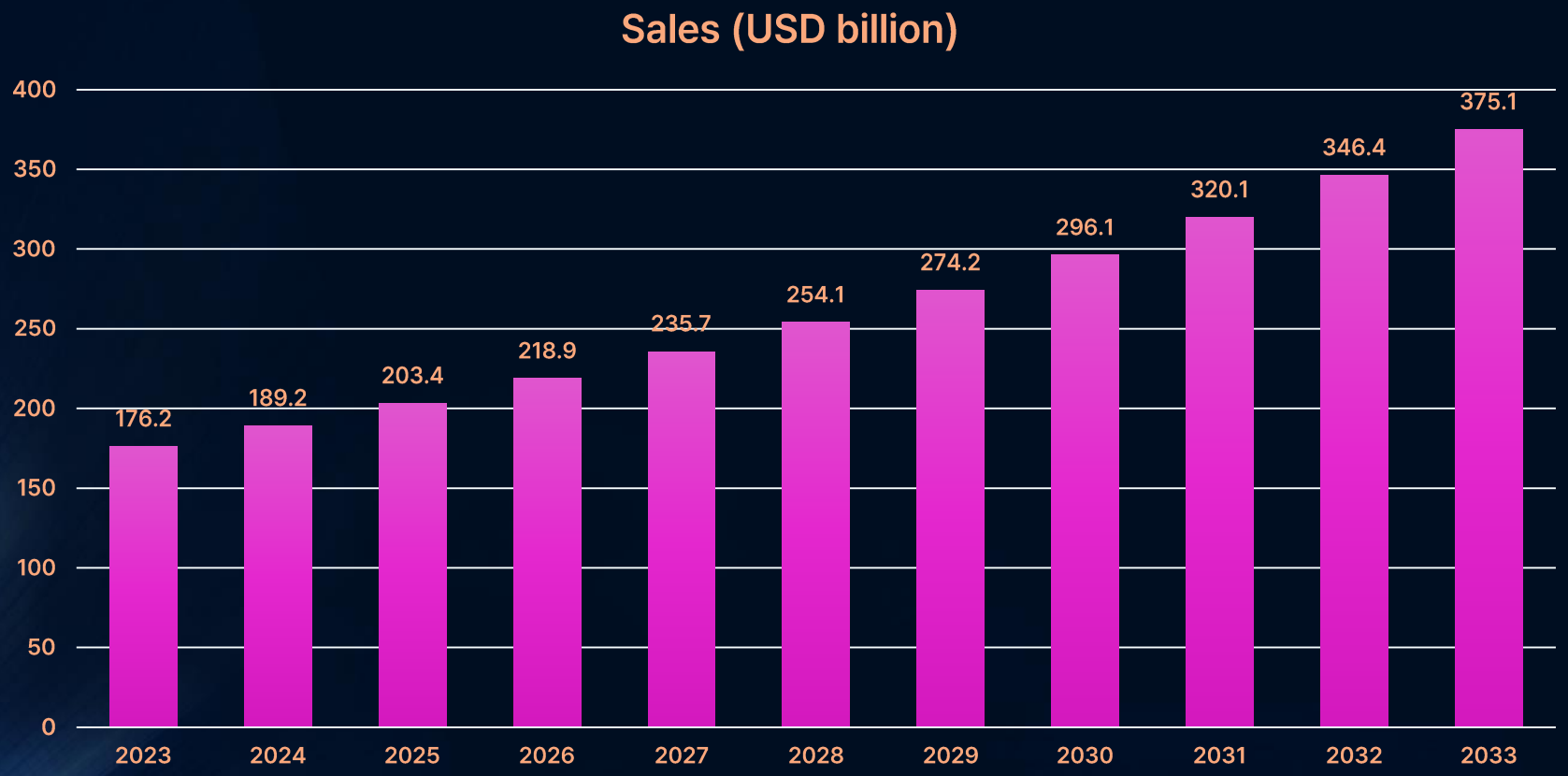
2025.07.23.

상명대학교 식품영양학과
박희정

Contents

글로벌 기능성 원료 시장 동향

세계 식이 보충제 시장규모 전망 (2024-2033)

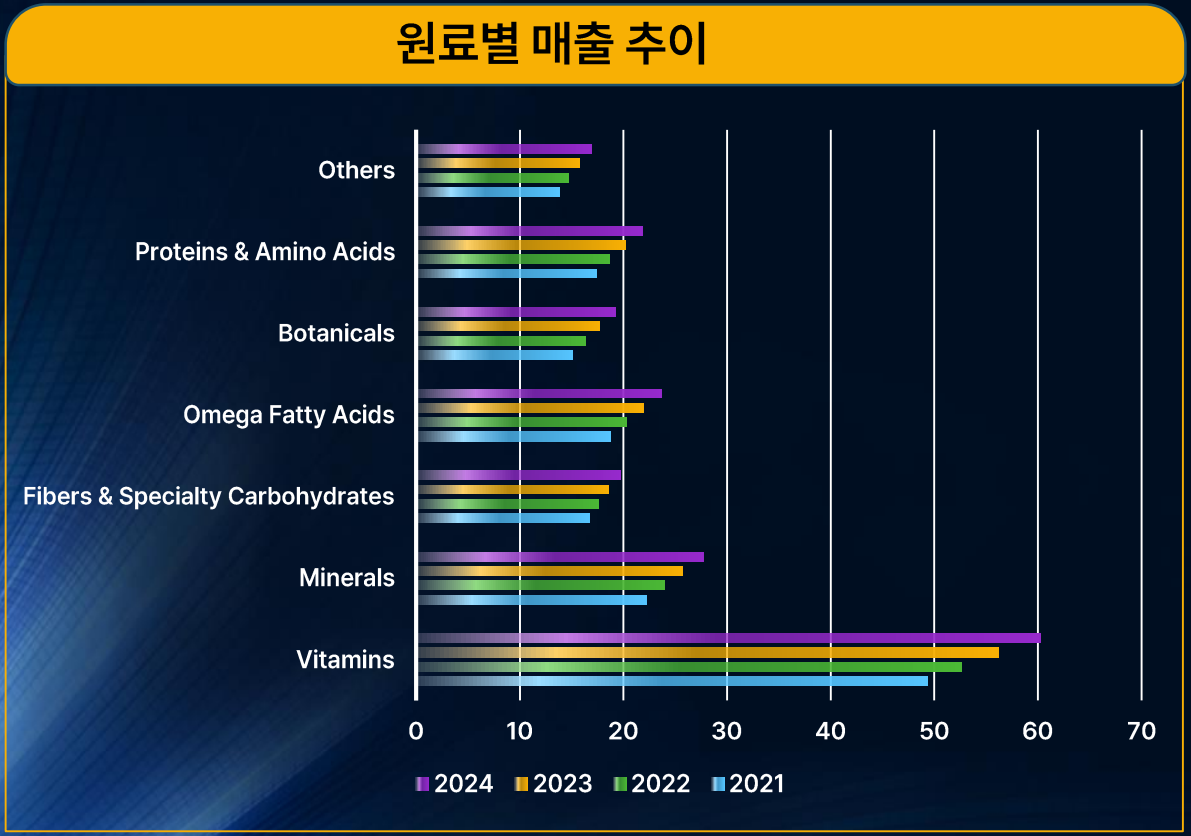


Source: Precedence Research, Dietary Supplements Market, 2024.05.

글로벌 기능성 원료 시장 동향

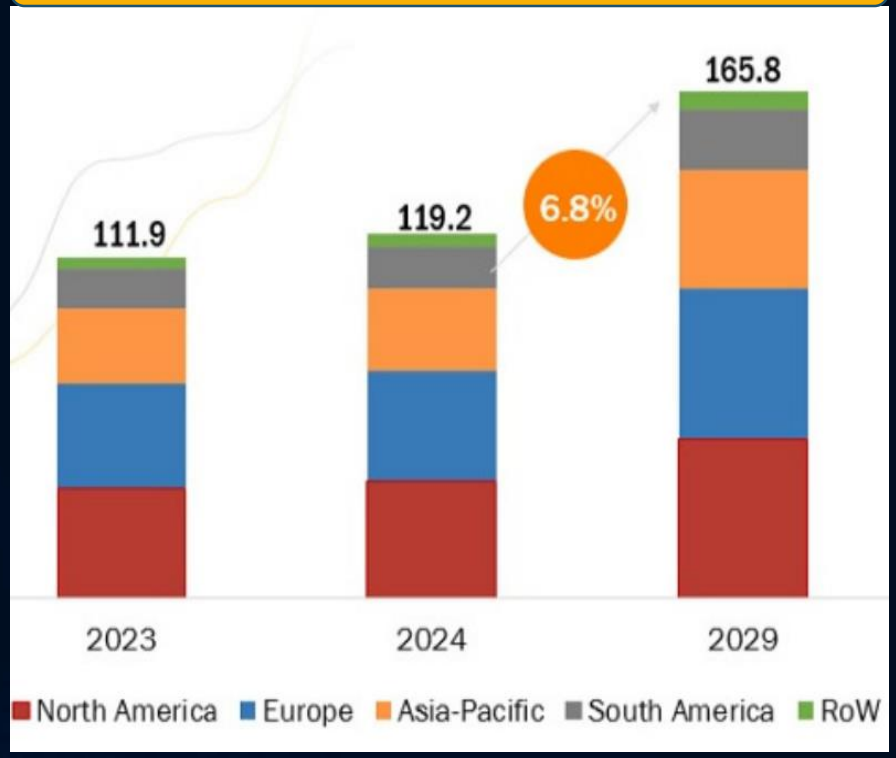
세계 식이 보충제 원료별 매출 추이 (2021-2024)

원료별 매출 추이



Source : Precedence Research, Dietary Supplements Market, 2024.05.

지역별 매출 추이

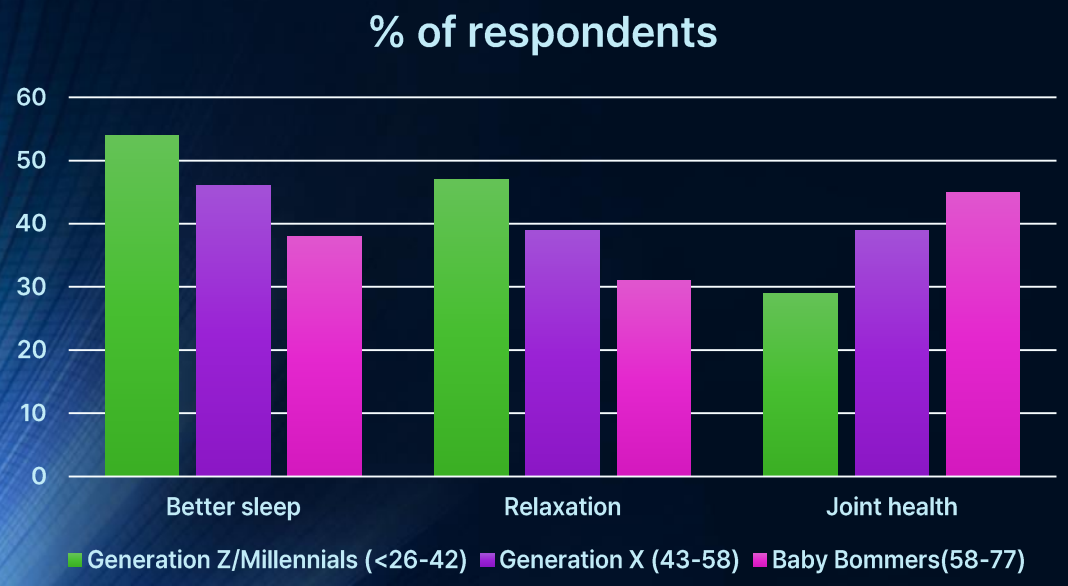


Source : Markets and Markets, Functional Food Ingredients Market, 2024.04.

글로벌 기능성 원료 시장 동향

세계 기능성 원료 트렌드

- 세계 기능성 원료 트렌드 (예: 식물성 원료, 프리/포스트 바이오틱스 등)
- 원산지 주요 국가(미국, 유럽, 인도, 일본 등)



Source: Kantar Profiles/Mintel, March 2023

아슈와간다(Adaptogen, 인도)

아스타잔틴(항산화, 미국 등)

커큐민(항산화, 인도)

해외 기능성 원료의 국내 도입 현황

❑ 수입 주요 품목 및 활용 제품

원료명	기능성	원산지	국내 제품 적용 예시
커큐민	근력개선	인도	개별인정
아스타잔틴	눈건강	미국 등	고시
로즈힙	관절 및 연골건강	유럽	개별인정
엘더베리	면역 기능	유럽/북미	컨셉
퀘르세틴	항산화	미국, 유럽 등	지표물질

해외 기능성 원료의 국내 도입 현황

❑ 수입 원료 활용 가능성

원료명	해외	국내
CBD (Cannabidiol)	미국, 캐나다 등에서 불면/불안/통증 완화용 건강기능식품	마약[illegible]리법에 따라 사용 금지 비[illegible]귀질환용)만 제한적 허용
Melatonin (멜라토닌)	수면 보조제로 일반의약품 또는 보충제 사용	의약품 분류
Yohimbe (요힘베)	체중감량 보[illegible]	식약처 고시 금지 원료 (심혈관계 부작용 우려)
Kava 추출물	체[illegible]용	간독성 이슈로 한국 금지
Vinpocetine	[illegible]개선	의약품 분류
NMN(Nicotinamide Mononucleotide)	항노화, 일본/미국 사용	-
Huperzine A (후퍼진 A)	기억력 개선, 인지기능 보완 보충제	의약품 분류

국내 법적 제약(건강기능식품 공전 미등재, 의약품 오인 우려 등)
때문에 사용이 제한되는 원료

제도적 대응과 확대 방안

◻ 멜라토닌의 경우

구분	A사	B사	C사	D사
제품명	멜라OO	멜라 OO	멜라OO	멜라OOO
가격 (30정)	3만 9천	1만 9천	9천	3만 9천
주원료	타트체리추출분말	토마토추출분말	피스타치오추출물	피스타치오추출물
멜라토닌 함량	2mg	2mg	2mg	1mg
식품유형	**과·채가공품**	**과·채가공품**	**과·채가공품**	**과·채가공품**

제도적 대응과 확대 방안

멜라토닌의 경우

Country	Products	Melatonin dosage	Other ingredients	Type
USA	Natrol Melatonin	1, 3, 5, and 10 mg	Gummy type: Tapioca syrup, cane sugar, carnauba wax, citric acid, coconut oil, fruit and vegetable juice, hypromellose, mannitol, pectin, sodium citrate	Time release, rapid
	NOW Foods Melatonin	1, 3, 5, and 10 mg	Tablet: Microcrystalline cellulose, hypromellose (cellulose capsule) and stearic acid (vegetable source)	Time release, rapid
	GNC Melatonin	1 and 10 mg	Tablet: Dicalcium phosphate, microcrystalline cellulose, stearic acid vegetable source, magnesium stearate vegetable source, silicon dioxide	Rapid
	OLLY Sleep	3mg	Gummy: L-Theanine, chamomile extract, passionflower extract, lemon balm extract, glucose syrup, sugar, water, gelatin pectin, citric acid, coloring (from carrot and blueberry juices), natural flavors, sodium citrate, vegetable oil (coconut) and carnauba wax (to prevent sticking)	Rapid
Canada	Nature's Bounty Melatonin	1, 5, and 10 mg	Softgel: Soybean oil, gelatin, vegetable glycerin, yellow beeswax. Contains < 2% of Soy lecithin, titanium dioxide color	Time release, rapid
	Jamieson Melatonin	1, 3, 5, and 10 mg	Caplet: Cellulose, dicalcium phosphate, water-soluble cellulose, vegetable stearic acid, vegetable magnesium stearate, modified cellulose gum, sodium copper chlorophyllin, silica, hydroxypropyl cellulose	Time release, rapid
	Webber Naturals Melatonin	1, 3, 5, and 10 mg	Tablet: Dibasic calcium phosphate dihydrate, microcrystalline cellulose, carbohydrate gum, vegetable grade magnesium stearate	Time release, rapid
China	Byhealth Melatonin	2.24 mg	Microcrystalline cellulose, film coating agent (hydroxypropyl methyl cellulose, talc, glyceryl triacetate), magnesium stearate	Rapid
	容茂轩牌褪黑素片	0.5 mg	Edible corn starch, lactose, magnesium stearate	Rapid

Data obtained from the official website of each company

제도적 대응과 확대 방안

Melatonin efficacy related to overall sleep quality

Author, Year	Study design	Subjects	Mean age or range	Numbers	Period	Daily dose	Primary endpoint	Side effects
Byun et al., 2023. Korea	Clinical trial	Patients with iRBD (sleep behavior disorder)	?	40	4 wks	Clonazepam 0.5 mg vs. melatonin 2 mg	Four weeks of clonazepam, but not PR melatonin, improved RWA	No reports
Hadi et al., 2022, Iran	RCT	Patients with Parkinson's disease and sleep complaints	50–80	Melatonin (n = 31), trazodone (n = 31), clonazepam (n = 31)	4 wks	Melatonin 3 mg/day vs. clonazepam 1 mg/day vs. trazodone 50 mg/day	Significant decrease in PSQI scores after 4 weeks of treatment in all groups	No adverse events in melatonin group
Duffy et al., 2022, USA	Cross-over	Healthy olders	> 55	24	2 wks	Placebo vs. melatonin 0.3 mg/day or 5 mg/day	Sleep efficiency 69.4% vs 75.6 % in 5 mg (P = 0.0007) Average duration of awakenings 7 vs. 4.93 in 5 mg (P=0.0014) Significantly increased prolonged Stage 2 NREM in 5 mg	No reports
Wade et al., 2007, UK	RCT	Insomnia patients	≥ 55	354	3 wks	2 mg vs. placebo	Significant difference in LSEQ: 26% vs. 15% (P = 0.014), Sleep latency reduction : −24.3 vs. −12.9 min (P = 0.028)	No reports
Grima et al., 2018, Australia	RCT	Patients with traumatic brain injury	37	33	4 wks	2 mg vs. placebo	Significant improvement in PSQI score (P ≤ 0.0001)	No serious adverse events
Ahn et al.,[14] 2020, Korea	RCT	Parkinson's disease patients with poor sleep quality	55–80	Melatonin (n = 16), placebo (n = 18)	4 wks	2 mg vs. placebo	Significant improvement in PSQI score	No adverse events

Food Suppl Biomater Health. 2025 Mar;5(1):e1

제도적 대응과 확대 방안

Melatonin effects on sleep latency

Author, Year	Study design	Subjects	Mean age or range	Numbers	Period	Daily dose	Primary endpoint	Side effects
Sletten et al., 2018, Australia	RCT	Delayed Sleep-Wake Phase Disorder	16–65	116	4 weeks	0.5 mg vs. placebo	Sleep onset time: 34 min earlier in the melatonin group	No adverse events
Wade et al., 2007, UK	RCT	Insomnia patients	≥ 55	354	3 weeks	2 mg vs. placebo	Significant difference in LSEQ: 26% vs. 15% (P = 0.014), Sleep latency reduction: −24.3 vs. −12.9 min (P = 0.028)	No reports
Bonuccelli et al., 2022, Italy	Double-blind case control study	Pediatric patients	1–6	100	Single dose	3 mg (1–3 yr), 5 mg (4–6 yr) vs. placebo	Significant difference in sleep latency 10.8 vs. 18.1 min (P = 0.002)	No adverse events
Onyeakazi et al., 2024, UK	RCT	Participants with severe chronic pain for at least 3 months	24–79	60	6 weeks	2 mg vs. placebo	Significant difference in sleep latency (P = 0.04),	No adverse events
Dodge & Wilson, 2001, USA	RCT	Children with developmental disabilities	3–14	20	6 weeks	0.5 mg vs. placebo	Significant difference in sleep latency (P < 0.05)	No side effects
Siegrist et al., 2001, Argentina	Clinical trail	Insomniac patients	60.1	22	6 months	3 mg	Significant decrease in sleep latency	No side effects
Maras et al.,2018, Multi center	Prospective, open-label	Children and adolescents with autism spectrum disorder and neurogenetic disorders	9 (2–17.5)	Melatonin (n = 51), placebo (n = 44)	52 weeks	2, 5, or 10 mg (dose optimization)	Significant decrease in sleep latency (P < 0.001)	Mild adverse effects
Yuge et al., 2020, Japan	Uncontrolled, open-label	Children with sleep problems	10.4 (6–15)	99	26 weeks	1, 2, or 4 mg	Significant improvement in sleep onset latency (P < 0.0001)	No adverse events
Gringras et al., 2017, UK	RCT	Children and adolescents With Autism Spectrum Disorder	2–17.5	125	13 weeks	2 mg escalated to 5 mg vs. placebo	Significant improvement in sleep onset latency (P = 0.011), total sleep time (P = 0.034)	No reports
De Leersnyder et al., 2010, France	RCT	Children and adolescents with neurodevelopmental and behavioral disorders.	5–20	88	6-72 months	4–6 mg vs. placebo	Significant decrease in sleep latency (P < 0.001)	Mild adverse effect
Wade et al., 2010, UK	RCT	Adult outpatients with primary insomnia	18–80	791	29 weeks	2 mg vs. placebo	Significant reduction in sleep latency compared to the placebo (P = 0.002)	No adverse events
Wade et al., 2011	RCT	Adult with primary insomnia	18–80	555	6 months	2 mg vs. placebo	Significant decrease sleep latency	Mild adverse effects

Food Suppl Biomater Health. 2025 Mar;5(1):e1

제도적 대응과 확대 방안

Melatonin effects on sleep latency

Subject	Period	Daily dose	Adverse events	Reference
Children and adolescents	52 weeks	2, 5, or 10mg	Fatigue (5.3%), Mood swings (3.2% of patients)	Maras et al.,2018
Children and adolescents	104 weeks	2, 5, or 10mg	Fatigue (6.3%), Somnolence (6.3%), Mood swings (4.2%)	Malow et al.,2021
Children and adolescents	6–72 months	4–6 mg	Somnolence (2.27%)	De Leersnyder et al., 2011
Adults	24 weeks	2mg	Most adverse events were mild with no significant differences between PRM and placebo groups in any safety outcome.	Wade et al., 2011

Food Suppl Biomater Health. 2025 Mar;5(1):e1

제도적 대응과 확대 방안

Melatonin effects on sleep latency

Subject	Period	Daily dose	Physiological changes	Reference
Children	single dose	3 mg (1–3 yr), 5 mg (4–6 yr)	No difference in EEG abnormality between groups	Bonuccelli et al., 2022
Children and adolescents	104 weeks	2, 5, or 10 mg	No difference in child growth parameters (Z-score for weight, height, BMI) between groups	Malow et al., 2021
Adults	24 weeks	3 mg	Serum concentrations of prolactin, FSH, TSH, or estradiol did not exhibit changes after 6 months of melatonin administration, nor were any indications of hematologic or blood biochemistry alteration found	Siegrist et al., 2001

Food Suppl Biomater Health. 2025 Mar;5(1):e1

향후 도입 가능성 ?

Supporting ingredient

DHEA

Human study

- Furostanol → AR ↑
- 4-Hydroxyisoleucine → muscle ↑
- Protodioscin → Testosterone ↑

5-HTP

L-Tryptophan

↓ (Vitamin B_6, Mg 필요)

5-HTP (5-Hydroxytryptophan)

↓

Serotonin (세로토닌)

↓

Melatonin (멜라토닌)

5-HTP → serotonin ↑

향후 도입 가능성 ?

DHEA-Associated Adverse Events

Subject	Period	Daily dose	Adverse events	Reference
Healthy older adults (60-79, 140men/140 women)	1 year	50 mg	None significant; slight cholesterol increase in men over 70	Baulieu et al., 2000
Postmenopausal women with fibromyalgia	3 months	50 mg	Androgenic (greasy skin, acne, hair growth)	Finckh et al., 2005
Healthy older adults, postmenopausal women, men	2 weeks–24 months	50–75 mg	None significant; broad adverse event categories assessed	Evans et al., 2006
Postmenopausal women	26–52 weeks	50 mg	Androgenic (acne, hair growth)	Panjari et al., 2009
Healthy men	12 weeks	100 mg	None reported	Wallace et al., 1999
30-year-old woman, fragile X syndrome, IVF	1 month	No mention	Generalized seizure	Karp et al., 2009
Elderly men and women with low dehydroepiandrosterone	2 years	No mention	None major	Nair et al., 2006
Women with adrenal failure	9 months	25 mg	Sweat odor, scalp itching	Løvås et al., 2003
SLE patients (SR)	3 months	No mention	Androgenic (acne)	Crosbie et al., 2007
Perimenopausal women	3 months	50 mg	None reported	Barnhart et al., 1999

향후 도입 가능성 ?

Supporting ingredient

DHEA

Human study

- Furostanol → AR ↑
- 4-Hydroxyisoleucine → muscle ↑
- Protodioscin → Testosterone ↑

5-HTP

L-Tryptophan

↓ (Vitamin B_6, Mg 필요)

5-HTP (5-Hydroxytryptophan)

↓

Serotonin (세로토닌)

↓

Melatonin (멜라토닌)

5-HTP → serotonin ↑

향후 도입 가능성 ?

Supporting ingredient

St. John's Wort

- hypericin
- hyperforin

H. boissieri,

H. barbatum,

H. montbretii,

H. triquetrifolium

Passion flower

종류	함유 식물/식품
아피제닌 (Apigenin)	파슬리, 셀러리, 카모마일
루테올린 (Luteolin)	셀러리, 파슬리, 고수, 민들레 잎, 녹차
하스바틴 (Hispidulin)	타임, 민트, 페퍼민트, 레몬밤 (멜리사)
크리스인 (Chrysin)	꿀풀(황금버들), 파슬리, 프로폴리스

Thank you

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