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‘Boost Your Confidence and Trust:
Evidence-Based Resources and Application
of Tools to Help Make Informed Decisions
about Safe Dietary Supplement Use’

April 11, 2024

Objectives & Plan

Participants will be able to...

- Identify and readily-access evidence-based resources that consumers and providers, can turn to for trusted information about dietary supplements
- Utilize OPSS.org educational tools to rapidly evaluate whether ingredients listed on a product label may be risky
- Identify issues associated with dietary supplements and examine possible solutions for enhancing practitioner-patient communication strategies related to dietary supplement use

Plan for the Experiential Workshop:

- Introduction to Operation Supplement Safety & Group Activity (15 min)
- Small Group Activity (15 min)
 - Using the OPSS scorecard, patient scenarios, and supplement labels
- Large group discussion on activity (20 min)
- Wrap-up (10 min)

US regulation

- Mostly post-market
- 1994 Dietary Supplement Health and Education Act
 - Defined DS as new category
 - "...a product (other than tobacco) that is intended to supplement the diet that bears or contains one or more of the following dietary ingredients: a vitamin, a mineral, an herb or other botanical, an amino acid, a dietary substance for use by man to supplement the diet by increasing the total daily intake, or a concentrate, metabolite, constituent, extract, or combinations of these ingredients."
 - Protected industry from attempts to declare products as unapproved food additives
 - Gave FDA more enforcement power (did not use for first 10 years)
 - Established the Office of Dietary Supplements at NIH

DSHEA provisions

- Manufacturers can make “structure/function claims” and very limited health claims—must substantiate and notify FDA 30 days before marketing
 - “Builds strong bones”
 - “Maintains digestive regularity”
 - “Use as part of your diet to maintain healthy blood sugar levels”
 - “Promotes sexual arousal and performance”
 - NOT Helps alleviate the pain associated with Migraine headaches
 - (from [Venable](#))
- Requirement of Supplement Facts box on label with dietary ingredients
- Products must display a disclaimer on the label stating that any claims have not been evaluated by the FDA

Supplement Facts	
Serving Size 1 Capsule	
Amount Per Capsule	% Daily Value
Calories 20	
Calories from Fat 20	
Total Fat 2 g	3%*
Saturated Fat 0.5 g	3%*
Polyunsaturated Fat 1 g	†
Monounsaturated Fat 0.5 g	†
Vitamin A 4250 IU	85%
Vitamin D 425 IU	106%
Omega-3 fatty acids 0.5 g	†

* Percent Daily Values are based on a 2,000 calorie diet.
 † Daily Value not established.

Ingredients: Cod liver oil, gelatin, water, and glycerin.

Current regulatory environment

- FDA Office of Dietary Supplement Programs (ODSP),
Cara Welch, Director
 - Created to tighten up enforcement of current rules
 - The growth of the industry makes adequate regulation challenging
 - “ [industry grew](#) from \$4 billion with roughly 4,000 products to \$40 billion with over 50,000 products over the past 25 years, it is imperative [modernization efforts promote](#) safety...” Christine Burdick-Bell, Dietary Supplements Quality Collaborative
 - Market also different
 - Global supply chain
 - Improvement in manufacturers
 - Designer ingredients and complex mixtures

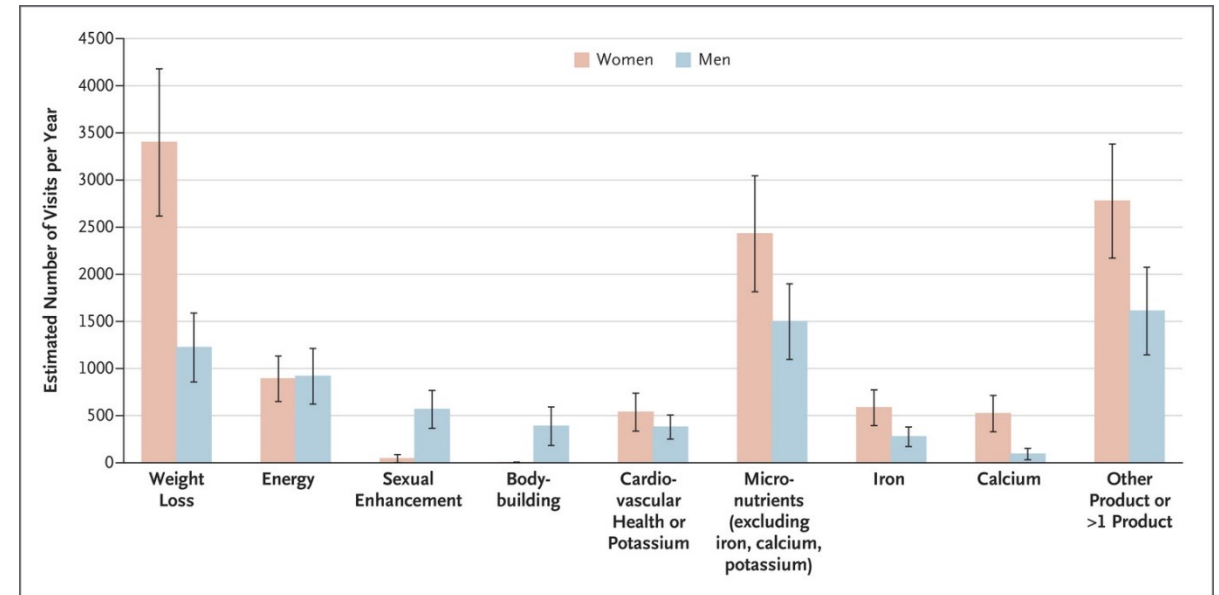


Challenges

- Dietary supplement regulation largely relies on post-marketing surveillance
 - No pre-market approval and limited review
 - Inspections limited by budget
 - “FDA has no systematic way to know when new dietary supplements are introduced or what they contain”, Cara Welch
- Need to
 - Modernize current dietary supplement statutes
 - Strengthen regulation of new dietary ingredients
 - Address the need to test imported products
 - Figure out how to collaborate with third-party testing services

Adverse events associated with supplements

- Figure 1. National Estimates of Emergency Department Visits for Adverse Events Associated with Dietary Supplements, According to Sex and Product Category (2004–2013).
- Shown are the estimated number of emergency department visits per year, after the exclusion of unsupervised ingestion of dietary supplements by children, during a 10-year period



Partial Solutions

- Operation Supplement Safety
 - Department of Defense initiative to identify problematic or harmful ingredients in dietary supplement products
 - Currently led by Andrea Lindsey, MS and Patricia Deuster, PhD
- Office of Dietary Supplements
 - Label database
 - Monographs and other educational materials

- MedWatch
 - Main Adverse event reporting site for the FDA
 - FDA contacts clinicians to alert them of problems with products.
 - Unproven ingredients/false claims
 - e.g., supplements to reverse Alzheimer's disease are unproven
 - Ingredients may interact with medications, are a waste of money
 - Undeclared drug ingredients
 - Heavy metal contamination
 - Bacterial contamination

Example: FDA MedWatch: UNDECLARED DRUG INGREDIENTS

- **ISSUE:** FDA is warning consumers that **Reumofan Plus**, marketed as a natural dietary supplement contains several active pharmaceutical ingredients not listed on the label that could be harmful.
- **Super Arthgold by Nano Well-being Health: Recall - Undeclared Drug Ingredients**

Operation Supplement Safety

OPSS is the DoD's **go-to program** for anything related to health, wellness, and performance products. OPSS partners with other federal departments, professional organizations, and academic institutions to **provide evidence-based information**, resources, and tools for education and decision making.

OPERATION
SUPPLEMENT
SAFETY | OPSS.ORG

 Prohibited List

 Check Your Supplement

 Exploring Supplements

 Ask the Expert

 USU
Uniformed Services University

 CHAMP
Consortium for Health and Military Performance





OPSS.org Website

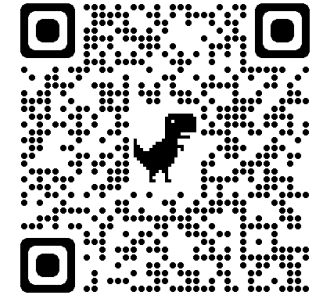
- Evidence-based articles
- Ask the Expert portal
- Other resources
 - Videos
 - Handouts
 - Infographics
 - More





Screen your supplement for safety. Read the label on your supplement and mark 1 for “yes” and 0 for “no.”

Key questions you can answer:	Yes=1	No=0
Is any one of these third-party certification seals on the product label? <div style="display: flex; justify-content: center; gap: 10px;">     </div>		
Are there less than six ingredients on the Supplement Facts label?		
Is the label free of the words proprietary, blend, matrix, or complex ?		
Can you easily pronounce the name of each ingredient on the Supplement Facts label?		
Is the amount of caffeine listed on the label 200 mg or less per serving? (If caffeine is not listed, mark “1.”)		
Is the label free of questionable claims or statements ?		
Are all the % Daily Values (% DV) on the Supplement Facts label less than 200% ? (If % DV is not listed, mark “0.”)		
Total: Add up the “1s.” 4 or more is okay. Less than 4 is a “no-go.”		



Questions about dietary supplements?

Ask the OPSS experts at OPSS.org/ask-the-expert

OPERATION SUPPLEMENT SAFETY (OPSS)



OPSS Scorecard Questions

Third-Party Certification

- Products with third-party certification/verification seals have been evaluated for *quality* and *purity*:
 - Banned Substances Control Group (BSCG)
 - Informed-Choice
 - NSF International
 - United States Pharmacopeia (USP)



Combination of Ingredients

- More ingredients = Higher risk of interactions
 - Interactions could occur from mixing together the ingredients in the product itself, other dietary supplements, medications, etc.
- “Other Ingredients” not included in total

Supplement Facts			
Serving Size 2 Packs		Servings Per Container 22	
Amount Per Serving	%DV	Amount Per Serving	%DV
Calories	40	Glutamine	123mg **
Total Carbohydrates	4g <2%*	Glycine	287mg **
Dietary Fiber	2g 8%*	Histidine	93mg **
Protein	6g 12%*	Isoleucine (BCAA/EAA)	282mg **
Vitamin A (as carotenoids [β-carotene, α-carotene], acetate)	9900IU 198%	Leucine (BCAA/EAA)	514mg **
Vitamin C (as ascorbic acid, ascorbyl palmitate)	1g 1667%	Lysine (EAA)	417mg **
Vitamin D (as cholecalciferol)	680IU 170%	Methionine (EAA)	157mg **
Vitamin E (as d-α, d-β, d-γ, d-Δ tocopherols & tocotrienols)	300IU 1000%	Phenylalanine (EAA)	232mg **
Thiamin (as mononitrate)	76mg 5067%	Proline	143mg **
Riboflavin	76mg 4471%	Serine	285mg **
Niacin (as niacinamide)	82mg 410%	Threonine (EAA)	266mg **
Vitamin B6 (as pyridoxine AKG, pyridoxine HCl)	180mg 9000%	Tryptophan (EAA)	84mg **
Folic Acid	400mcg 100%	Tyrosine	192mg **
Vitamin B12 (methylcobalamin, cyanocobalamin)	17mcg 283%	Valine (BCAA/EAA)	314mg **
Biotin	300mcg 100%	Performance Complex	
Pantothenic Acid	76mg 760%	Argentine Liver (bovine)	3900mg **
Calcium	2g 200%	Carnitine	25mg **
Phosphorus	1330mg 133%	Choline Bitartrate	950mg **
Iodine (from kelp)	150mcg 100%	Eleuthero (root)	1750mg **
Magnesium (as oxide)	400mg 100%	Hawthorne (berry)	250mg **
Zinc (as oxide)	30mg 200%	Milk Thistle	500mg **
Selenium (as sodium selenite)	50mcg 71%	Oriental Ginseng (root)	250mg **
Copper (as sulfate)	600mcg 30%	Para-Aminobenzoic Acid	400mg **
Manganese (as sulfate)	5mg 250%	Pyridoxine α-Ketoglutarate	200mg **
Chromium (as chloride)	60mcg 50%	Antioxidant Complex	
Potassium (as sulfate)	200mg 6%	Alpha Lipoic Acid (ALA)	100mg **
Amino Amino Complex		Citrus Bioflavonoids	1000mg **
Alanine	339mg **	Coenzyme Q10 (CoQ10)	5mg **
Arginine	1326mg **	Grapeseed Extract	50mg **
Aspartic Acid	503mg **	Lutein	1mg **
Cystine	104mg **	Lycopene	1mg **
Glutamic Acid	752mg **	Pine Bark Extract	200mg **
		Digestive Enzyme Complex	
		Bromelain	100mg **
		Inulin	250mg **
		Lipase (6000 LU)	10mg **
		Pancreatin	700mg **
		Papain	64mg **
		Pepsin	64mg **

* Percent Daily Values are based on a 2,000 calorie diet. ** Daily Value (DV) not established.

OTHER INGREDIENTS: Dicalcium phosphate, whey protein concentrate (milk), microcrystalline cellulose, glucose polymers, arginine α-ketoglutarate, stearic acid, magnesium stearate, calcium carbonate, d-calcium pantothenate, silicon dioxide, carnitine fumarate, calcium citrate, alfalfa, rose hips, rice bran, parsley, burdock. Made in a GMP facility that uses milk, soy, egg, peanuts.

Percent Daily Value (%DV)

- How much of a nutrient in a single serving of a dietary supplement contributes to your daily diet.
- 35 nutrients have established daily values

	% Daily Value*
Total Fat 9g	12%
Saturated Fat 4.5g	23%
<i>Trans</i> Fat 0g	
Cholesterol 35mg	12%
Sodium 850mg	37%
Total Carbohydrate 34g	12%
Dietary Fiber 4g	14%
Total Sugars 6g	
Includes 0g Added Sugars	0%
Protein 15g	
Vitamin D 0mcg	0%
Calcium 320mg	25%
Iron 1.6mg	8%
Potassium 510mg	10%

Proprietary Blends

- The amount of each individual ingredient does not have to be listed
- May be listed as a
 - “Blend”
 - “Complex”
 - “Matrix”
 - “Formulation”
- Especially important in the case of stimulants

Supplement Facts	
Serving Size: 1 Capsule	
Servings per Bottle: 60	
	Amount Per Serving
Proprietary Blend	377mg
1,3,7 - Trimethylxanthine; Beta-Phenylethylamine; Synephrine HCL; N,N-dimethyl-4-hydroxyphenyl- ethylamine; Schizandrol A; 5-Hydroxytryptophan; Yohimbine HCL	
** Daily Value Not Established	

Other Ingredients:

Magnesium Stearate; Silicon Dioxide.

Caffeine

Other sources/names of caffeine:

- Cacao
- Caffeine anhydrous
- Coffee
- Green coffee bean
- Guarana
- Kola nut
- Methylxanthine
- Tea
- Trimethylxanthine
- Xanthine
- Yerba maté



Questionable Claims

- *Prevents severe memory loss*
- *Boosts testosterone levels and sex drive*
- *Lose weight 6x faster*
- *Maximizes muscle recovery and growth*
- *Rapid sleep enhancer*
- *Legal steroid*
- *Natural cure for diabetes*
- *Cures COVID-19*



XTEND Sport



Prohibited Ingredients: None

SUPPLEMENT FACTS

Serving Size: 1 Level Scoop (11.5 g)

Servings Per Container: 30

	Amount Per Serving	%DV
Calories	0	
Total Carbohydrate	0 g	0%*
Sugars	0 g	**
Magnesium	10 mg	3%
Sodium	220 mg	9%
Potassium	180 mg	5%
L-Leucine	3500 mg	**
Electrolyte Blend	1890 mg	**
[BetaPower® Betaine Anhydrous, Sodium Citrate, Potassium Chloride, Sodium Chloride, Magnesium Citrate, Coconut (<i>Cocos nucifera</i>) water powder]		
L-Isoleucine	1750 mg	**
L-Valine	1750 mg	**

*Percent Daily Values (%DV) based on a 2,000 calorie diet.

**Daily Value (DV) not established.

Other Ingredients: Malic Acid, Citric Acid, Silicon Dioxide, Natural & Artificial Flavors, Sucralose, Acesulfame Potassium, FD&C Red #40.

CONTAINS: Tree Nuts (Coconut).

XTEND Sport



SUPPLEMENT FACTS

Serving Size: 1 Level Scoop (11.5 g)

Servings Per Container: 30

	Amount Per Serving	%DV
Calories	0	
Total Carbohydrate	0 g	0%*
Sugars	0 g	**
Magnesium	10 mg	3%
Sodium	220 mg	9%
Potassium	180 mg	5%
L-Leucine	3500 mg	**
Electrolyte Blend [BetaPower® Betaine Anhydrous, Sodium Citrate, Potassium Chloride, Sodium Chloride, Magnesium Citrate, Coconut (<i>Cocos nucifera</i>) water powder]	1890 mg	**
L-Isoleucine	1750 mg	**
L-Valine	1750 mg	**

*Percent Daily Values (%DV) based on a 2,000 calorie diet.

**Daily Value (DV) not established.

Other Ingredients: Malic Acid, Citric Acid, Silicon Dioxide, Natural & Artificial Flavors, Sucralose, Acesulfame Potassium, FD&C Red #40.

CONTAINS: Tree Nuts (Coconut).

Is any one of these third-party certification seals on the label?*



Are there less than six ingredients on the Supplement Facts label?

Is the label free of the words proprietary, blend, matrix, or complex?

Can you easily pronounce the names of each ingredient on the Supplement Facts label?

Is the amount of caffeine listed on the label 200 mg or less per serving? (If caffeine is not listed, mark "1.")

Is the label free of questionable claims or statements?

Are all the % Daily Values (% DV) on the Supplement Facts label less than 200%? (If % DV is not listed, mark "0")

Total Score

Small group product evaluations

A patient comes to you with each of the following products.

How would you have a conversation with them about the product?

How might the scorecard influence your conversation?



REPORT BACK!

Arsynist



SUPPLEMENT FACTS

Serving Size: 2 Capsules
Servings Per Container: 30

	Amount Per Serving	%DV
Vitamin B12 (as Methylcobalamin)	300 mcg	5000%
L-Tyrosine	375 mg	**
Caffeine Anhydrous	300 mg	**
2-aminoisheptane Hydrochloride	200 mg	**
White Willow Extract (bark)(≥25% Salicin)(Salix alba L.)	100 mg	**
Matcha Green Tea Powder (leaf)(Camellia sinensis L.)	50 mg	**
Synephrine Hydrochloride	50 mg	**
Higenamine Hydrochloride	50 mg	**
Hordenine Hydrochloride	50 mg	**
Cayenne Pepper Powder (fruit)(40,000 SHU) (Capsicum annum)	25 mg	**
Grapefruit Extract (seed) P.E 10:1 (Citrus paradisi)	25 mg	**
Paradoxine® Grains of Paradise Extract (seed) (≥12.5% 6-Paradol)(Aframomum melegueta)	15 mg	**
Vinpocetine	5 mg	**
BioPerine®(fruit)(Black Pepper Extract) (≥95% Piperine)(Piper nigrum)	5 mg	**
Yohimbine Hydrochloride	3 mg	**
Huperzia serrata (aerial) (≥1% Huperzine A)	300 mcg	**

Percent Daily Values (%DV) are based on a 2000 calorie diet

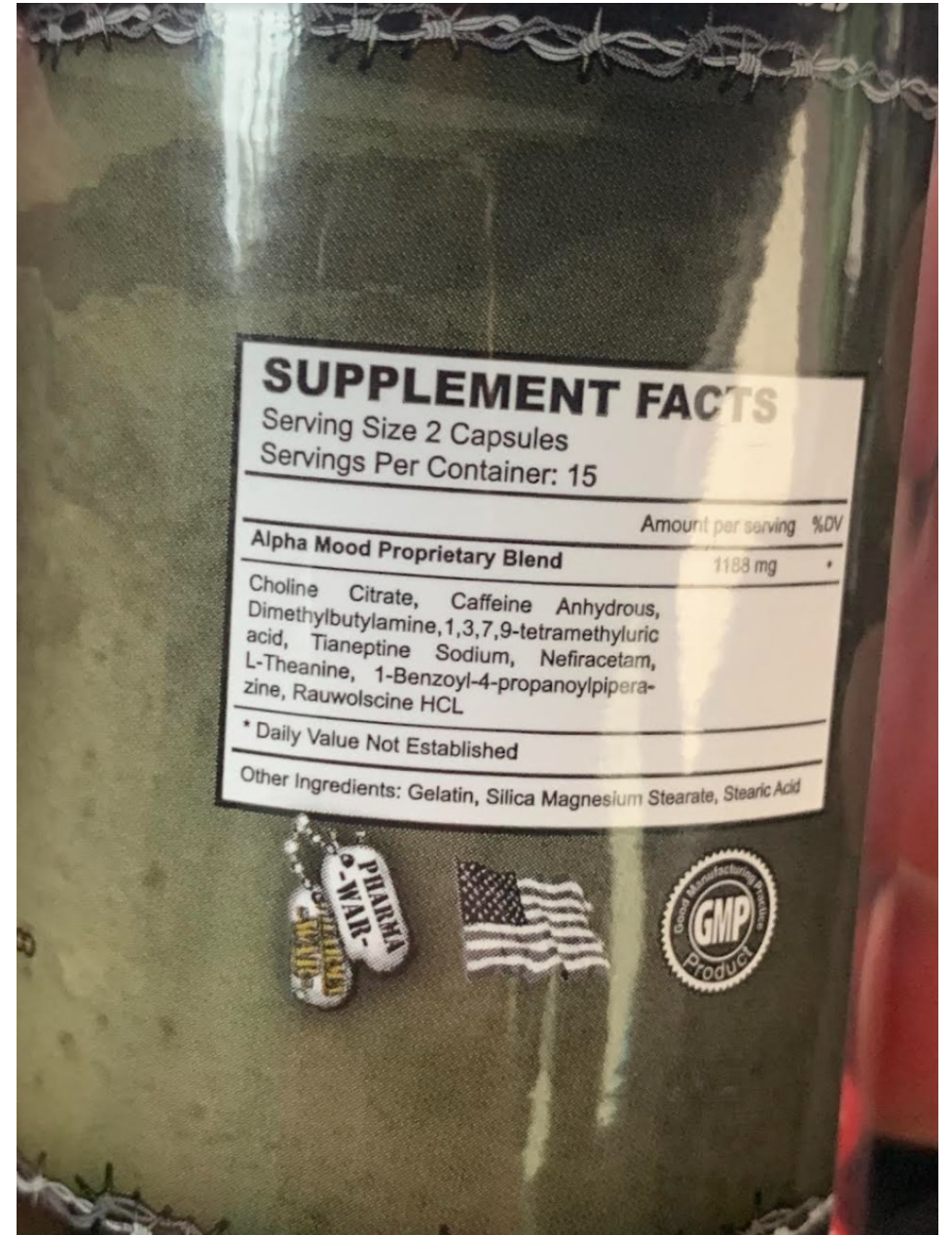
** Daily Value Not Established.

Other Ingredients: Gelatin, Rice Flour, Magnesium Stearate, Silica.

Concerns with Arsynist

- **Ingredients on the DoD Prohibited List**
 - 2-aminoisoheptane (DMHA)
 - Higenamine
 - Hordenine
 - Vinpocetine

Alpha Mood



Concerns with Alpha Mood

- **Ingredients on the DoD Prohibited List**
 - 1-benzoyl-4-propanoylpiperazine (Sunifiram)
 - Dimethylbutylamine (DMBA)
 - Nefiracetam
 - Tianeptine

Dr. Furhman men's daily

Supplement Facts

Serving Size: 2 capsules
Servings Per Container: 60

	Amount Per Serving	%DV
Vitamin C (as calcium ascorbate and acerola fruit extract)	100 mg	111%
Vitamin D [as D3 vegan cholecalciferol (Vitashine®)] (2000 IU)	50 mcg	250%
Thiamin (as thiamin HCl)	0.75 mg	63%
Riboflavin	0.425 mg	33%
Vitamin B12 (as methylcobalamin)	75 mcg	3,125%
Biotin	15 mcg	50%
Pantothenic acid (as D-calcium pantothenate)	5 mg	100%
Iodine (from kelp)	150 mcg	100%
Magnesium (as magnesium aspartate and magnesium amino acid chelate)	100 mg	24%
Zinc (as zinc bisglycinate chelate and zinc picolinate)	10 mg	91%
Chromium (as chromium amino acid chelate)	17.5 mcg	50%
Taurine	250 mg	*
Pomegranate fruit extract	160 mg	*
Reishi mushroom extract	50 mg	*
Cranberry fruit extract	50 mg	*
Tomato/Lycopene concentrate (providing 2 mg lycopene)	50 mg	*
Vitamin K2 [as natural menaquinone-7 (K2Vital®)]	40 mcg	*
Vanadium (as vanadium amino acid chelate)	10 mcg	*
Fruit, Veggie and Greens Blend:	150 mg	*

Organic broccoli sprout, organic acai fruit extract (*Euterpe oleracea*), organic lycium (goji) berry extract, organic cranberry, organic apple, organic kale, organic broccoli, organic spinach, organic carrot, organic parsley, organic beet, organic green cabbage, organic blueberry, organic raspberry, organic strawberry, organic tomato

*Daily Value (DV) not established.



Gaia Herbs Turmeric Supreme



Supplement Facts

Serving Size 1 Capsule

Servings Per Container 60

Amount Per Serving

Proprietary Extract Blend 482 mg†

Organic Turmeric (*Curcuma longa*) root extract, Turmeric (*Curcuma longa*) root extract, Turmeric (*Curcuma longa*) root supercritical CO₂ extract

Curcuminoids 36 mg†

Black Pepper (*Piper nigrum*) fruit supercritical CO₂ extract 7 mg†

† Daily Value not established.

Other ingredients: Organic soy lecithin, vegetable glycerin, water and vegan capsule (hypromellose, chlorophyll).

Gaia Herbs, Inc., 101 Gaia Herbs Drive, Brevard, NC 28712

◇ *Extra Strength* provides more Curcuminoids per capsule than other members of our *Turmeric Supreme*® Phyto-Cap® family of products.

** *Extra Strength* is the #1 selling Turmeric product in SPINS Natural Channel, as of data ending 08-13-2023

SUGGESTED USE

Adults take 1 capsule 1-2 times daily with meals.

Not for use during pregnancy or lactation. If you have a medical condition or take medications, please consult with your doctor before use. **Store away from children.** Use only as directed on label. Safety-sealed for your protection. Keep bottle capped at all times and store in a cool, dry place. Natural separation may occur. This does not affect product quality.

*** THIS STATEMENT HAS NOT BEEN EVALUATED BY THE FOOD AND DRUG ADMINISTRATION. THIS PRODUCT IS NOT INTENDED TO DIAGNOSE, TREAT, CURE, OR PREVENT ANY DISEASE.**

Kirkland Mature Multi



Supplement Facts

Serving Size 1 Tablet

Each Tablet Contains	% Daily Value	Each Tablet Contains	% Daily Value
Vitamin A 750 mcg RAE (40% as Beta Carotene)	83%	Magnesium 50 mg	12%
Vitamin C 90 mg	100%	Zinc 11 mg	100%
Vitamin D ₃ 12.5 mcg (500 IU)	63%	Selenium 55 mcg	100%
Vitamin E 22.5 mg	150%	Copper 0.9 mg	100%
Vitamin K 30 mcg	25%	Manganese 2.3 mg	100%
Thiamin (Vit. B ₁) 1.5 mg	125%	Chromium 45 mcg	129%
Riboflavin (Vit. B ₂) 1.7 mg	131%	Molybdenum 45 mcg	100%
Niacin 20 mg	125%	Chloride 72 mg	3%
Vitamin B ₆ 3 mg	176%	Potassium 80 mg	2%
Folate 833 mcg DFE (500 mcg Folic Acid)	208%	Silicon 2 mg	**
Vitamin B ₁₂ 25 mcg	1,042%	Lycopene 300 mcg	**
Biotin 30 mcg	100%	Lutein (Flower) 250 mcg	**
Pantothenic Acid 10 mg	200%	Boron 150 mcg	**
Calcium 220 mg	17%	Vanadium 10 mcg	**
Phosphorus 110 mg	9%	Nickel 5 mcg	**
Iodine 150 mcg	100%		

**Daily Value not established.