# OSAplex<sup>™</sup> Formulas

### **Overall Bone Health and Strength\***



OSAplex<sup>™</sup> and OSAplex MK-7<sup>™</sup> are available in 60 packets

#### Discussion

Bone health is dependent on a constant supply of micronutrients for maintenance and repair. Instead of adopting a single-nutrient, unbalanced approach to supplementation, XYMOGEN<sup>®</sup> utilizes an array of complementary, well-researched nutrients in its OSAplex line of formulas to build and maintain bone over time.<sup>\*</sup>

**OSAplex<sup>™</sup>** is our original formula, and it provides ch-OSA<sup>®</sup>, MCHC (microcrystalline hydroxyapatite concentrate), and vitamin D3.

#### ch-OSA® (Choline-Stabilized Orthosilicic Acid)

ch-OSA is a patented, stabilized, readily absorbed, and bioactive form of silicon called orthosilicic acid. Because regular orthosilicic acid is highly unstable, leading it to form polymers, and because the polymers are too large for the human body to absorb, ch-OSA features patented "choline stabilization" technology. This stabilization prevents polymers from forming, ensuring optimal absorption of orthosilicic acid.<sup>\*</sup>

Decades of research suggest that there is a positive association between dietary silicon and bone mineral density (BMD).[1] The mechanisms of action appear to be silicon's support of collagen synthesis and stabilization, extracellular matrix mineralization, and connective tissue integrity.<sup>[2,3]</sup> Cell-line studies have shown that type I collagen synthesis is stimulated by orthosilicic acid (silicon).<sup>[4]</sup> Type I collagen is a dense, heavily cross-linked protein that creates an extremely high tensile strength<sup>[5]</sup> and contributes to bone strength and flexibility. These strong collagen strands are believed to create core-post "binding sites" for calcium and other bone minerals.\*[6-8] In a 12-month clinical trial conducted at St. Thomas' Hospital in London, women already taking 1000 mg of calcium and 800 IU of vitamin D, to which they added ch-OSA, saw thighbone mineral density at the hip (i.e., femoral neck) increase by 2.00% compared to placebo. This was as a result of an increase in actual bone formation, not just a decrease in loss.<sup>[9]</sup> Furthermore, the procollagen marker P1NP (procollagen type-1 N-terminal propeptide) increased significantly after 12 months in women who took ch-OSA compared to women in the placebo group. P1NP is known as the most sensitive marker for bone collagen formation and an early marker of bone formation.<sup>[9]</sup> Animal studies support the human clinical findings for ch-OSA with respect to collagen formation and BMD.\*[6,7,10]

#### Microcrystalline Hydroxyapatite Concentrate (MCHC)

XYMOGEN uses standardized, safe, bovine-sourced MCHC (Ossopan) from New Zealand. The OIE-World Organisation for Animal Health has classified New Zealand as a "negligible BSE risk country," the most favorable official classification a country can be given.<sup>[11]</sup> MCHC is manufactured under proprietary processes that meet FDA,

## **Clinical Applications**

- » Provide a Multifaceted Approach to Bone Maintenance and Strength\*
- $\,\,$  » Provide Foundational Bone Support with Choline-Stabilized Orthosilicic Acid (ch-OSA®)^\*
- » Support Bone Collagen Formation, Bone Mineral Density, and Bone Calcium Binding Sites\*
- » Provide a Complementary Combination of Micronutrients\*

**OSAplex™** formulas offer a variety of micronutrient profiles that allow scope for individualized nutritional support of bone health and maintenance. The foundation of each of these distinct formulas is choline-stabilized orthosilicic acid (ch-OSA®), a source of the mineral silicon. Silicon has been researched for its role in collagen synthesis and bone mineral density (BMD). By adding other bone-specific nutrients to the ch-OSA foundation, each OSAplex formula is tailored to meet individual needs.<sup>+</sup>

USDA, and EU regulatory requirements, and frequent heavy metal assays assure purity. Proprietary techniques preserve the bioactive contents of bone and create a naturally balanced formula because whole-bone extract provides an array of nutrients found in healthy bone: calcium, phosphorus, magnesium, bioactive growth factors, type I collagen, amino acids, glycosaminoglycans, and a broad range of essential trace elements. Gentle processing retains the delicate protein matrix and organic factors, and X-ray-diffraction analysis confirms the microcrystalline structure. The MCHC is assayed for hydroxyproline content and the collagen occurring in bone."

Decades of scientific studies suggest that Ossopan/MCHC supplementation fundamentally supports BMD and bone health.<sup>[12-15]</sup> A meta-analysis of six controlled studies suggested that hydroxyapatite was significantly more effective than calcium carbonate in supporting bone structure and BMD, and another study favorably compared its absorption to calcium gluconate.<sup>\*[16,17]</sup>

#### Vitamin D3

Although vitamin D3 (cholecalciferol) is made in the skin when 7-dehydrocholesterol reacts with sunlight, many things affect the degree to which this biosynthesis occurs, including time of day, seasons, location, smog/pollution, clothing, shade of skin (darker skin requires more sun), and sunscreen use. Low-cholesterol diets and certain cholesterol therapies can also affect vitamin D formation. By some estimates, one billion people worldwide have vitamin D deficiency or insufficiency.<sup>[18]</sup> The body needs vitamin D to absorb calcium, and the importance of vitamin D in skeletal health and bone density is well-established. Without adequate absorption, the body must take calcium from its stores in the skeleton, which weakens existing bone and prevents the formation of strong, new bone. Researchers suggest that vitamin D supplementation may decrease bone turnover and increase BMD.<sup>[19]</sup> A pooled analysis evaluating 11 randomized, double-blind, placebo-controlled trials supported this analysis. It concluded that vitamin D supplementation (> 800 IU daily) was favorable in maintaining hip and nonvertebral bone integrity in individuals aged 65 and older.<sup>\*[20]</sup>

Although D2 and D3 are similar biochemically, one study demonstrated D3 to be approximately 87% more potent in raising and maintaining serum calcidiol (the body's storage form) concentrations and in producing two- to threefold greater storage of vitamin D than did equimolar D2.<sup>[21]</sup>

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**Male Health** 

#### OSAplex<sup>™</sup> Supplement Facts

Serving Size: 1 Packet

	(2) Microcrystalline Hydroxyapatite Concentrate with vitamin D3 Capsules		(1) Choline- stabilized orthosilicic acid Capsule	
	Amount Per Serving	%DV	Amount Per Serving	%DV
Vitamin D3 (cholecalciferol)	50 mcg (2000 IU)	250%		
Choline (as choline-stabilized orthosilicic acid) <sup>S1</sup>			60 mg	11%
Calcium (as MCHC) <sup>s2</sup>	550 mg	42%		
Phosphorus (as MCHC) <sup>S2</sup>	198 mg	16%		
MCHC <sup>S2</sup>	2.2 g	**		
Microcrystalline Hydroxyapatite (as MCHC) <sup>S2</sup>	1.32 g	**		
Silicon (as choline-stabilized orthosilicic acid) <sup>S1</sup>			3 mg	**
** Daily Value (DV) not established.				

Other Ingredients for Microcrystalline Hydroxyapatite Concentrate with vitamin D3 capsule: Capsule (hypromellose and water), vegetable stearic acid, vegetable magnesium stearate, medium-chain triglyceride oil, and silica. Other Ingredients for Choline-stabilized orthosilicic acid capsule: Microcrystalline cellulose,

capsule (hypromellose), and purified water.

DIRECTIONS: Consume the contents of one packet with a meal, one to two times daily, or as directed by your healthcare professional.

Consult your healthcare professional prior to use. Individuals taking medication should discuss potential interactions with their healthcare professional. Do not use if tamper seal is damaged.

STORAGE: Keep closed in a cool, dry place out of reach of children.

FORMULATED TO EXCLUDE: Wheat, gluten, yeast, soy, dairy products, fish, shellfish, peanuts, tree nuts, egg, ingredients derived from genetically modified organisms (GMOs), artificial colors, artificial sweeteners, and artificial preservatives.

S1. Choline-stabilized orthosilicic acid (ch-OSA®) is a registered trademark of and manufactured by Bio Minerals n.v., Belgium. Produced under U.S. Patents 5,922,360; 7,968,528;and 8,771,757. S2. Microcrystalline Hydroxyapatite Concentrate

VEGETARIAN

#### OSAplex MK-7<sup>™</sup> Supplement Facts

Serving Size: 1 Packet

	(2) Microcrystalline Hydroxyapatite Concentrate with vitamins D3 and K2 Capsules		(1) Choline-stabilized orthosilicic acid Capsule	
	Amount Per Serving	%DV	Amount Per Serving	%DV
Vitamin D3 (cholecalciferol)	25 mcg (1000 IU)	125%		
Choline (as choline-stabilized orthosilicic acid) <sup>S1</sup>			60 mg	11%
Calcium (as MCHC) <sup>S2</sup>	550 mg	42%		
Phosphorus (as MCHC) <sup>s2</sup>	198 mg	16%		
MCHC <sup>S2</sup>	2.2 g	* *		
Microcrystalline Hydroxyapatite (as MCHC) <sup>S2</sup>	1.32 g	**		
Silicon (as choline-stabilized orthosilicic acid) <sup>\$1</sup>			3 mg	**
Vitamin K2 (as menaquinone-7)	45 mcg	**		
** Daily Value (DV) not established				

Other Ingredients for Microcrystalline Hydroxyapatite Concentrate with vitamins D3 and K2 capsule: Capsule (hypromellose and water), vegetable stearic acid, vegetable magnesium stearate, medium-chain triglyceride oil, and silica.

Other Ingredients for Choline-stabilized orthosilicic acid capsule: Microcrystalline cellulose, capsule (hypromellose and water), and purified water.

DIRECTIONS: Consume the contents of one packet with a meal, one to two times daily, or as directed by your healthcare professional.

Consult your healthcare professional prior to use. Individuals taking medication should discuss potential interactions with their healthcare professional. Consider total vitamin K intake (food + supplements) if you are taking blood-thinning medication. Do not use if tamper seal is damaged.

STORAGE: Keep closed in a cool, dry place out of reach of children.

FORMULATED TO EXCLUDE: Wheat, gluten, yeast, soy protein, dairy products, fish, shellfish, peanuts, tree nuts, egg, sesame, ingredients derived from genetically modified organisms (GMOs), artificial colors, artificial sweeteners, and artificial preservatives.

S1. Choline-stabilized orthosilicic acid (ch-OSA®) is a registered trademark of and manufactured by Bio Minerals n.v., Belgium. Produced under U.S. Patents 5,922,360; 7,968,528;and 8,771,757. S2. Microcrystalline Hydroxyapatite Concentrate



OSAplex™ MK-7 provides the same ingredients found in OSAplex (ch-OSA, MCHC, and D3) as well as vitamin K2 as menaguinone-7 (MK-7).

#### Vitamin K2

MK-7 is a bioactive, bioavailable form of vitamin K2.[22] The biological role of vitamin K in relation to calcium and bone is to help deposit calcium into appropriate areas in the body, such as bones and teeth. Conversely, vitamin K is needed to prevent the accumulation of calcium in other areas, such as in arteries and soft tissues, through vitamin K-dependent carboxylation of Gla proteins. Vitamin K also supports bone integrity by moderating the synthesis of prostaglandin E2 (PGE-2) and interleukin-6 (IL-6) by osteoclasts.<sup>[23,24]</sup> A three-year study utilizing 180 mcg/d of MK-7 concluded that MK-7 significantly improved vitamin K status, supported bone mineral content and BMD, and favorably supported bone strength and integrity in healthy postmenopausal women.\*[25]

Male Health

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Additional references available upon request

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All XYMOGEN® Formulas Meet or Exceed cGMP Quality Standards.