



Ovacore™ BiovaFlex™: A new, natural solution for everyday aches and pains

What is BiovaFlex™?

BiovaFlex™ is a new, all natural joint health ingredient comprised of proteins and peptides. Uniquely water-soluble, BiovaFlex™ offers the formulator (and eventual consumer) all of the nutrients contained within egg membrane. Egg membranes are the unique protective barrier between the egg white and the mineralized egg shell. Utilizing an all natural and patented method to separate this membrane from the eggshell and further processing the concentrated membrane via the patent-pending Hydro5™ solubilization process, Biova™ effectively isolates the membrane from the eggshell and hydrolyzes it to produce the family of Ovacore™ ingredients, including the dietary supplement-grade BiovaFlex™.

What does BiovaFlex™ do?

When formulated within a dietary supplement, BiovaFlex™ helps:

- Alleviate everyday joint aches and pains
- Reduce joint discomfort
- Improve joint mobility, flexibility and function
- Improve range of motion
- Promote a normal inflammatory response
- Provide antioxidants that reduce free radicals for healthy joints
- Provide joints with the building blocks needed to build cartilage for normal joint function
- Support healthy joints

These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

This information is for educational and assessment purposes only. Marketing claims provided herein serve as a guideline of substantiated, FDA-compliant-copy for label and marketing material development.

This document, and the information it contains, does not constitute legal or medical advice. Any marketing or labeling claims made for products containing this material are subject to FDA enforcement discretion and are not the responsibility of Biova™, LLC.

What are the active components in BiovaFlex™?

The most recognized components of BiovaFlex™ are:

- **Collagen** – a fibrous protein critical to cartilage, connective tissue and skin health. Collagen gives cartilage its strength and elasticity;
- **Elastin** – a protein critical to skin, cardiovascular, cartilage, and spinal column health. As its name implies, elastin gives tissue the elastic tension and ability to resume its shape after stretching;
- **Hyaluronic acid, Glucosamine, Chondroitin** and other **Glycosaminoglycans (GAGs)** – polysaccharides that are vital structural components of connective tissue, interstitial fluids and skeletal structures. GAG molecules characteristically offer high viscosity and low compressibility which are essential to the highly viscous fluids found in joint spaces that act as shock absorbers and protect the bone surfaces from jarring together under impact. This is particularly important for athletes whose joints are continually being shocked and jarred and for easing the everyday aches and pains associated with aging;
- **Transforming growth factor-β** – a protein that plays a crucial role in tissue repair, cellular differentiation and immune function;
- **Desmosine** and **isodesmosine** – two little known peptides that are responsible for elastin's elastic or "rubbery" properties.

The Scientific Support

Initial observations indicated that people taking 500 mg of BiovaFlex™ experienced improved joint and tissue comfort, mobility and flexibility. These reports led Biova™ to commission formal research on BiovaFlex™.

An open-label animal study was conducted by Richard Baird, VMD, (Animal Medical Center, Uniontown, PA) during the fall of 2008. Fifty-seven (57) canines with limited joint mobility were administered daily dosages (5 mg/lb body weight) of product for twenty eight (28) days. Observations were made daily by the pet owners and reported weekly to the study administrator. Positive changes in joint mobility scores were reported within 7 days, and by the conclusion of the 28-day observation period, all subjects exhibited increased activity and mobility; many pet owners reported their pets returned to activities previously abandoned such as running, playing with their owner, climbing stairs and jumping up on furniture.

An open-label pilot study was commissioned and completed to evaluate the safety and efficacy of 450 mg BiovaFlex™ as nutritional support for musculoskeletal pain and flexibility, specifically of the knee joint. Forty-two (42) subjects were recruited and assigned to receive 450mg of BiovaFlex™ daily for 6 weeks. Daily online tracking and measurement of the subjects' joint pain was recorded using the Western Ontario and McMaster University (WOMAC) Abbreviated Index. The impressive results included:

These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

This information is for educational and assessment purposes only. Marketing claims provided herein serve as a guideline of substantiated, FDA-compliant-copy for label and marketing material development.

This document, and the information it contains, does not constitute legal or medical advice. Any marketing or labeling claims made for products containing this material are subject to FDA enforcement discretion and are not the responsibility of Biova™, LLC.

- Pain symptoms reduced by 8.25% within the first 7 days of administration and 16.42% after 14 days.
- A 20.78% reduction in total pain symptoms at the end of the 6 week study ($p \leq 0.0001$).
- A 37.8% improvement in the relative functionality of the knee (range of motion compared to the inverse of the level of pain) over the course of the study.
- No adverse events were reported.

While the BiovaFlex™ study concluded at 6 weeks, ongoing observations of those consuming of BiovaFlex™ for extended periods has continued to yield observations of continuing improvements within the same parameters measured within the official study.

A sixty-seven (67) patient study published in March 2009 issue of *Clinical Rheumatology* found that supplementation with 500 mg of egg membrane for 8 weeks produced a statistically significant reduction in pain and stiffness, with relief coming in as little as 10 days of supplementation (mean response time).

The results of an open-label study published in the May 2009 issue of *Clinical Interventions in Aging* concluded that supplementation with egg membrane produced a significant improvement in flexibility within seven days (27.8% increase; $P = 0.038$), a significant reduction in pain (72.5% reduction; $P = 0.007$), significant improvement in flexibility (43.7% increase; $P = 0.006$), and significant reduction in range of motion-associated pain (75.9% reduction; $P = 0.021$) all within 30 days.

This promising data, along with the body of research on the individual components within BiovaFlex™ suggest that it will prove to be a powerful new joint health solution.

These studies also provide direction for future research efforts, which will be conducted to further prove the benefits of BiovaFlex™ as a stand-alone ingredient but also as formulated with other nutrients.

Applications and Suggested Usage

BiovaFlex™ is a water-soluble powder that can be used in many dietary supplement applications targeting joint health, everyday aches and pains, and simple protein fortification through many delivery mechanisms including:

- Capsules
- Tablets
- Softgels
- Drinks
- Instant Drink Packets
- Functional Foods

These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

This information is for educational and assessment purposes only. Marketing claims provided herein serve as a guideline of substantiated, FDA-compliant-copy for label and marketing material development.

This document, and the information it contains, does not constitute legal or medical advice. Any marketing or labeling claims made for products containing this material are subject to FDA enforcement discretion and are not the responsibility of Biova™, LLC.

Biova™ recommends formulation inclusion at the research supported 450 mg BiovaFlex™ per day.

Safety Data

A complete review of published scientific literature was conducted and did not yield any indications or suggestions of possible concern regarding the safety and tolerability of eggshell membrane.

- The Radioallergosorbent Test Inhibition (RAST-inhibition) indicated that “it is highly unlikely that eggshell membrane would present any risk to egg allergic individuals...”
- A Bacterial Reverse Mutation Assay concluded that “the test sample was not cytotoxic to the test system” and...”there was no detectable genotoxic activity associated ...”
- Additional investigation confirms that Ovacore:
 - is “not a sensitizer” in evaluated subjects,
 - is “not a primary dermal irritant”,
 - should not come into direct contact with the eye.

Sustainable Production and Process

Biova™ is committed to the production of a high quality all natural product in a sustainable, environmentally sensitive manner.

The process begins by harvesting the raw material from “egg breaking” facilities that produce and market commonly utilized liquid egg products. Eggshells and their attached membranes are currently underutilized in their processes. Biova™ captures these totally natural raw materials and utilizes an all natural, patented mechanical process to separate the egg membrane from the egg shell.

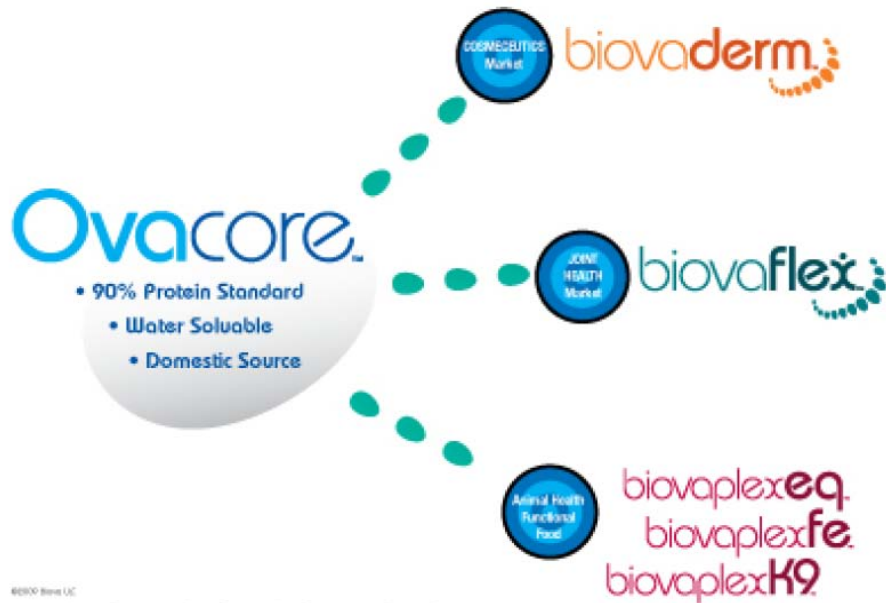
The egg membrane is further processed utilizing Biova’s patent pending proprietary Hydro5™ process (developed Iowa State University Research Park) to yield the membrane’s nutritional components more available and water soluble. The resulting product is Ovacore™.

Ovacore™ is classified and packaged for sale according to its intended market requirements and the specifications of Biova’s individual finished product brands;

These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

This information is for educational and assessment purposes only. Marketing claims provided herein serve as a guideline of substantiated, FDA-compliant-copy for label and marketing material development.

This document, and the information it contains, does not constitute legal or medical advice. Any marketing or labeling claims made for products containing this material are subject to FDA enforcement discretion and are not the responsibility of Biova™, LLC.



©2020 Biova LLC

More Information

For more information regarding Biova™, Ovacore™, any of its finished products, or the research reports referenced within this document, contact:

Biova Marketing Department

Biova, LLC

Iowa State Research Park
2325 North Loop Drive, Suite 6400
Ames, IA 50010
1-877-OVACORE
1(877.682.2673)

These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

This information is for educational and assessment purposes only. Marketing claims provided herein serve as a guideline of substantiated, FDA-compliant-copy for label and marketing material development.

This document, and the information it contains, does not constitute legal or medical advice. Any marketing or labeling claims made for products containing this material are subject to FDA enforcement discretion and are not the responsibility of Biova™, LLC.