

# Kre-Celazine®

## A Revolutionary Approach to Joint Pain Management

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#### The Painful Thread That Binds Us All

The one thing that athletes and fitness enthusiasts all have in common is ***pain***. We're not talking about the "good" pain that comes from a satisfying bout of intense training. We're talking about that nagging and sometimes debilitating pain associated with out-of-control inflammation. It's the kind of pain that makes knees throb, wrists ache, and shoulders and necks temporarily seize in agony.

To help counter body aches and joint pain, athletes and active fitness enthusiasts have traditionally turned to over-the-counter Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), glucosamine, or both. While each of these compounds may offer *some* form of relief, neither provides a fully viable, long-term solution to the root source of pain...inflammation.

#### An Inflammatory Topic

Let's take a moment to fully appreciate (or loathe) the concept and implications of inflammation; its negative effects on health are widespread. In fact, you may be surprised to learn that ***chronic inflammation is a primary reason for doctor visits*** as well as increased costs to our already burdened healthcare system.<sup>1</sup>

It gets worse. The Arthritis Foundation has estimated that immune-related joint degenerative conditions (which are associated with inflammation) are expected to strike more than 27 million Americans during the next decade.<sup>2</sup> That's not including the untold myriad of those afflicted with ligament weakness, fibromyalgia, idiopathic (conditions of unknown origin) pains and muscle trauma.<sup>3,4</sup>

#### Inflammation Explained

Now, if you are alive and kicking you experience inflammation on a regular basis. It is a natural component of the body's highly complex defense mechanism. It is part of an ingenious design that fights infections and trauma to tissues. It is the body's way of removing pathogens and irritants and for triggering the healing process.

If you've ever had sunburn, a cut, a sprain, or a strain, you've experienced inflammation. It is revealed as localized pain, heat, redness, swelling, and temporarily restricted range of motion (ROM). These are quite normal and necessary responses to injury. However, ***chronic inflammation*** is a completely different and an altogether highly detrimental issue.

#### Fanning the Flames of Inflammation

Inflammation is a necessary factor in launching the body's defense mechanism. Therefore, it can flare up anywhere in the body at any time in response to foreign matter and "unwanted" molecules. These "unwanted" molecules might be introduced into the

body through a variety of means, including unwise dietary choices. For example, foods that have been overly cooked, fried at high temperatures, or barbequed tend to trigger the inflammatory response.

Technically, this dietary-induced inflammatory response is due to Advanced Glycation End Products (AGES). AGES are produced when a glucose molecule binds to a protein molecule. This molecular configuration is very difficult for the body to break down. Your body sometimes treats AGES as invaders.

In response to the AGES “invaders”, immune cells start to pump out large volumes of cytokines (inflammatory signaling molecules). This response is exactly what happens when your body combats infection. In other words, AGES are treated as infectious materials. The end result is out-of-control inflammation that can flare up anywhere in the body. This can be a major contributory factor to the development of cataracts, memory loss, heart disease, premature aging, and of course, **joint damage**.

### **Chronic Inflammation — The Cell-Destroyer**

Let’s get a bit more specific about the issue of chronic inflammation. To do so we will need to take a closer look at cells themselves. A cell membrane (outer layer) is an incredibly organized structure. It is comprised of specialized fatty compounds called phospholipids. The layer of phospholipids forms a barrier to other cells and other outside factors – such as stressors that contribute towards cellular destruction.

Additionally, the phospholipid layer is critical to cellular function; it regulates the flow of vital nutrients, minerals, electrolytes, and other compounds in and out of the cell. Needless to say, the very life of a cell is totally dependent upon the integrity of its phospholipid layer. If conditions arise that compromise these fatty structures, such as chronic inflammation, complete and utter cellular obliteration can occur.

Again, this negative effect can arise anywhere in the body, **including joint tissues**.

### **A Pill Popping Catastrophe**

To combat inflammation-related pain, physicians may prescribe medications. Granted, certain prescription medications may indeed work to mask pain. However, any temporary relief they may offer is often accompanied by a host of unwanted side effects. Additionally, the exorbitant cost of some of these prescriptions may be a deterrent to using them.

To help avoid expensive doctor’s office visits and prescription medications, many turn Non-Steroidal Anti-Inflammatory Drugs (NSAIDS). Their use may be more prolific than you think. In fact more pain medications (like NSAIDS) are purchased for arthritic conditions than any other disorder. Unfortunately, over-the-counter (OTC) NSAIDS **are not without risk**.<sup>5</sup>

### **Why NSAIDS and Glucosamine Fall Short**

When used in higher doses over a period of time, NSAIDS are known to cause liver damage and kidney failure. Incredibly, over 20,000 deaths in the USA **annually** are

attributed to long-term use of NSAIDS. If that alarming tidbit of info isn't enough to raise some concern, check this next statistic.

Over 121,000 North Americans are hospitalized **each year** from NSAIDS side effects. We're not talking about minor stomach upset here. NSAIDS are associated with substantial gastrointestinal complications (bleeding, nausea, vomiting, ulcers), liver damage, immune system depression, mental confusion, and even kidney failure. Maybe you should think twice about using over-the-counter NSAIDS...at least on a regular basis.

Instead of subjecting their bodies to the pitfalls of NSAIDS, many athletes and fitness enthusiasts turn to natural remedies such as glucosamine.<sup>5,6</sup> This isn't a bad thing, *per se*. When consumed in high doses, on a consistent basis, glucosamine has been shown to provide **some** joint-related pain relief.<sup>7</sup> However, when taken in these high doses, glucosamine has **also** been demonstrated to elevate blood sugar.

Furthermore, glucosamine **does nothing to address the bigger issue of chronic inflammation**.

### **Compounding the Problem with Acid — Adding Insult to Injury**

Few things are more important to the overall health of our bodies than maintaining proper pH (alkaline/acid balance). Various systems in the body may require different levels of pH. However, in order for the body to function at optimal efficiency, all of these pH-dependent systems must be maintained in an overall balance.

Levels of pH are measured on a scale from 1–14. On this scale, 1 represents maximum acidity and 14 represents the highest level of alkalinity. The **optimal** pH for good health, at the cellular level, must be maintained within the range of 6.8–7.4. If pH levels plummet below 6.8 (i.e., into the acidic range), negative implications can arise. Following are just a few examples:

- Irritability
- Anxiety
- Low grade fevers
- Joint pain & inflammation
- Depression
- Susceptibility to infection
- Digestive problems

The body is either kept in optimal pH balance, or thrown into total pH chaos, primarily by the foods we eat. Overconsumption of acidic foods, such as sodas, fried foods, and processed foods, may promote a state of severe pH imbalance (particularly a low pH). Remember, a low pH is acidic.

Furthermore, a substantial number of **today's dietary supplements contain loads of citric acid** as part of flavoring systems. Here is the problem: the consumption of citric acid may drop the body's pH into a state of acidity. Because the body "likes" to be slightly alkaline, it will strive to correct this imbalance. Unfortunately, the process of re-establishing normal pH levels is very stressful to the body.

## **A Brilliant Solution — Address Whole Body Inflammation – and More**

Kre-Celazine® is a unique, patented “non-drug” ingredient. It has been shown in clinical studies to reduce pain and inflammation while promoting fast-acting joint support, improved flexibility and mobility<sup>8,9</sup>. It is a complex material produced by bonding Kre-Alkalyn® (US Patent 6,399,661) brand creatine with esterified fatty acid carbons.

To be clear, the creatine in this product is not esterified (like creatine ethyl ester). Instead, it's the **fatty acids** that are esterified. “What the heck does esterified mean, and why does it matter?” you ask.

In very simple terms, esterification is the process of combining a molecule of alcohol with a type of acid (like a fatty acid). This new molecule is said to be esterified. The esterifying process makes molecules stable. In the case of Kre-Celazine®, the esterified fatty acids are stabilized so they do not react negatively with oxygen.

Because Kre-Celazine® is formulated with genuine Kre-Alkalyn® brand creatine, it offers an additional benefit – a pH-balancing effect. Remember, to function at peak efficiency, the body's pH balance must be stabilized within a specific range. When the body becomes too acidic, inflammation can raise its ugly head!

## **A Muscle-Fueling Bonus**

Kre-Alkalyn®, a key ingredient in Kre-Celazine®, is a highly effective form of creatine. Creatine, a naturally occurring molecule in the body, is integrally involved in generating short-burst energy during sprints, and the first few reps of resistance exercise.<sup>10,11,12</sup>

To be a bit more precise, creatine helps to replenish spent ATP (adenosine triphosphate) molecules. ATP molecules are the body's “energy machines”...and your cells hold only a limited supply of them. During exercise, available ATP molecules are quickly expended. Stored creatine helps to “re-fuel” depleted ATP molecules until new ATP molecules can be produced.

Supplemental creatine, like Kre-Alkalyn®, may help to build greater available stores of ATP-replenishing fuel in muscle tissue. In turn, this may equate to promoting greater athletic potential. For example, an athlete may be able to sustain an all-out sprint for just a bit longer and a weight lifter may be enabled to squeeze out a few more reps. Additionally, a greater intramuscular pool of creatine may support faster recovery between sets and workouts.

Not a bad bonus for a joint support product!

## **Kre-Celazine® — Complete Joint Support, Health, and Performance System**

Kre-Celazine® is not a typical “joint support” formula with over-used and underwhelming ingredients. ***It is not*** a potentially harmful non-steroidal anti-inflammatory drug (NSAID).

***It is*** a powerful, patented compound that has been ***clinically demonstrated*** to address joint pain, inflammation, mobility, and exercise performance.<sup>8</sup> It is so effective that it has been granted the prestigious status of orphan drug designation by the FDA, but at this time is not licensed and still going through the NDI process.

## **Kre-Celazine® — 4x Joint and Fitness Support**

One of the most powerful features of Kre-Celazine® is its multifunctional power to support both joint health *and* performance potential. This is not your typical, “one-dimensional” joint formula; this is a **complete support system**. Kre-Celazine® delivers a quad core of critical factors:

### **Core Factor 1:** Supports Cellular Integrity<sup>10,13</sup>

Kre-Celazine® supports the integrity of cell membranes to enhance their function with a precision blend of specialized lipids. This enables cell membranes to better repel stressors and offer greater cellular protection. Additionally, Kre-Celazine® assists in enabling cells to become more fluid, permeable, efficient at accepting nutrients, and “youthful” & restored to a healthier state.

### **Core Factor 2:** May Help Address Inflammation and Reduce Pain<sup>6,8,13</sup>

Our hypothesis is that Kre-Celazine®, with patented Kre-Alkalyn® technology, may play a role in suppressing inflammation by reducing the activities of the COX-2 enzyme, a primary inflammatory trigger. We theorize that this could be accomplished on several fronts: by inhibiting pro-inflammatory arachidonic acid, by decreasing the pro-inflammatory effects of other fatty acids, and by helping to reduce the production of the inflammatory signaling Interleukin 6 (IL 6) molecule.

### **Core Factor 3:** Restore and Support Optimal pH

The alkalizing power of Kre-Celazine® is crucial to combating inflammation. It helps get your body working in a state that may be likened to a “greenhouse effect.” This is a pH where your body’s cells and biological systems work in perfect harmony to function, grow, and recover optimally.

### **Core Factor 4:** Support Muscle Energy and Strength<sup>10,11,12</sup>

Kre-Celazine® features Kre-Alkalyn® (US Patent 6,399,661), a premium form of alkalized creatine. Creatine, a naturally-occurring molecule in the body, is integrally involved in generating short-burst energy during sprints and the first few reps of resistance exercise. Supplemental creatine, like Kre-Alkalyn®, may boost the muscles’ stores of creatine. In turn, this may allow for greater exercise potential and muscle stimulation that can strengthen muscles, like those around joints.

## **Get Real Relief NOW**

Kre-Celazine®, a unique, science-based, dietary solution has shown its ability to reduce site-specific inflammation and pain in clinical studies.<sup>8,9</sup>

Kre-Celazine® is available as a capsule or a topical cream and is used daily to build and sustain optimal, whole body pH balance, muscle integrity, cell function, and joint mobility. Kre-Celazine® topical cream can be applied directly to sites of pain **any time** fast relief is needed.<sup>13,14</sup>

## In-Text References

1. McCarberg BH, Nicholson BD, Todd KH, et al. The impact of pain on quality of life and the unmet needs of pain management: results from pain sufferers and physicians participating in an Internet survey. *Am J Ther.* 2008; 15(4):312-320.
2. Lawrence RC, Felson DT, Helmick CG, et al. National Arthritis Data Workgroup. Estimates of the prevalence of arthritis and other rheumatic conditions in the United States. Part II. *Arthritis Rheum.* 2008; 58(1):26-35.
3. Silver FH, Bradica G, Tria A. Relationship among biomechanical, biochemical, and cellular changes associated with osteoarthritis. *Rev Biomed Eng.* 2001; 29(4):373-379.
4. Silver FH, Bradica G, Tria A. Do changes in the mechanical properties of articular cartilage promote catabolic destruction of cartilage and osteoarthritis? *Matrix Biol.* 2004; 23(7):467-476.
5. Wilcox CM, Cryer B, Triadafilopoulos G. Patterns of use and public perception of over-the-counter pain relievers: focus on nonsteroidal anti-inflammatory drugs. *J Rheumatol.* 2005; 32(11):2218-2224.
6. Morelli V, Naquin C, Weaver V. Alternative therapies for traditional disease states: osteoarthritis. *Am Fam Physician.* 2003; 15:67(2):339-344.
7. McAlindon TE, LaValley MP, Gulin JP, Felson DT. Glucosamine and chondroitin for treatment of osteoarthritis: a systematic quality assessment and meta-analysis. *JAMA.* 2000; 15:283(11):1469-1475.
8. Golini J,<sup>(a)</sup> Beeson M, ND, Medical Director,<sup>(b)</sup> Angersbach D, ND,<sup>(b)</sup> Moore J, ND,<sup>(b)</sup> Holl P, DC,<sup>(b)</sup> Amicone C, ND,<sup>(b)</sup> Jones W, MS.<sup>(c)</sup> A Single-Center, Double-Blind Placebo Controlled Study to Evaluate the Efficacy of Kre-Celazine<sup>®</sup>, an Oral Buffered Creatine-Cetylated Fatty Acid Compound, in its Ability to Reduce Site-specific Inflammation and Pain. A Peer-Reviewed *Journal on Nutraceuticals and Nutrition* Mark Houston, MD Editor-in-Chief ISSN-1521-4524.  
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9. Golini J. A controlled case study with Kre-Celazine, September 4, 2007, BioCeutical Research and Development Laboratory, BRDL Study No. 1251
10. O'Connor RS, Steeds CM, Wiseman RW, Pavlath GK. Phosphocreatine as an energy source for actin cytoskeletal rearrangements during myoblast fusion. *J Physiol.* 2008; 15;586(Pt 12):2841-2853.
11. Wallimann T; Wyss M; Brdiczka D; Nicolay K; Eppenberger HM (January 1992). "Intracellular compartmentation, structure and function of creatine kinase isoenzymes in tissues with high and fluctuating energy demands: the 'phosphocreatine circuit' for cellular energy homeostasis". *The Biochemical Journal.*
12. Buford TW, Kreider RB, Stout JR, Greenwood M, Campbell B, Spano M, Ziegenfuss T, Lopez H, Landis J, Antonio J. International Society of Sports Nutrition position stand: creatine supplementation and exercise. *Journal of the International Society of Sports Nutrition* 2007, 4:6 doi:10.1186/1550-2783-4-6.
13. Kraemer WJ, Ratamess NA, Maresh CM, et al. A cetylated fatty acid topical cream with menthol reduces pain and improves functional performance in individuals with arthritis. *J Strength Cond Res.* 2005; 19(2):475-480.
14. Kraemer WJ, Ratamess NA, Anderson JM, et al. Effect of a cetylated fatty acid topical cream on functional mobility and quality of life of patients with osteoarthritis. *J Rheumatol.* 2004; 31(4):767-774.

## General References

Ameye LG, Chee WS. Osteoarthritis and nutrition. From nutraceuticals to functional foods: a systematic review of the scientific evidence. *Arthritis Res Ther.* 2006; 8(4):R127. And at [www.arthritis-research.com/content/8/4/R127](http://www.arthritis-research.com/content/8/4/R127) Pages 1-22. [Accessed on 10-1-2008]

Ameye LG, Young MF. Animal models of osteoarthritis: lessons learned while seeking the "Holy Grail." *Curr Opin Rheumatol.* 2006; 18(5):537-547.

Christensen R, Bartels EM, Astrup A, Bliddal H. Symptomatic efficacy of avocado-soybean unsaponifiables (ASU) in osteoarthritis (OA) patients: a meta-analysis of randomized controlled trials. *Osteoarthritis Cartilage.* 2008; 16(4):399-408.

Henrotin Y. Avocado/soybean unsaponifiable (ASU) to treat osteoarthritis: a clarification. *Osteoarthritis Cartilage.* 2008; 16(9):1118-1119.

Little CV, Parsons T. Herbal therapy for treating osteoarthritis. *Cochrane Database Syst Rev.* 2001; (1):CD002947.

Nomura A, Zhang M, Sakamoto T, et al. Anti-inflammatory activity of creatine supplementation in endothelial cells in vitro. *Br J Pharmacol.* 2003; 139(4):715- 720.