

NATURAL APPROACHES TO PAIN MANAGEMENT

Seeking relief from pain has been identified as the leading cause of doctors visits. In the US it is reported that 70 million visits per year to health care practitioners are pain-related. Furthermore, a study undertaken in 2002 by the US National Center for Complementary and Alternative Medicine (NCCAM)¹ reveals that pain was the most frequently identified reason for taking natural health products, with 38.7% of adult Americans reporting having used some form of natural health product for pain during the year. Back pain, neck pain, arthritis and joint pain were identified as the leading causes of pain.

In allopathic medicine, non-steroidal anti-inflammatory drugs (NSAIDs) have long been regarded as the "drug of choice" to prescribe for patients suffering from pain and inflammation. Yet, this class of drugs is not free of risks or side effects. According to a March 2000 study, based on epidemiological data, in the US alone traditional NSAIDs (excluding COX-2 inhibitors) were responsible for over 16,000 deaths annually.² Until recently, this ominous statistic was used to point out that, in comparison, the introduction of the COX-2 inhibitor group of drugs was having the effect of "saving many lives".

What are COX-2 Inhibitors?

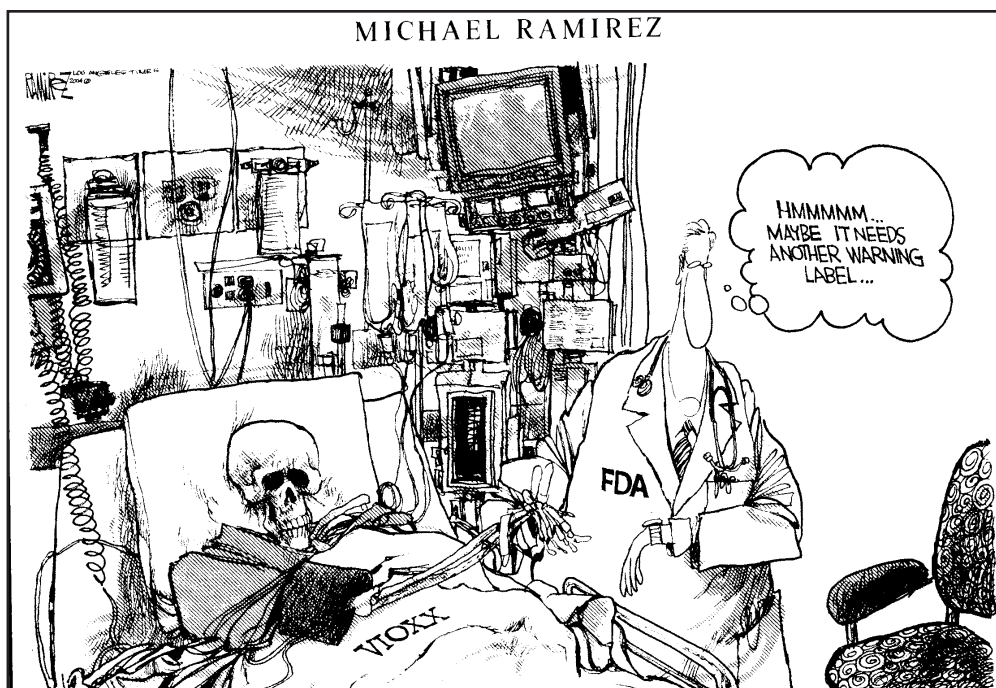
COX-2 inhibitors are a type of drug that selectively blocks the enzyme COX-2 (cyclooxygenase-2) and thereby impedes the production of prostaglandins, the chemical messengers that cause pain, swelling and tenderness associated with arthritic inflammation. Although widely prescribed for patients with osteoarthritis and rheumatoid arthritis, these drugs only work symptomatically and do not prevent the progression of or damage caused by arthritis.

The popularity of these drugs is because, unlike other NSAIDs, they do not block the COX-1 enzyme, which means they cause less inflammation and ulceration of the stomach and intestine.

Vioxx[®] withdrawn from the market

Yet, unfortunately this "safer" classification assigned to prescription COX-2 inhibitors seems to no longer be appropriate, as over the past several months new questions have emerged about the safety of these drugs. On September 30, 2004, the pharmaceutical giant Merck & Co. announced a worldwide withdrawal from the market of Vioxx[®] (rofecoxib), its arthritis and acute pain COX-2 inhibiting medication.³ The company made this decision based on the results of studies, which showed that after 18 months of use Vioxx caused increased risk of cardiovascular events, such as heart attack and stroke. Vioxx's market withdrawal, coupled with similar findings from another study involving Celebrex[®] (the leading drug in the same class), prompted the US Food and Drug Administration (FDA) on Dec. 27, 2004 to issue a Public Health Advisory in which it recommended "limited use of COX-2 inhibitors". The FDA health advisory states: "The FDA is issuing an advisory because of recently released data from controlled clinical trials showing that the COX-2 selective agents (Vioxx, Celebrex, and Bextra) may be associated with an increased risk of serious cardiovascular events (heart attack and stroke) especially when they are used for long periods of time or in very high risk settings (immediately after heart surgery)."⁴

The combined sales of these three drugs of over \$5.2 billion represents over 40% of the COX-2 inhibitor medication market in the US, with the largest group of users being arthritis sufferers who had assumed they would be able to use these drugs over an extended period of time.



* Excerpt from Biomed Report, Winter 2004, pages 8 - 11, © BIOMED International

NPF mono™

Natural COX-2 Inhibitor



- Anti-inflammatory agent
- Naturally manages pain
- Inhibits COX-2 enzyme's genetic expression
- Does not lead to increased cardio-vascular risk

Each vegetarian capsule contains

Ingredients	Mode of action
Nexrutine®250 mg (Phellodendron amurense)	COX-2 inhibitor, pain and anti-inflammatory agent

ADULT DOSAGE: Take one to two capsules three times a day with food or as directed by a practitioner.

NOTE: Monograph available upon request

The FDA's Health Advisory regarding COX-2 inhibitors caused considerable concern and confusion on the part of the public who had come to rely on these drugs for relief from arthritis pain and inflammation. Faced with uncertainty over the health risks associated with the leading COX-2 inhibitors, patients started to switch back to NSAIDs, despite misgivings about the gastrointestinal problems associated with their use.

FDA Warning Extended to NSAIDs

In addition to the well-known gastrointestinal complications associated with taking NSAIDs, concern has now also been raised about naproxen (one of the leading NSAIDs, sold under the brand name Aleve®) after the US National Institutes of Health halted a study examining the use of naproxen and Celebrex in the treatment of Alzheimer's disease. Study researchers had discovered that people taking naproxen were 50% more likely to have heart attacks or strokes. These study results prompted the FDA to encourage naproxen users to contact their doctors and to avoid taking the drug for longer than 10 days.⁵ Obviously, for the thousands of long-term arthritis sufferers being told to limit the use of their pain medication to not greater than 10 days is not exactly what they wanted to hear.

Natural Inflammation and Pain Management

This current state of disarray respecting the health risks of NSAIDs and COX-2 Inhibitors has prompted heightened awareness and interest in natural remedies which offer a viable alternative to Vioxx, Celebrex and NSAIDs. Fortunately, there are natural COX-2 inhibitors and other remedies that have a role to play in reducing inflammation and pain, without the known side effects of comparable allopathic drugs.

Natural COX-2 Inhibitor (NPF mono™)

Recognizing the need for a remedy which provides relief from pain and inflammation and avoids the side effects associated with traditional COX-2 inhibitors and other NSAIDs, Biomed now offers **NPF mono™**. NPF stands for "natural pain formula" and "mono" identifies it as a single ingredient formula. NPF mono™ works to inhibit the COX-2 enzyme, but unlike the prescriptive alternatives, it does so by inhibiting the gene expression of the COX-2 enzyme and not by COX-1 enzyme that is necessary in maintaining a healthy stomach lining.

A double blind placebo controlled trial investigating the benefits of the Phellodendron amurense proprietary extract (Nexrutine®) in 28 subjects with serious joint pain documented a significant improvement in total quality of life measurements; whereas the placebo group did not.⁶ In another study fifty-three subjects were treated with the product for two weeks at a recommended dosage of 250 mg three times daily. In this study post-trial analysis revealed a high level of satisfaction (79%) in overcoming

pretrial concept general aches and pains associated with physical activity and over exertion. Overall effectiveness was reported by 72% of patients, based on easing soreness in joints and muscles and greater comfort in undertaking daily activities. No significant side effects were reported.⁷

Clinical study results and the bio-chemical properties indicate that at the proper therapeutic dosage **NPF mono™** offers a viable alternative to allopathic anti-inflammatory and pain medications.

Other Natural Anti-inflammatory and Pain Relief Remedies

Three other natural anti-inflammatory and pain relief formulas Biomed offers are:

- o **NPF™ (Natural Pain Formula)**
- o **SerraNatto™**
- o **Flexizyme™**

NPF™ (Natural Pain Formula) is a synergistic combination of 12 ingredients (herbs, vitamins and minerals) that is a refinement of the former PSI (Pain, Spasm and Inflammation) formula. It has been enhanced through the use of standardized ingredients and reference to the recommended dosage (per ingredient) in compliance with National Health Products Directorate (NHPD) requirements.

Bromelain, in **NPF™**, is an enzyme from pineapples that works to breakdown and remove fibrins and other waste products found in the vicinity of damaged tissue, thereby helping to reduce swelling and speed the healing process. Bromelain also seems to block the production of inflammatory prostaglandins that increase swelling and cause pain.

The active ingredient in white willow bark, salicin, is the same ingredient that is used to make aspirin. Studies with white willow bark extract have shown it to be effective in treating pain associated with osteoarthritis and in reducing lower back pain.⁸ DL-phenylalanine stimulates the production of endorphins, which are the body's natural painkiller, whereas the vitamin B-6 in **NPF™** is a co-factor in serotonin production, which helps to decrease pain thresholds. The other ingredients in **NPF™** act in other ways to reduce inflammation and relieve pain, such as by supporting proper blood circulation and preventing muscle cramping. **NPF™** is particularly useful in the treatment of acute injuries (e.g. sprains and strains) that result from pain, inflammation, cramping and spasm.



1-800-665-8308

www.biomedicine.com

NPF™

Natural Pain Formula



NPF is an enhanced reformulated supplement that synergistically incorporates herbs with vitamins and minerals in easing pain, strain and inflammation associated with the musculoskeletal system.

Each vegetarian capsule contains: Ingredients*

Vitamin B-3 (niacinamide)	.25 mg
Vitamin B-6 (pyridoxial HCL)	12.5 mg
Calcium (citrate/carbonate)	.25 mg
Magnesium (citrate/oxide)	.25 mg
Potassium (citrate)	12.5 mg
Copper (gluconate)	0.0625 mg
L phenylamine	.50 mg
Bromelain (2400 mcu/g)	.75 mg
White willow bark 4:1	.75 mg
Wild yam root 4:1	.25 mg
California poppy 4:1	.25 mg
Rosemary 4:1	12.5 mg

* Refer to "Arthritis, Pain and Inflammation brochure or mono graph for mode of actions by ingredients.

ADULT DOSAGE: Take one to two capsules three times a day (between meals) or as directed by a practitioner.

NOTE: Monograph available upon request

SerraNatto™ is a proprietary blend of Nattokinase and Peptizyme SP® (Serrapeptidase). Nattokinase (or natto) is an enzyme from fermented soybeans that supports blood circulation and helps to maintain normal blood clotting. It also promotes the natural production of plasmin, which reduces fibrin. It is considered to be a more potent fibrinolytic agent than bromelain. Studies have shown that in rheumatoid arthritic patients fibrin deposits adhere to the synovial surface of rhomboidal joints where it aggravates the joint cavity.⁹ Natto may be useful in reducing this build-up.

The Peptizyme SP® in **SerraNatto™** is an enteric-coated proprietary form of the enzyme Serratia Peptidase (now, more commonly known as Serrapeptase), which is derived from the bacteria Serratia sp. Used clinically for over 20 years in Europe and Asia, Serrapeptase is recognized as an effective alternative to aspirin, ibuprofen and the more recent COX-2 inhibitor NSAIDs such as Vioxx® and Celebrex®.¹⁰ In contrast to NSAIDs, Serrapeptase causes no damaging gastrointestinal side effects because it does not inhibit prostaglandins. While originally used primarily to treat cardiovascular disease, it is now widely used as an anti-inflammatory and pain blocker, including in the treatment of rheumatoid and osteo-arthritis, wound healing, carpal tunnel syndrome and post surgical healing. It treats inflammatory disorders, by not only fighting inflammation, but also by relieving pain and swelling, improving recovery time (by speeding wound and tissue repair time) and stimulating the immune system.

SerraNatto's synergistic combination of the two powerful enzymes nattokinase and serrapeptase makes it another potent formula in addressing conditions associated with pain and inflammation.

Flexizyme™ is a powerful complimentary combination of systemic enzymes from three different sources: plant (Bromelain, papain), fungal (Peptizyme SP®) and animal (Pancreatin – with trypsin and chymotrypsin) which act together to rebalance the body's inflammatory response mechanism and speed healing to damaged tissue. Formulated as an enhancement on the now thirty-year old Wobenzym® formula, **Flexizyme™** offers a more effective formulation¹¹ and in a capsule format (with two ingredients Peptizyme SP® and Pancreatin being individually enteric coated). This potent formula assists in reducing swelling, bruising and discomfort associated with inflammation due to rheumatoid and osteo-arthritis; trauma (e.g sprains and strains); fibromyalgia; surgical procedures and sports injuries.

Conclusion

With this rich and varied combination of natural remedies available, the knowledgeable health practitioner has a whole palette of medications to draw upon in meeting the pain and inflammation requirements of his/her patients.

** Contact Biomed for a copy of footnotes

SerraNatto™

**A powerful fibrinolytic,
anti-inflammatory,
anti-edemic pain blocking
enzymatic formula.**



This potent proprietary combination of Serrapeptidase and Nattokinase is an effective alternative to NSAIDs and COX-2 inhibitors in treating a range of conditions, including arthritis, wound healing and cardio-vascular disease.

Each vegetarian capsule contains: Ingredients

SEBkinase® (20,000 FU/g)..... 100 mg
A proprietary blend of Nattokinase, enteric-coated Peptizyme® (Serrapeptidase), Calcium and Magnesium

ADULT DOSAGE: Take one to two capsules three times a day (between meals) or as directed by a practitioner.

NOTE: Monograph available upon request