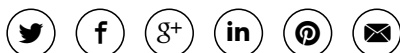


Traumeel Plus Zeel an Emerging Alternative to Intra-Articular Steroids and Viscosupplement Injections for Pain Associated with Moderate to Severe Osteoarthritis of the Knee

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MediNatura announced today that a recent double-blind, randomized, controlled trial presented at the European League against Rheumatism (EULAR) meeting in Rome, Italy demonstrated that its biological/mineral multi-extract combinations Traumeel and Zeel can be considered a safe and effective treatment for pain in moderate-to-severe knee OA. Effect sizes of pain relief were reported to be comparable to standard treatments such as viscosupplements and steroids, which make combined Traumeel plus Zeel injections a valuable option for many patient types.

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According to analysis of the first ever double-blind [trial of Traumeel and Zeel](#) on moderate to severe osteoarthritis of the knee, this treatment showed efficacy effect sizes that were consistent with those observed for the widely used intra-articular injections of hyaluronic acid (HA viscosupplementation), corticosteroids, and oral NSAIDs.^{3,4} Unlike oral NSAIDs, the safety profile of this treatment was benign with no signals of cardiovascular, gastrointestinal, or other concerning risks.^{3,4} The analysis, which highlights the efficacy and excellent safety profile of this treatment, was presented at the annual meeting of the European League against Rheumatism (EULAR) in Rome, Italy. The presentation was made by Dr. Carlos Lozada of the University of Miami, who along with Dr. Roland Moskowitz of University Hospitals Case Medical Center, Cleveland, contributed to the study design.

Osteoarthritis (OA), a progressive disorder characterized by structural damage to joints, affects more than 600 million people worldwide and over 10 million adults in the US. Musculoskeletal conditions, including OA, are the second leading cause of disability worldwide. Individuals who are the most severely affected by OA are seniors and women over age 55.¹

The vast majority of people with OA of the knee have at least one other chronic health condition, which can complicate the pharmacological treatment of pain related to OA due to the potential of drug-to-drug interactions and an increased risk of adverse events.¹ Therefore, treatment approaches must be evaluated according to not only their efficacy compared to standard treatments, such as injected corticosteroids and oral NSAIDs, but also based on their risk-benefit ratio.

"We believe that our products will become an important treatment for physicians caring for patients with osteoarthritis of the knee," said Stefan Luft, PhD, National Director of Sales and Medical Education, MediNatura™. "The products' unique approach and proven clinical efficacy offer an innovative treatment option to patients who are seeking clinically relevant but safe pain relief."

"These compounds have been available and used intra-articularly for a long time," according to lead study author Carlos Lozada, MD, a rheumatologist in the University of Miami Health System. Among clinicians who have administered the treatment, the impression "has been that there was something there, but there were no double-blind data to support that," he said, which was the rationale for the trial. "The study was undertaken to see if there was a true effect."

The study enrolled 232 patients at 30 sites in the United States and was first presented at the recent annual meeting of the American College of Rheumatology (ACR). Eligible patients were men and women ages 45 to 80 with moderate-to-severe chronic knee osteoarthritis, based on both clinical and radiographic criteria, who were taking either an NSAID or acetaminophen for pain.^{4,5}

Patients were randomized 1:1 to either Tr14 (Traumeel) plus Ze14 (Zeel) or a matching placebo, injected intra-articularly on days 1, 8, and 15, the standard injection schedule in clinical treatment. Patients were evaluated every 2 weeks.

On the primary endpoint, which involved the change from baseline on the knee subscale of the WOMAC A (Pain) Scale, treatment with Tr14/Ze14 performed significantly better than placebo beginning at day 15 (at the time of the final injection) and continuing through at all study visits except for day 29. The treatment's superiority to the placebo was also seen in the secondary endpoint of pain following a 50 meter unassisted walk.⁵

Adverse events were generally mild and unrelated to treatment, Lozada said, and there were no treatment-related serious adverse events.^{2,4}

References

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About MediNatura™ Inc.

MediNatura™ Inc., is headquartered in greater Philadelphia and operates a factory and product development facility in Albuquerque, New Mexico. MediNatura™ provides effective Rx and OTC medicines that have exceptionally safe side-effect profiles. It does this by using active ingredients predominantly from natural sources. For more information on MediNatura™ and its products, please visit <http://www.medinatura.com/pro>

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These statements have not been reviewed by the Food and Drug Administration. They are supported by traditional homeopathic principles.



MediNatura Inc.

“The products’ unique approach and proven clinical efficacy offer an innovative treatment option to patients who are seeking clinically relevant but safe pain relief,” Stefan Luft, PhD, National Director of Sales and Medical Education, MediNatura.”

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