MediNatura is the exclusive US importer of Injection Solutions manufactured by Heel GmbH, Baden-Baden, Germany
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Disclaimer: This folder contains helpful health information based on scientific data. This information does not constitute medical advice or treatment and does not replace medical examination; patients should consult a medical professional before deciding on a course of treatment. Medication names, indications, and formulas may vary from country to country; package inserts provide country-specific information.

The statements in this brochure have not been reviewed by the Food and Drug Administration. They are supported by traditional homeopathic principals.

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1. Introduction

Traumeel Injection Solution has been in use for over 70 years. Its success story started in Germany, where it was developed by the German physician, Dr. Hans-Heinrich Reckeweg who later also started to market it in other countries. Today, Traumeel in its different dosage forms is available in over 50 countries, including the US, where it was introduced roughly 30 years ago. This product monograph represents the current evidence base for Traumeel Injection Solution in order to support physicians in their decision making process.

Traumeel Injection Solution is a multi-component and multi-targeting medication containing 14 active ingredients in low dilutions. The exact mechanism of action of Traumeel Injection Solution has not been fully elucidated. However, in vitro and animal studies point to a multi-targeted mechanism of action. Various cellular and biochemical pathways appear to be modulated by the ingredients of Traumeel Injection Solution, which act synergistically on the different phases of the inflammatory response. It appears to reduce acute local inflammation without affecting the normal defensive and homeostatic functions of granulocytes or platelets. Traumeel Injection Solution seems to regulate the orchestration of the overall acute local inflammatory process instead of interacting with a specific cell type or biochemical mechanism. Preclinical studies suggest that Traumeel Injection Solution inhibits the secretion of pro-inflammatory mediators, and regulates lymphocytes and their messengers. Traumeel also appears to act by accelerating the healing process rather than blocking edema development from the start, with beneficial effects on tissue repair and wound healing.

With Traumeel Injection Solution there is no known toxicity to granulocytes, lymphocytes or platelets so their functions stay intact in the healing cascade reactions. In other words, Traumeel Injection Solution decreases the ‘bad inflammation’ and allows the ‘good healing’ inflammation to take place.

Over the decades, physicians have used Traumeel Injection Solution to treat muscular pain, acute sprains of the ankle, plantar fasciitis, capsulitis of the metatarsal joints, all forms of tendinitis, as well as a variety of other conditions ranging from dislocations and contusions to pain from osteoarthritis, rheumatoid arthritis and gouty arthritis, to name a few. The product’s flexibility is often seen as one of its key strengths.

In contrast to using steroid injections, one can administer Traumeel injections multiple times and also near to tendon structures. It seems not to be associated with the adverse cardiovascular, gastrointestinal, renal, hepatic or central nervous system reactions that physicians may regularly encounter with other pain relievers and anti-inflammatory drugs like corticosteroids or NSAIDs.

Pain management is most of the time a multi-modal approach, so having a medication that has an excellent safety profile and has no known interactions with other treatments is essential. Traumeel Injection Solution can be seen as a necessary option for an integrative approach to treat pain and inflammation. This treatment approach is appealing because of its immediate effects combined with a low side effect profile compared to steroid injections and anti-inflammatory medications.
2. Therapeutic indications and main benefits of Traumeel Injection Solution

**Traumeel Injection Solution is indicated:**
- As a mono-therapy, for the treatment of injuries, inflammatory and degenerative conditions of the musculoskeletal system and for the relief of associated symptoms such as pain.
- In combination with Zeel Injection Solution, for the treatment of inflammatory and degenerative conditions of the musculoskeletal system, such as arthrosis/osteoarthritis and/or rheumatic joint diseases, and for the relief of symptoms including pain, swelling, and joint stiffness.

**Traumeel Injection Solution offers:**
- Over 70 years of clinical experience with millions of patients treated in over 50 countries worldwide
- Established efficacy and safety data published in multiple clinical trials that also include studies under “real life” conditions"\(^{13,14}\)
- Multi-targeted mechanism of action mediated by its various ingredients that activate anti-inflammatory cytokines and inhibit pro-inflammatory cytokines.\(^{1,8}\)
- Unlike NSAIDs and corticosteroids, it is thought that Traumeel Injection Solution enters the inflammation cascade well before the prostaglandin synthesis begins, thus modulating the inflammation as well as the pain associated with arthritis and other relevant conditions. The protective action of the prostaglandin synthesis remains intact and the healing and repair in joints continues.\(^{13}\)
- An excellent safety profile with very rarely reported adverse effects, few contraindications and no known drug interactions that make Traumeel Injection Solution suitable for acute and longer-term treatment.\(^{14}\)
- A treatment that can be safely combined with other treatments but is effective as mono-therapy as well
- High patient and physician satisfaction with therapy.\(^{19}\)

**Traumeel Injection Solution should be considered for**
- Patients with acute and chronic injuries and inflammation that seek an effective treatment option combined with an excellent safety profile
- Patients with moderate to severe knee pain related to osteoarthritis of the knee that were considered for Viscosupplementation in the past. In June 2013, the American Academy of Orthopaedic Surgeons (AAOS) released a revised clinical practice guideline (CPG) on the treatment of osteoarthritis of the knee. One of the key changes from their 2009 guideline is that intra-articular hyaluronic acid (Viscosupplementation) is no longer recommended as a treatment for patients with symptomatic osteoarthritis of the knee.\(^{20}\) The American College of Rheumatology has no recommendations for or against the use of intra-articular hyaluronates for the initial management of knee OA in their 2012 guidelines.\(^{21}\)
- Patients that have frequent pain episodes and have to limit the number of steroid injections per year
- Patients who need to be injected near tendon structures where parenteral corticosteroids should be avoided
- Patients that generally have to avoid or be careful with corticosteroid injections.\(^{22-25}\)
- Patients with sensitivity to NSAIDs and NSAID side effects.
3. Composition

Table 1: The compositions of Traumeel Injection Solution, including dilution, quantity and excipients, is shown below (per 2.2 ml ampoule)

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Potency</th>
<th>Quantity</th>
<th>Final Dilution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aconitum napellus</td>
<td>2X</td>
<td>1.32 μl</td>
<td>5.22X</td>
</tr>
<tr>
<td>Arnica montana, radix</td>
<td>2X</td>
<td>2.20 μl</td>
<td>5.00X</td>
</tr>
<tr>
<td>Bellis perennis</td>
<td>2X</td>
<td>1.10 μl</td>
<td>5.30X</td>
</tr>
<tr>
<td>Belladonna</td>
<td>2X</td>
<td>2.20 μl</td>
<td>5.00X</td>
</tr>
<tr>
<td>Calendula officinalis</td>
<td>2X</td>
<td>2.20 μl</td>
<td>5.00X</td>
</tr>
<tr>
<td>Chamomilla</td>
<td>3X</td>
<td>2.20 μl</td>
<td>6.00X</td>
</tr>
<tr>
<td>Echinacea</td>
<td>2X</td>
<td>0.55 μl</td>
<td>5.60X</td>
</tr>
<tr>
<td>Echinacea purpurea</td>
<td>2X</td>
<td>0.55 μl</td>
<td>5.60X</td>
</tr>
<tr>
<td>Hamamelis virginiana</td>
<td>1X</td>
<td>0.22 μl</td>
<td>5.00X</td>
</tr>
<tr>
<td>Hepar sulphuris calcareum</td>
<td>6X</td>
<td>2.20 μl</td>
<td>9.00X</td>
</tr>
<tr>
<td>Hypericum perforatum</td>
<td>2X</td>
<td>0.66 μl</td>
<td>5.52X</td>
</tr>
<tr>
<td>Mercurius solubilis</td>
<td>6X</td>
<td>1.10 μl</td>
<td>9.30X</td>
</tr>
<tr>
<td>Millefolium</td>
<td>3X</td>
<td>2.20 μl</td>
<td>6.00X</td>
</tr>
<tr>
<td>Symphytum officinale</td>
<td>6X</td>
<td>2.20 μl</td>
<td>9.00X</td>
</tr>
<tr>
<td>Inactive Ingredients</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Water for injection</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sodium Chloride</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2,179.10 μl</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>19.40 μl</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
4. Mechanism of Action

It has been postulated that Traumeel Injection Solution has beneficial anti-traumatic and anti-inflammatory activities as indicated in a wide range of cases.

It has been assumed that the anti-inflammatory effect of Traumeel results from the activity of the various components on the different phases of the inflammatory response. For example, different concentrations of Aconitum napellus, Hamamelis virginiana, and Hypericum perforatum may reduce pain associated with inflammation; Mercurius solubilis may be anti-inflammatory; while Arnica montana, Calendula officinalis, Echinacea, and Symphytum officinale may accelerate wound healing.  

Study of single components of Traumeel Injection Solution has shown that Arnica montana, Hamamelis virginiana, Millefolium, Aconitum napellus, Belladonna, and Mercurius solubilus exert a considerable inhibitory effect on edema, while other components have a pro-inflammatory effect (Calendula officinalis, Echinacea purpurea); yet others are reported not to influence the development of edema (Symphytum officinale, Hypericum perforatum, Hepar sulphuris calcareum).  

However, the effect of Traumeel was found to be greater than the ‘sum’ of the active components, suggesting a synergistic interaction between all components of the preparation have a bearing on the final effect.  

Despite its long history of use as an anti-inflammatory agent, little was known until relatively recently regarding Traumeel Injection Solution’s effects on immune cell function. Preclinical evidence is provided by an in vitro study investigating the effects of Traumeel Injection Solution on human T-cells, monocytes, and gut epithelial cells in terms of their ability to secrete pro-inflammatory mediators interleukin-1beta (IL-1β), tumor necrosis factor alpha (TNFα), and interleukin-8 (IL-8).  

Traumeel Injection Solution was found to modulate the secretion of these mediators, inhibiting secretion in resting and activated cells by up to 54–70% (p =0.01 for all cells). These findings suggest that Traumeel Injection Solution acts on cells of the ‘mobile’ arm of the immune system (blood-borne leukocytes) and also on the first line of defense of the ‘nonmobile’ gut-associated immune system (gut epithelial cells).  

Other preclinical evidence suggest that Traumeel Injection Solution reduces microvascular leakiness to albumin in the mesenteric microcirculation and subsequent mast cell degranulation in rats exposed to daily 15-min episodes of 90-dB SPL noise for 3–5 weeks. Compared to controls, the number and area of leaks per venule in the rats that received Traumeel Injection Solution were significantly smaller and mast cell degranulation was significantly lower than those in rats exposed to noise only.  

This result is consistent with the in vitro study showing that Traumeel Injection Solution inhibited secretion of pro-inflammatory mediators from immune cells such as monocytes and T cells, and it is suggested that Traumeel Injection Solution may act by stabilizing immune cells.
There is evidence to suggest that Traumeel Injection Solution does not act in the same way as NSAIDs. While reducing acute local inflammation (first phase of acute arthritis) in vivo, the preparation did not affect granulocyte function (e.g., superoxide anion production and adhesion) or human platelet adhesion in vitro, indicating that the normal defensive and homeostatic functions of these cells are preserved. Traumeel Injection Solution appears to act by regulating the orchestration of the overall process of acute local inflammation rather than by interacting with a specific cell type or biochemical mechanism. Further studies concluded that Traumeel Injection Solution also seems to act by speeding up the healing process instead of blocking edema development from the start.\textsuperscript{13,14,45}

Additionally, Traumeel Injection Solution may play a role in situations where regulatory lymphocytes actively help control inflammatory reactions by producing the messenger,
transforming growth factor beta (TGF-β). Low potencies of plant extracts (including Bellis perennis and Belladonna) used in Traumeel Injection Solution have demonstrated stimulatory effects on lymphocyte synthesis of the inhibitory cytokine TGF-β in whole blood cultures. Through TGF-β synthesis, other pro-inflammatory T-lymphocytes (via, for example, TNFα and IL-1) are prevented from supporting the inflammatory process. This action has been supported by results in vivo.1,7,13,14

The nuclear factor-κB (NF-κB) family of transcription factors has a crucial role in the expression of genes that control the inflammatory response. In acute inflammation, NF-κB is activated rapidly in response to a wide range of stimuli (including pro-inflammatory cytokines, particularly TNF and IL-1) and increases the expression of several pro-inflammatory cytokines and chemokines.1,13 Traumeel Injection Solution, therefore, indirectly inhibits the activation of NF-κB by its effects on pro-inflammatory cytokines.1,13 There is evidence that it may also directly inhibit helenalin, an anti-inflammatory sesquiterpene lactone found in the Asteracea plant family (which includes Arnica montana and Bellis perennis, components of Traumeel Injection Solution) and has been shown to selectively inhibit NF-κB.1

The concept of ‘U’- or ‘J’-shaped dose-response curves (the dose-response hypothesis of which is also referred to as hormesis) is well established.46 The pharmacokinetic response of Traumeel Injection Solution, which comprises low concentrations of each component, is biphasic – high dilutions have no effect, but an
effect is seen within a certain range of low concentrations, after which higher doses have the opposite effect. Between dilutions of $10^{-1}$ to $10^{-7}$, Traumeel Injection Solution has a selective inhibitory effect on the pro-inflammatory mediators, IL-1β, TNFα, and IL-8.¹

In another study, researchers investigated the potential of Traumeel Injection Solution to affect chondrocyte proliferation and differentiation as well as activity of matrix metalloproteinases (MMPs) that are implicated in matrix degradation.⁴⁷

Chronic joint diseases, such as osteoarthritis, are associated with insults to articular cartilage. Imbalance between extracellular matrix production and degradation as well as defects in chondrocyte proliferation and differentiation lead to progressive degeneration of cartilage. To study the possible effects of Traumeel Injection Solution, cultured chondrocytes from porcine knee joints were used. Addition of Traumeel enhanced TGF-β induced proliferation, but did not affect basal proliferation of chondrocytes. In chondrocytes in the differentiated state, Traumeel Injection Solution enhanced viability of the cells and stimulated biosynthesis of sGAG.

Several MMPs were screened for inhibition by Traumeel Injection Solution; MMP-13 was found to be most inhibited (by 30%), while MMPs-2, -3, and -9 were not affected. While influence of Traumeel Injection Solution on proliferation of chondrocytes appears to be context-dependent, differentiation was supported under all tested conditions. Since Traumeel Injection Solution is also known to inhibit the production of cytokines which may reduce the functional capacity of chondrocytes, survival and function of these cells is likely to be improved by Traumeel Injection Solution on various levels.

Remarkably, Traumeel Injection Solution inhibited MMP-13 which is closely associated with the pathology of joint destruction.⁴⁷ Thus Traumeel might also indirectly slow down the progression of cartilage degeneration. The data suggest that Traumeel Injection Solution offers a potential therapeutic option for chronic joint diseases.⁴⁷ Heel Inc. is currently conducting a

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¹ Traumeel Injection Solution is used to reduce swelling, pain, and other signs of inflammation in acute and chronic musculoskeletal conditions, as well as to support tissue reorganization after injury. It contains a complex of plant materials and enzymes that work together to reduce inflammation and promote healing. The selective inhibitory effect on specific pro-inflammatory mediators is a key feature of its therapeutic profile. Further research is ongoing to explore its potential in various clinical settings.
A clinical trial to determine the effectiveness of combined intra-articular injections of Traumeel and Zeel Injection Solution in patients with moderate to severe pain associated with osteoarthritis of the knee. Further studies should be performed with Traumeel to expand the present knowledge of its potential mechanisms of action and to confirm the existing data. The evidence presented herein is still preliminary. Further investigations are certainly required to fill these gaps in evidence.

Figure 4. The observed effects of Traumeel® on mediators of inflammation.
THP-1 and Jurkat cells were maintained under tissue culture conditions while exposed to serial dilutions of Traumeel® for 24 hrs and 72 hrs.

Cells from the human gut epithelial cell line, HT-29, were incubated (24 hrs) with the indicated concentrations of Traumeel® and IL-8 secretion was measured using ELISA.
Figure 5. Effects of varying Traumeel® concentration on secretion of TNF-α (A), IL-8 (B), and IL-1β (C). Each data point represents the mean (±SD) of triplicate ELISA wells.

Figure 6. Traumeel’s effects on cytokines

Stimulation of inflammation reducing cytokines

- TGFβ ▲
  (regulatory lymphocytes [Treg-cells])

Reduction in inflammatory activity

Inhibition of pro-inflammatory mediators

- TNFα ▼
- IL-1β ▼
- IL-8 ▼

TGF, transforming growth factor; TNF, tumor necrosis factor; IL, interleukin
In cooperation with the St Laurent Institute (SLI), Cambridge, USA, Heel Inc., the manufacturer of Traumeel Injection Solution, started recently a Genomics Initiative. The “Heel SLI Genomics Initiative” is an ongoing scientifically-driven collaboration with the aim to further explain the mechanisms of action of multi-target treatments at the level of molecular and systems biology using genomics approaches. This includes HE230, as a model of an inflammation controlling agent, and Traumeel Injection Solution.

Biology is network based; from social networks to disease networks, to metabolic networks. For example, human proteins have been shown to have extensive interactions between each other. Therefore, scientists suggested, approaches that tackle mechanisms of disease and multi-target therapies have to be global: systematic, genome-wide and network driven.

Pharmaceutical science has identified inflammation as a significant driver of many diseases. Similarly, in multi-target medicine, inflammation is considered the most important single pathway in the human system. Applying experimental methods used in the RNA sequencing and mapping them to the genome in mice may bring promising results and support our current understanding of disease processes. This can provide an indication of how genes are activated over time during biological processes, for example within the LPS-induced inflammatory cascade.

When a treatment is also introduced, comparisons can be made between the gene pathways activated that can shed light on how the treatment exerts its effects. For example, a genomic test can distinguish between inflammation alone, corticosteroid treatment, or the multi-component experimental treatment, HE230, with 92% accuracy. Furthermore, pathways responsible for side effects with corticosteroids can also be elucidated. 48

For the first time, coherent, genome-wide changes in gene expression could be shown resulting from treatment with Traumeel Injection Solution, a complex multi-target preparation. The deep sequencing data provide evidence of therapeutic effects and their mechanisms of action by modulation of gene expression pathways. Small changes at multiple network nodes can lead to potentially important therapeutic effects, supporting the concept of multi-target therapy.

Wound healing is a complex but well-characterized process, in which inflammation plays a key role; it provides a well-established framework to study multi-target medicines like Traumeel Injection Solution and to apply transcriptome deep sequencing (RNAseq) as a primary diagnostic and analytical tool for systems biology studies. 48

Recently, the SLI committed in-depth analysis of novel and therapeutically relevant changes in the transcriptome at several time points during wound healing in the presence of Traumeel Injection Solution in a mouse model, compared with control and comparator treatments, by using high-throughput Helicos RNAseq.

Gene expression changes induced by Traumeel Injection Solution include many genes in the TGF-β pathway, and associated extra-cellular matrix genes. In addition, Traumeel Injection Solution has effects on the expression of a number of genes in growth factor and tissue regeneration pathways, such as epiregulin (EREG), and platelet derived growth factor receptor α chain (PDGFra). Non-coding RNAs that play increasingly recognized roles in wound healing, such as miR-99b and miR-223, are also changed after treatment with Traumeel Injection Solution. 48

Based on these preliminary results the researchers concluded that a broad range of transcriptome changes occur after Traumeel therapy during the wound healing time course, which suggest that its therapeutic action may involve multiple network nodes. The data support the hypothesis that Traumeel affects both resident fibroblasts and infiltrating immune
cells. They hypothesized that this may result from increased levels of pluripotency among cells in the wound, and/or facilitation of cell migration and tissue organization during the wound healing process in the Traumeel treated animals. The Traumeel transcriptome database will facilitate further studies evaluating disease mechanisms and the benefits of natural multi-target therapies in inflammatory conditions.

**Untreated time course**

Figure 7. A: Graphical depiction of the phases of wound healing over time that occur in mammalian skin. B: The log (base 2) of the p-value of some of the Gene Ontology (GO) categories that exhibit the most striking changes over time when compared to the unwounded (0H) time point. A positive y-axis value depicts up regulation of those categories and a negative y-axis value depicts down regulation.
Figure 8. A) The average normalized expression (RPK10M – Reads Per Kilobase per 10 Million aligned reads) of members of the EGF Receptor and Stefin families over time are plotted, comparing animals treated with both injected and topical Traumeel (Traumeel injection and ointment) with animals treated with injected saline alone (Saline). B) The number of genes identified as being down regulated in the ‘Cellular Differentiation’ GO category are given for animals treated with both injected and topical Traumeel in comparison to those treated with injected Traumeel alone. There is a significant overlap between the two treatments, with a combined topical and injected treatment providing a stronger response.
Figure 9. The average normalized expression (RPK10M) of various genes integral to inflammation signaling, cell stress, DNA damage, microRNAs, cell mobility and pattern signaling are plotted, comparing animals treated with both injected and topical Traumeel (Traumeel injection and ointment) with animals treated with injected saline alone (Saline).
5. The evidence base –
clinical efficacy, safety and tolerability

Several clinical trials with Traumeel Injection Solution have demonstrated its efficacy, excellent safety and tolerability profile, and ability to improve relevant symptoms. The clinical evidence base supporting Traumeel Injection Solution is detailed in the following pages.

5.1 Management of Knee Osteoarthritis with combined intra-articular injections of Traumeel and Zeel Injection Solutions (MOZArT Study)

Reference: Presented at the Annual Meeting of the American College of Rheumatology 2014 in Boston by Dr. C. Lozada (University of Miami – Miller School of Medicine) and Dr. R. W. Moskowitz (University Hospitals – Case Medical Center, Division of Rheumatology, Cleveland)\textsuperscript{107}

In this multi-center, double-blind, randomized, controlled trial, 232 patients with moderate-to-severe chronic knee OA were randomized to three weekly IA injections of either 2.2 mL Traumeel plus 2.0 mL Zeel (1 ampoule each) or saline.

Study Design

Patients with moderate-to-severe chronic knee OA were randomized to 3 weekly IA injections of either combined Traumeel & Zeel Injection Solutions or saline by clinical investigators experienced with use of the IA injection route. The primary efficacy variable was change in knee pain from Baseline to End-of-Study (Week 17) as measured by the WOMAC OA Pain Subscale (Section A, 1–5) 100 mm VAS. Secondary measures included Total WOMAC and sub-scores for stiffness (B), and physical function (C), change in pain following a 50 ft. walk (100 mm VAS), patient and physician global assessments. Clinical relevance was assessed by comparing proportions of patients with reductions from baseline in WOMAC A scores greater than a validated benchmark Minimal Clinically Important Difference (MCID). This was chosen as =32.6 mm (the most conservative value) based on a study of outpatients with knee or hip OA where WOMAC VAS MCIDs ranged from=7.9 mm to=32.6 mm [see Tauback et al., Ann Rheum Dis. 2005; 64(1):29–33 in the description of the WOMAC index published by ACR]. Safety was assessed by monitoring of vital signs, physical examinations of the target knee, adverse events and concomitant medications.

Results

232 patients were randomized and treated (All Traumeel & Zeel Injection Solutions, n=119, All Placebo, n=113; Intention-to-Treat (ITT) Traumeel & Zeel Injection Solutions, n=117, Placebo, n= 111). Treatment arms were well balanced across demographic and baseline characteristics. Traumeel & Zeel Injection Solutions did not discriminate for WOMAC A Pain as expected after only 1 of 3 injections on Day 8 (p=0.3715), but subsequently was significantly different (p=0.05) on Days 15, 43, 57, 71, 85 and 99 (primary endpoint day), and approached significance on Day 29 (p=0.0686) (see Fig 1). Logistic regressions showed the proportion of MCID responders was not significant on Day 8. As this was an expected finding, it served as a no-effect internal-model-validation. Traumeel & Zeel Injection Solutions was significantly different (p=0.05) on all subsequent days except Day 29 (approached significance,
p=0.0599, Fig 2). 50’ walk pain was similarly discriminating as was the physician global assessment (Fig 3). Total WOMAC and sub-scores B&C were directionally consistent with WOMAC A. There were no related SAEs. AEs were generally mild and unrelated to treatment. Local knee-related AEs, lab assessments, ECGs and vital signs were unremarkable and similar between treatments.

**Fig 1:** Mean WOMAC A (Pain) Changes from baseline

**Fig 2:** Percentage of subjects achieving decrease in WOMAC pain subscale score of ≥ 32.6 mm from baseline
Conclusion

Traumeel & Zeel Injection Solutions provided statistically significant and clinically relevant pain relief on days 15 to 99 in comparison to placebo. In this double-blind, randomized, controlled trial, a biological/mineral multi-extract combination was shown to be a safe and effective treatment for pain in moderate-to-severe knee OA.
5.2 Treatment of arthralgia of knee and hip joints with intra-articular injections of Traumeel

Reference: Hieber F. Treatment of arthralgia of knee and hip joints with intra-articular injections of Traumeel. Therapiewoche 18, 789 (1968) (German)

110 patients (36 to 79 years) with pre-arthritis and arthritic pain in the knee and hip joint were treated with intra-articular injections of Traumeel Injection Solution. Each patient received four injections into the affected joint (one ampoule of 2.2 cc per week). As adjuvant therapy all patient applied Traumeel ointment to the affected area on a daily basis.

Table 2: 88% of patients reported a good to very good improvement of their pain symptoms. The six patients without relief showed severe degeneration of their joints. There were no side effects observed.

<table>
<thead>
<tr>
<th>Patient No.</th>
<th>Self-reported Improvement of Symptoms</th>
<th>Reported side effects</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Very Good</td>
<td>Good</td>
</tr>
<tr>
<td>Pre-arthritic Arthralgia of the knee</td>
<td>21</td>
<td>17</td>
</tr>
<tr>
<td>Arthritic Arthralgia of the knee</td>
<td>43</td>
<td>30</td>
</tr>
<tr>
<td>Mild Coxarthrosis</td>
<td>27</td>
<td>18</td>
</tr>
<tr>
<td>Moderate to severe Coxarthrosis</td>
<td>19</td>
<td>12</td>
</tr>
<tr>
<td>Totals</td>
<td>110</td>
<td>77</td>
</tr>
</tbody>
</table>

5.3 Treatment of acute traumatic effusions of the knee joint (hemarthrosis and hydrarthrosis) with intra-articular Traumeel injections


In this early pilot study administration of intra-articular Traumeel injection (1 ampoule, 2.2 cc) after hematoma aspiration in 28 patients with acute traumatic effusions of the knee joint (hemarthrosis and hydrarthrosis) were shown to reduce the rate of recurrence after 3 weeks compared to standard basic treatment (only hematoma aspiration without Traumeel injection). A total of 89% (25/28) of patients treated with Traumeel were without detectable effusions compared with 21% (4/19) patients in the control group. These early findings were later basically confirmed by the following study.
5.4 The treatment of recent traumatic blood effusions of the knee joint


Study design

Patients with acute, post-traumatic irritation of the knee joint with hemarthrosis (10–50 cc effusion) were randomized to receive:

- Traumeel n=37: 24 male, 13 female; mean age 36 years
- Physiological saline solution n=36; 24 male, 12 female; mean age 36 years.

All patients were given an intra-articular injection on days 1, 4 and 8 with 2 ml Injection Solution after which a support dressing was applied. The observation period for each patient was 36 days.

End points

- Extent of swelling by measuring circumference of knee joint.
- Mobility of injured and healthy joints.
- Pain at rest, on movement and under pressure measured using 3-point scale (0=none, 1=slight, 2=severe).
- Volume and nature of puncture fluid.

Results

- After a single injection, only 13.5% of the patients in the Traumeel group required further punctures, compared with 25% in the placebo group.
- On the 8th day after the start of treatment, the punctuate was still bloody in 5.4% of the Traumeel group vs. 19.4% of the placebo group.
- Degree of movement was improved on day 8: 82.8% with Traumeel vs. 56% with placebo.
- Swelling was reduced by 73.2% in the Traumeel group and 51.3% in the placebo group.
- Success of treatment by day 8 is shown in Figure 10.
- Greater reductions in pain were seen in the Traumeel group compared with the placebo group through day 8 (see Figure 11).
- By day 36, 95% of Traumeel patients questioned had resumed normal activities compared with only 58% of placebo patients.
- In all patients, treatment was tolerated without side effects or complications.
Figure 10. Success of treatment by day 8 (maximum difference in circumference of joint 0.5 cm and maximum difference in mobility 10 degrees between healthy and injured joints).

Figure 11. Mean values for total pain score on days 1, 4 and 8.
Conclusion

- This study shows that intra-articular injection therapy with Traumeel produces fast regression of blood effusions of the knee.

Note: The therapeutic process for treating recent traumatic blood effusions of the knee joint not involving any ligament or cartilage bone structures involves effusion (the escape of fluid) punctures in the area under sterile conditions to drain the hemarthrosis. During the puncture process, the joint may also be flushed using a neutral liquid, such as physiological saline solution, and this is usually followed by an intra-articular injection of an anti-inflammatory agent.
5.4 Traumeel compared with NSAIDs for symptomatic treatment of epicondylitis


Study design

Patients with diagnosed epicondylitis were treated with:

- Traumeel injection (local infiltration) n=86: 40 male, 43 female; mean age 48.6 years
- NSAIDs (unspecified, mainly diclofenac 51.9%) injection (systemic, mainly intramuscular) n=77: 40 male, 36 female; mean age 45.8 years.
- Other treatments were allowed, e.g. oral analgesics or physiotherapy, but while Traumeel patients were allowed further injections, they were not allowed oral NSAIDs: 41.6% of the NSAID group received oral NSAIDs.
- Assessments conducted at weeks 1 and 2.

Outcome measures

- Pain: local pressure pain, pain with movement, pain at rest. 5-point scale: 0=no pain, 1=light, 2=moderate, 3=strong, 4=severe.
- Mobility: extensional joint mobility, torsional joint mobility. 4-point scale: 1=normal, 2=lightly impaired, 3=moderately impaired, 4=heavily impaired.
- Global assessment of efficacy: time to first improvement, outcome of therapy (very successful, successful, moderate, unsuccessful), compliance (very high, high, moderate, low).

Results

- Both treatments showed similar improvements in all five variables in the first week with no significant differences in time to onset of action.
- Traumeel showed markedly greater improvements in the variables pain at rest (p<0.01), change in extensional joint mobility (p<0.05) and change in torsional joint mobility (p<0.01) compared with NSAIDs, particularly in the second week of treatment (p values from non-inferiority analysis at end of week 2).
- Although the study was designed to assess non-inferiority, the analysis showed Traumeel to be equivalent to NSAIDs on all variables and trended towards superiority on the variables pain at rest, extensional joint mobility and torsional joint mobility (see Figure 12).
- In global assessment, treatment was judged “very good” or “good” in 71% of Traumeel patients compared with 44% of NSAID patients (p=0.013).
- Compliance was reported as “very high” or “high” in 92% of Traumeel patients compared with 81% of NSAID patients (p=0.11).

Conclusion

- Traumeel was at least equivalent to NSAID therapy in reducing pain and improving mobility in the early treatment of epicondylitis.
Figure 12. Mean difference with 97.5% confidence interval between symptom scores after two weeks for patients treated with NSAIDs (n=77) and Traumeel (n=86).
5.5 Drug surveillance study with Traumeel Injection Solution


Study design

- 348 physicians completed surveys for patients in their care receiving Traumeel Injection Solution: 3,241 patients: 49.1% male, 50.5% female; mean age 47.5 years.
- The most frequent complaint was forms of degenerative joint disease (primarily of the knee and hip), followed in descending order of frequency by myogelosis and sprains. Periarthropatia humeroscapularis, epicondylitis and tendovaginitis were also treated.
- Duration of symptoms was <1 week for 33.9% of patients, between 1 week and 1 month for 31.0%, and over 1 month for 33.7%.
- Traumeel was the only treatment for 19.2% of patients: 33.3% received nonmedical therapy (e.g. application of heat or cold, massage), 14.9% received additional medical therapy (which could include other preparations of Traumeel), and 31.1% combined additional medical and non-medical therapy.
- Frequency of application: daily 15.2%, 3 times a week 27.7%, twice weekly 40.1%, once weekly 13.6%.
- Manner of application: intramuscular 24.0%, subcutaneous 17.8%, periarticular 14.6%, intra-articular 10.6%, peritendineal 7.0%, intravenous 4.3%, intracutaneous 2.8%, other 18.6%.
- Duration of treatment: <1 week 15.9%, 1 week to 1 month 62.7%, 1-3 months 15.2%, 3-6 months 3.2%, >6 months 2.1%.

Outcome measures

- Physician-rated therapy outcome: very good, good, satisfactory, unsuccessful, worsened.

Results

- The overall therapeutic results were graded as “very good” or “good” in 78.6% of cases. Treatment was “unsuccessful” in only 3.5% of cases and only five cases (0.1%) were reported as “worsening” (see Figure 13).
- Results were rated as “good” or “very good” in 95.0% of patients with sprains, 86.9% tendovaginitis, 80.1% myogelosis, 78.6% epicondylitis, 74.8% periarthropatia humeroscapularis and 59.5% degenerative joint disease.
- Ratings appear higher when Traumeel was administered without concomitant therapies: 85.2% “good” or “very good” for monotherapy, 79.6% additional non-medical therapy, 82.8% additional medical therapy, and 71.7% additional medical and non-medical therapies.
- The fraction of “good” or “very good” results was greater with shorter administration intervals between injections than for applications with longer time periods between injections; e.g. daily application resulted as “good” and “very good” comments in 90.1%, weekly application only in 68.2%.
- Traumeel was well tolerated.
Conclusion

- Traumeel Injection Solution is effective for therapy of post-traumatic conditions (sprains), as well as inflammatory and degenerative processes affecting the musculoskeletal system.

Figure 13. Results of therapy among patients treated with Traumeel injection (n=3,421).
5.6 Pilot Study: Comparative outcomes of cervical and lumbar spine facet injections


Study design

- 68 chronic pain patients were asked to complete the Pain Disability Questionnaire (PDQ), a functional outcomes measurement tool, at the onset and prior to each facet procedure.
- The PDQ tracks 13 subjective responses to pain on emotional state, financial impact, and activities of daily living (ADL).
- Data was collected over a four month period on patients with a minimum of three procedures for the same complaint.
- A comparison was made between patients receiving a steroid solution containing Betamethasone (n=27) and a non-steroidal solution containing Traumeel (n=41). The primary efficacy outcome was based on pain relief reports, and the secondary efficacy outcome was the emotional state changes.

Results

- Preliminary results indicate that 25 patients (60.98%) treated with the Traumeel solution demonstrated significant improvement, while 8 patients (19.51%) worsened, and 8 (19.51%) stayed the same.
- Patients treated with Celestone-Betamethasone had poorer outcomes: 13 patients (48.15%) demonstrated improvement; 9 patients (33.33%) worsened, and 5 (18.52%) stayed the same.

![Figure 14. Based on these preliminary results it appears that cervical and lumbar spine facet injections with Traumeel Injection Solution may lead to beneficial results.](image-url)
Conclusions

- These preliminary results indicate that Traumeel Injection Solution improves pain and functional scores at a higher rate when compared with Celestone (Betamethasone) in patients with chronic back pain receiving cervical and lumbar facet injections.
- The mechanism of action of Traumeel Injection Solution includes the regulation rather than ablation of the cyclooxygenase pathway, therefore, pain is still addressed and normal physiologic mechanisms are otherwise unaffected.

5.7 Treatment of Lumbar and Cervical Pain


Study design

Over a course of three years patients that suffered from lumbar or cervical pain in different clinical stages were assessed by clinicians and either corticosteroids or Traumeel Injection Solution applied as CT-guided i.a. injections.

Lumbar Pain Syndrome:

- Patients with lumbar pain syndromes that were resistant to therapy for longer than six weeks and who previously had been treated by an orthopedic specialist, assessment of the status of the lumbar spine was carried out using computed tomography
- After assessing the presence of intravertebral arthrosis and making adequately sure that no disc pathologies were present, these patients received i.a. therapy for 5 days
- In the absence of risk factors (e.g. diabetes, osteoporosis or pronounced lumbalgia) corticosteroids were administered i.a. over a period of five days
- In cases of slightly restricted bodily functioning, i.a. injections of 40 mg corticosteroid were administered on both sides on days 1, 3, and 5, while one ampoule of Traumeel Injection Solution was injected to each side on days 2 and 4
- In higher risk groups, with active metabolic disorders or pronounced osteoporosis, only Traumeel Injection Solution was administered i.a. on all five days
- In total, 236 patients were treated; 76 of them could be assessed in follow-up visits after four and sixteen weeks

Cervical Pain Syndrome:

- 24 patients were treated for cervical complaints and received peri-articular injections into the nerve roots of the cervical vertebral joints with one ampoule of Traumeel Injection Solution on each side
- Therapy was administered on days 1, 3, and 5.
- The joints C4/5, C5/6, and C6/7 were targeted for injection
Results

- After four weeks, positive results were observed in the 76 patients that were monitored.
- In most cases, subjective reports on improvement coincided with observation of improved back function.
- The positive development after sixteen weeks were surprising as successful results continued to be noted in the majority of patients.
- The authors pointed out that combining corticosteroids with Traumeel in graduated amounts allows to individualize the treatment of patients with back pain.
- Especially in patients with pronounced metabolic disorders, targeted injections with Traumeel Injection Solution make it possible to treat back pain without or with reduced amounts of corticosteroids.

5.8 Therapy of acute and chronic soft-tissue sport injuries with intradermal injections


Study Design

- Retrospective study with 158 male athletes who presented various types of acute (< 4 weeks, 22% of cases) and chronic (> 4 weeks, 78% of cases) injuries; see table 3 for details.

Table 3: No of patients per treatment and lesion treated. T= Traumeel injection, Z=Zeel injection, S=Spascupreel injection.

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Lesion treated</th>
<th>Total</th>
<th>Acute</th>
<th>Chronic</th>
</tr>
</thead>
<tbody>
<tr>
<td>T+Z</td>
<td>Tendinitis</td>
<td>90</td>
<td>3</td>
<td>87</td>
</tr>
<tr>
<td></td>
<td>Sprains</td>
<td>14</td>
<td>13</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Capsular Lesions</td>
<td>12</td>
<td>2</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td>Periostitis and compartemental syndromes</td>
<td>8</td>
<td>2</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>Bursitis</td>
<td>8</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>T+Z+S</td>
<td>Lesions muscle</td>
<td>26</td>
<td>10</td>
<td>16</td>
</tr>
</tbody>
</table>

Procedure

- Traumeel + Zeel Injection Solution applied i.d. (1-2 sessions per week; 1 ampoule of each product per session in total divided into at least 10 injections each at least 4 mm deep) to the affected and surrounding area; in cases of muscle lesions 1 ampoule of Spascupreel Injection Solution was added to the therapy.
- Evaluation: WOMAC Index; medical examination/evaluation of lead symptoms (physician); global assessment of treatment at the end of the observation period (physician).
Results

• Therapy was equally effective in acute and in chronic conditions
• The efficacy was independent of the number of weekly dosages
• In 71.5% of patients symptoms fully disappeared without relapse; 16.4% showed noticeable improvement of symptoms, 8.2% slight improvement and 3.7% no improvement.
• Most positive results could be observed after four treatment session.
• This method of treatment was well accepted by the athletes and no adverse effects were observed.

Figure 17. Evaluation of Efficacy. NI = Noticeable Improvement SI = Slight Improvement WI =Without Improvement

Figure 18. Number of sessions needed to achieve results
5.9 Efficacy of combined use of Traumeel and Spascupreel Injection Solutions before osteopathic manipulation compared to use of osteopathy alone (Unpublished pilot study)

Dr Marcos Martínez Catalán, Private Clinic, Aranjuez, Madrid, Spain

Objective
- To assess the efficacy of Traumeel and Spascupreel* injections before osteopathic manipulation compared to use of the osteopathy alone.

Study design
- A longitudinal study with 1,560 patients with structural and functional musculoskeletal lesions amenable to manipulation
- Patients were randomised to one of the two treatment groups following diagnosis
- The number of treatment sessions was based on lesion severity
- Patient assessments:
  - Number of treatment sessions
  - Subjective perception of symptoms by patients; graded as no improvement, slight improvement, marked improvement and condition resolved.

Patients
- Of the 1,560 patients, 87.8% were female, 12.2% were male
- Patient age range was 10 to 60 years (65.1% aged 31–50 years)
- Clinical conditions included cervical pain, back ache, lumbar pain, lumbar and sciatic pain, pseudosciatic pain, prolapsed disc, headache, migraine, functional scoliosis, shoulder pain, temporo-mandibular joint problems and ankle sprains
- Lesions were considered to be acute, intermediate and chronic in 6.9%, 30.0% and 63.1% of patients, respectively.

Procedure
- Osteopathic manipulation; technique depending on lesion location and extent of involvement (n=802) or
- Treatment with Traumeel and Spascupreel Injection Solution (n=758) administered before the appropriate osteopathic manipulation:
  - One ampoule each of Traumeel and Spascupreel combined in a 5 ml syringe (needle gauge 30G1/2, length 13 mm or more, as appropriate)
  - Preparation administered to trigger points
  - Injection usually intramuscular; also subcutaneous, subdermal, intradermal and periarticular administrations depending on lesion type
  - Volume administered (0.3–0.6cc) and number of sessions (1–12) depending on lesion severity

* = Spascupreel Injection Solution is a homeopathic drug indicated for the relief of spasms of the smooth musculature of the gastrointestinal and the urogenital tract as well as general muscle spasms.
Outcomes

Total number of treatment sessions received by patients with acute, intermediate and chronic lesions:

- Overall, lesions receiving Traumeel and Spascupreel injections before osteopathy required fewer treatment sessions than lesions receiving osteopathy alone
- The majority of lesions receiving Traumeel and Spascupreel before osteopathy required 1 to 3 treatment sessions, whereas similar numbers of lesions receiving osteopathy alone required 1 to 3 and 4 to 6 sessions.

Table 4. Total number of treatment sessions received by patients with acute, intermediate and chronic lesions (T = Traumeel Injection Solution; S = Spascupreel Injection Solution; total number of lesions in the osteopathy only group is 802, and in the Traumeel+Spascupreel+osteopathy group is 758; % is the % of the total number of acute, intermediate and chronic lesions in the group)

<table>
<thead>
<tr>
<th></th>
<th>1–3 sessions</th>
<th>4–6 sessions</th>
<th>7–9 sessions</th>
<th>10–12 sessions</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Osteopathy only</td>
<td>T + S + Osteopathy</td>
<td>Osteopathy only</td>
<td>T + S + Osteopathy</td>
</tr>
<tr>
<td>Acute lesions</td>
<td>58 (7.2)</td>
<td>34 (4.5)</td>
<td>14 (1.7)</td>
<td>1 (0.1)</td>
</tr>
<tr>
<td>Intermediate</td>
<td>204 (25.4)</td>
<td>212 (28.0)</td>
<td>31 (3.9)</td>
<td>21 (2.8)</td>
</tr>
<tr>
<td>Chronic lesions</td>
<td>81 (10.1)</td>
<td>293 (38.7)</td>
<td>323 (40.3)</td>
<td>160 (21.1)</td>
</tr>
<tr>
<td>Total lesions</td>
<td>343 (42.8)</td>
<td>539 (71.1)</td>
<td>368 (45.9)</td>
<td>182 (24.0)</td>
</tr>
</tbody>
</table>

Table 5. Improvement by patients with acute, intermediate and chronic lesions (T = Traumeel Injection Solution; S = Spascupreel Injection Solution; total number of lesions in the osteopathy only group is 802, and in the Traumeel+Spascupreel+osteopathy group is 758; % is the % of the total number of acute, intermediate and chronic lesions in the group)

<table>
<thead>
<tr>
<th></th>
<th>No improvement</th>
<th>Slight improvement</th>
<th>Marked improvement</th>
<th>Condition resolved</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Osteopathy only</td>
<td>T + S + Osteopathy</td>
<td>Osteopathy only</td>
<td>T + S + Osteopathy</td>
</tr>
<tr>
<td>Acute lesions</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>2 (0.2)</td>
</tr>
<tr>
<td>Intermediate</td>
<td>12 (1.5)</td>
<td>0 (0)</td>
<td>47 (5.9)</td>
<td>9 (1.2)</td>
</tr>
<tr>
<td>Chronic lesions</td>
<td>50 (6.2)</td>
<td>4 (0.5)</td>
<td>79 (9.9)</td>
<td>50 (6.6)</td>
</tr>
<tr>
<td>Total lesions</td>
<td>62 (7.7)</td>
<td>4 (0.5)</td>
<td>126 (15.7)</td>
<td>59 (7.8)</td>
</tr>
</tbody>
</table>

Improvement in acute, intermediate and chronic lesions following treatment:

- Total resolution of musculoskeletal conditions occurred in 70.1% and marked improvement occurred in 21.6% of the T + S + Osteopathy group (versus 60.8% and 15.7% in the Osteopathy alone group, respectively)
- The sum of these proportions gives values of 91.7% for the T + S + Osteopathy group versus 76.5% the Osteopathy alone group.
Conclusions

- Combined administration of Traumeel and Spascupreel injections before osteopathic manipulation effectively complemented the treatment of musculoskeletal lesions that are amenable to osteopathic manipulation.
- The number of treatment sessions was reduced by these injection therapies when used before osteopathic manipulation.

5.10 Utilization of a multi-target medicine that regulates inflammation in the treatment of pseudosciatica (piriformis syndrome) in long distance runners


Objective

- The objective of the study is to demonstrate if the inclusion of Traumeel Injection Solution in the protocol for manual treatment recommended for the pyramidal syndrome improves the clinic and shortens the functional recovery process in long distance runners.

Patients

The pathology under study is the pyramidal syndrome in non-professional long distance runners. The clinical criteria required for selecting patients were:

- Pseudo-sciatic clinic
- Significantly positive palpation to pain (higher than or equal to 8 cm on the VAS) in three points of reference: sacroiliac Fortin point, any of the two piriformis trigger points according to Travell and Simons and the trigger point of the insertion into the greater trochanter of the femur;
- Five orthopedic tests. Four of them had to be painful during exploration: The Freiberg sign to forced internal rotation in supine position, the Pace sign to resisted abduction and external rotation in sitting, the posterior shear test of the sacroiliac with knee and hip flexion and pressure on the femoral shaft in supine position and Fair test with hip and knee flexion, adduction and internal rotation in supine position. The fifth test, the straight leg raise test to look for the Lasègue sign, should not be painful, since the compression produced by the piriformis muscle is of dynamic or active nature and this is a test of passive nature.
- 50% of the patients were male (31/62). The average age differed significantly between men and women (p <0.0001), aged 45 (95% CI 43.1-46.8) and 40.7 years (CI 95% 39.4-42) respectively, with an age difference of 4.2 years (95% CI 2-6.4) being lower in women. Selected patients were between 37 and 53 years old (42.8 on average).
- The most frequently affected side is the right (in 47 out of 62 patients) in 75.8 % of cases. However we found differences between genders. Men (29/31, p=0.001) were mostly affected at the right side, whereas in women there is not such a clear predisposition (18/31).

Methods

A retrospective observational study with 62 patients with diagnosis of pyramidal syndrome. The patients were divided into two groups (31/31):
- Group 1 received manual treatment with massage, myofascial liberation, and postisometric stretches; group 2 received the same protocol and in addition weekly injections of Traumeel Injection Solution over the course of a 10 week follow up.
- Group 2 received two ampoules (4.4 cc) injected ID on three points of the sacrum lateral border below the posterior superior iliac spine of the hip bone and on the trigger point of the trochanteric insertion of the piriformis muscle. The procedure was done with a 27Gx1” 0.40x25 mm needle and a double-body syringe of 5 cc, making a subcutaneous wheal with an inclination to the skin plane of 45° and then entering into intradermal level perpendicularly to the mentioned plane. Therefore, in each of the four referenced points around 1 cc of the Traumeel Injection Solution was deposited.

The evaluation included four orthopedic tests that measure the presence or absence of pain: Freiberg sign, sign Pace, shear test and the Fair test. As secondary objective the patient’s pain perception was evaluated using a visual analog scale (VAS), and at the end of the study the patient valued their individual satisfaction with the treatment. All measurements were taken by the same examiner.

Results

- Patients treated with Traumeel Injection Solution showed a significant lower proportion of visits with pain (p< 0.0001), and an average of two visits less with pain (14 days) in all evaluated tests.
- Time until complete resolution of pain in all tests was significantly lower in the Traumeel group: Median, 6 weeks (CI95% 5.7-6.3), versus 8 weeks (CI95% 6.8-9.2) in the control group (p< 0.0001).
- The pain evaluation by the patients was significantly better in the group treated with Traumeel Injection Solution (p<0.0001).
- No adverse events were observed.

Table 6. A: Proportion of time with pain in the four orthopedic tests; B: Time to disappearance of pain. Survival median by number of examinations.

<table>
<thead>
<tr>
<th>Orthopedic Test</th>
<th>Control</th>
<th>Traumeel</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Freiberg</td>
<td>90</td>
<td>61</td>
<td>p=0.007</td>
</tr>
<tr>
<td>Pace</td>
<td>172</td>
<td>94</td>
<td>p&lt;0.0001</td>
</tr>
<tr>
<td>Shear</td>
<td>240</td>
<td>168</td>
<td>p&lt;0.0001</td>
</tr>
<tr>
<td>Fair</td>
<td>257</td>
<td>196</td>
<td>p&lt;0.0001</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Orthopedic Test</th>
<th>Control</th>
<th>Traumeel</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Freiberg</td>
<td>2.9</td>
<td>1.96</td>
<td>p=0.026</td>
</tr>
<tr>
<td>Pace</td>
<td>5.5</td>
<td>3</td>
<td>p&lt;0.0001</td>
</tr>
<tr>
<td>Shear</td>
<td>7.7</td>
<td>5.4</td>
<td>p&lt;0.0001</td>
</tr>
<tr>
<td>Fair</td>
<td>8.3</td>
<td>6.3</td>
<td>p&lt;0.0001</td>
</tr>
<tr>
<td>All tests</td>
<td>8</td>
<td>6</td>
<td>p&lt;0.0001</td>
</tr>
</tbody>
</table>
Conclusions

- The treatment with Traumeel Injection Solution significantly reduced the time with pain by up to two weeks compared to manual treatment alone and led to a higher patient satisfaction overall.
- Addition of Traumeel injections to this otherwise manual treatment protocol was beneficial.
6. Case Reports

6.1 Rectus abdominis overuse injury in a tennis athlete treated with Traumeel injections


Traumatic musculoskeletal pathology is frequent in athletes. Muscle injuries account for more than 30% of sport injuries. One of the more common injuries is a muscle strain. A strain causes microscopic tears within the muscle, but occasionally, in severe injuries, the muscle can be ruptured. The most frequent cause of partial or complete rupture of muscle is the eccentric overload of the muscle or muscle overstretching. Severe muscle strains can lead to hematoma formation.

This case report covers a case of an overuse injury of the rectus abdominis muscle following overstretching during a tennis service in an athlete treated with injection of Traumeel Injection Solution and modification of the serve technique.

A 21-year-old female tennis champion was injured on her abdominal wall during a service in competition play. Specifically, she felt pain on her contralateral of service abdomen after a service but did not stop playing. She continued to suffer from pain in her abdomen and tenderness with any attempt of movement. Her trainer observed a tender mass after the trauma and he tried to control the pain with ice packs in the field. She was not initially restricted from athletic competition. One week later, again during a service, she experienced severe pain in her abdomen.

Conservative treatment was performed by a team physician with rest, ice therapy and analgesics for 20 days. There was an improvement and she decided to participate in training. During the first day of training she felt the same pain during service. Conservative treatment was performed for 20 days with rest, ice application, anti-inflammatory medication, muscle relaxant drugs, ultrasound and iontophoresis, followed by active stretching of the muscle within the athlete’s pain limits and isometric exercises.

She was instructed to perform active, pain-free rectus abdominis stretching 15 times a day and to perform pain-free isometric rectus abdominis strengthening exercises. She started training and after 2 days she felt the same pain during the service. Three months after the initial injury and following a new injury, she underwent clinical examination in another clinic, where a hematoma in the left rectus abdominis muscle was found that was 7×2×3 cm.

The patient was not on any medication and had no known blood disorders. Due to the recurrence of symptoms and failure of conventional treatment, the physicians decided to modify the standardized treatment protocol and to use Traumeel Injection Solution.

The patient was treated under aseptic conditions, with injection of Traumeel. The hematoma was palpated and 2 ampoules of Traumeel Injection Solution were injected. The hematoma was not aspirated before injection. The treatment was administered on the 2nd, 4th, 6th post-traumatic days and 1 injection on the 10th post-traumatic day. The goals of treatment included pain-free rectus abdominis flexion and extension and unrestricted return to full athletic activities as soon as possible.

After 3 weeks of trauma the athlete started training and a rehabilitation program including controlled warm-up and muscle stretching. MRI revealed a nearly complete recovery and she...
had pain-free function. The patient was instructed to modify the service technique in cooperation with her trainer and returned to her former sport activities and competitions. Two years later there is no recurrence of her injury and she participates under competition conditions in her sport. In this case Traumeel injections and modification of service technique were effective and no recurrence of rectus abdominis muscle strain was reported at 2-year follow-up. The combination of Traumeel injections and modification of service technique can be used for treatment of rectus abdominis overused injuries according to the authors.

6.2 Treatment possibilities of painful musculoskeletal disorders

Dr. Ludwig, MD published in BT Journal Volume X, No. 3: 275-277.58

This publication presents a summary of eight cases covering various forms of musculoskeletal disorders. The basic therapy consisted of administration of Zeel and/or Traumeel Injection Solution into the afflicted areas. The authors concluded that since, in many cases, the physician cannot readily or definitely determine whether musculoskeletal disorders are exclusively degenerative in nature, or whether inflammatory processes also contribute to the complex of symptoms, it can often prove highly effective to provide combined administration of Zeel and Traumeel Injection Solution. Five of the cases reported in the following received this co-administration. Most of the patients treated in the context of this observational study experienced progressive improvement in their conditions, both with respect to their subjective complaints as well as to the objective findings of the treating physician. In six of the cases, electrotherapy was applied in addition to the injections. No mentionable side effects or intolerance to therapy among any of these patients was reported.

Figure 20. Development of pain score of a female patient diagnosed with Chondropathia patellae, on both sides, who suffered from severe pain in both knees while walking downhill, and upon other imposition of weight. Rotation while applying pressure to the patellae revealed distinctly palpable softening and produced a grinding sensation in the knee joint. Treatment included periarticular administration of Zeel and Traumeel Injection Solution and electrotherapy in the form of electro-galvanic high-voltage stimulation
Table 10. Summary of patient data for the eight cases covered in this combined case report. T = Traumeel Injection Solution; Z = Zeel Injection Solution.

<table>
<thead>
<tr>
<th>Sex</th>
<th>Age</th>
<th>Diagnosis</th>
<th>Therapy</th>
<th>Improvement according patient after</th>
<th>No Symptoms after</th>
<th>Adjuvant Therapy (Electro-therapy)</th>
</tr>
</thead>
<tbody>
<tr>
<td>M</td>
<td>42</td>
<td>Chondropathia patella, both sides</td>
<td>Z + T injection periarticular</td>
<td>7 days</td>
<td>19 days</td>
<td>yes</td>
</tr>
<tr>
<td>M</td>
<td>45</td>
<td>Pain upon pressure, movement and weight application above the base of the Os metatarsal V, right side</td>
<td>Infiltration with Z + T</td>
<td>7 days</td>
<td>N/A</td>
<td>yes</td>
</tr>
<tr>
<td>F</td>
<td>27</td>
<td>Chondropathia patella, right side</td>
<td>Z + T injection periarticular, followed by Z periarticular</td>
<td>5 days</td>
<td>N/A</td>
<td>yes</td>
</tr>
<tr>
<td>M</td>
<td>47</td>
<td>Proximal insertion tendopathy of the right M. biceps</td>
<td>Z + T injection periarticular</td>
<td>7 days</td>
<td>19 days</td>
<td>yes</td>
</tr>
<tr>
<td>F</td>
<td>30</td>
<td>Epicondylitis humeri, both sides</td>
<td>Infiltration with Z</td>
<td>3 days</td>
<td>21 days</td>
<td>no</td>
</tr>
<tr>
<td>F</td>
<td>50</td>
<td>Gonarthrosis, right knee</td>
<td>Z periarticular</td>
<td>3 days</td>
<td>N/A</td>
<td>yes</td>
</tr>
<tr>
<td>F</td>
<td>45</td>
<td>Insertion tendopathy of the biceps tendon</td>
<td>Infiltration with Z</td>
<td>3 days</td>
<td>N/A</td>
<td>no</td>
</tr>
<tr>
<td>F</td>
<td>44</td>
<td>Chondropathia patellae, both sides</td>
<td>Z + T injection periarticular</td>
<td>9 days</td>
<td>17 days</td>
<td>yes</td>
</tr>
</tbody>
</table>

6.3 A case of lateral epicondylitis

Dr Alvaro Maúrtua Briseño-Meigss, Magdalena Health Center, Valladolid, Spain (unpublished report)

A 33-year-old male elite athlete (tennis player and marathon runner) who had recurrent pain and limited movement in his right elbow due to overuse rather than to direct trauma.

He had previously received conventional non-steroidal anti-inflammatory drugs and had developed gastroesophageal reflux disease as a consequence. Physical examination revealed pain, swelling, increased local temperature and limited flexion-extension.

Over a period of up to 4 weeks, a questionnaire was administered to assess the following: elbow circumference, local skin temperature, muscle function, pain (based on a Visual Analogue Scale of 1–10), opinion of the treatment (improvement, no change). The diagnosis was right lateral epicondylitis. Treatment consisted of Traumeel injection into the elbow (1 ampoule every 8 hours). To support the effects, the patient was advised to take one Traumeel tablet (OTC) every 8 hours and rub Traumeel ointment (OTC) into the affected area and use of an elastic elbow guard, as appropriate.

Traumeel reduced elbow swelling, local skin temperature, and pain. Normal function and sports activities were resumed rapidly after the start of treatment. The patient reported improvement in retrosternal heartburn and epigastric pain (signs of gastroesophageal reflux disease). Traumeel provided an effective alternative to non-steroidal anti-inflammatory drugs and was well tolerated. The patient considered that his condition was fully resolved.
6.4 A case of acute trochanteritis

Dr Joaquín Carreño Renduelles, Capua Private Clinic, Gijón, Spain (Unpublished report)

Two female patients aged 17 and 18 years, respectively, with pain in the left hip. Both patients participated in sports activities (handball and basketball) and reported that pain prevented training.

On clinical examination, both women had tenderness in the greater trochanter, pain on external hip rotation, and pain on thigh flexion. Radiographic assessment of the hip to rule out necrosis of the femoral head (because of patient age, pain in the area of the coxofemoral joint, and overload of these joints in such athletes). Functional limitation was evaluated based on a Visual Analogue Scale for pain and on the ability to perform usual sports training. At baseline, tenderness in the greater trochanter was rated a VAS score of 7, pain on external hip rotation was rated a VAS score of 8–10, and pain on thigh flexion was rated a VAS score of 7–10.

Acute trochanteritis in the left hip due to overload was diagnosed. The treatment consisted of Traumeel injection: 1 ampoule every 3 days in the first week, followed by 1 ampoule weekly for 2 weeks, administered as a fan-like subdermal injection in the area of the greater trochanter of the left femur. To support therapy, the patient was advised to apply Traumeel ointment (OTC) 3 times daily for one month. Furthermore, active rest was recommended.

After 1 week of treatment, the Visual Analogue Scale pain score decreased by 2–3 points. Physical work of the lower body was resumed; patients could jog, but were to avoid multiple jumps and changes of pace.

After 3 weeks (injection therapy completed), the VAS pain score had further decreased to 2 on palpation and on thigh mobilisation against resistance. Patients returned to training and reported minor discomfort (VAS pain score of 3) during training that did not inhibit usual activity.

After 2 months, patients continued activities with minimal discomfort (VAS pain score of 1) and without problems. Therapy encouraged treatment adherence; injections caused little discomfort and did not alter daily schedules, while the ointment was easy to administer.

6.5 A case of patella tendonitis

Izabela Fołta MD, NZOZ-Vitamed Chylonia Medical Clinic, Gdynia, Poland (Unpublished report)

A 37-year-old soldier who had complained for several days of severe pain, warmth and swelling of the left knee. The problem had arisen the day after a visit to the beach where he participated in sports and long walks on the sand. His general practitioner had prescribed an oral non-steroidal anti-inflammatory drug (diclofenac), but there had been little improvement.

On examination, there was swelling primarily in the area below the left knee and local warming. He experienced intense pain when trying to straighten the leg and on palpation. There was no internal fluid accumulation. Radiological examination did not show any pathological changes to the knee joint. Patellar tendonitis, particularly around the attachment to the shin bone was diagnosed.

The treatment consisted of Traumeel injection around the patellar tendon and its attachment: 1 ampoule on days 1, 4 and 6. To support the healing, the patient also applied cold compress with water acidified by lemon and rubbed Traumeel ointment (OTC) into the affected area. Movement of the knee was restricted.
Subjective improvement occurred a few hours after the first injection of Traumeel. At the first check-up, pain on movement and swelling of the knee were considerably reduced. The soldier returned to military service. The physician observed that Traumeel had a fast clinical effect, with improvement noted a few hours after the first injection. Traumeel Injection Solution was effective in reducing pain and swelling of the knee, whereas an oral non-steroidal anti-inflammatory drug (NSAIDs, diclofenac) had provided little improvement.

6.6 Two cases of quadriceps aponeurosis

*Dr Marcin Domżalski, Dr Z. Radliński’s Provincial Center of Orthopedics and Rehabilitation, Łódź, Poland (Unpublished report).*

A 26-year-old male professional volleyball player who had complained for 6 months of pain during exertion on both sides of the patella anterior to the patella base. On palpation, he had pain at the base of the patella. He had a normal range of movement of the knee joint, which was stable and without exudation. The patella showed normal shifting and an undisturbed movement path. Meniscus tests were negative. Enthesopathy and overload inflammation of the quadriceps aponeurosis were observed.

Damage was an element of “jumper’s knee”, an overload syndrome of the extensor apparatus of the knee joint that may also lead to damage of the patella ligaments.

Further ultrasound examination showed thickening of the quadriceps aponeurosis at the attachment to the base of the patella (9 mm compared with the normal mean value on extension of 6.5 mm, and 8.5 mm for tendons with an inflammatory reaction) (Figure 21).

![Figure 21: Ultrasound of the affected area](image)

Local damage of aponeurosis fibres with the presence of hypoechoic regions was also observed. Small deposits of calcification near the base of the patella indicated an intensified enthesopathic process. B-flow coded ultrasound revealed proliferation of blood vessels.
penetrating into the aponeurosis, particularly approximately 10 mm anterior to the patella base.

The condition was treated with Traumeel injection in the aponeurosis region: 1 ampoule every 3 days for 2 weeks. In addition, the patient was advised to take a tablet of Traumeel (OTC) three times a day. Training activity was prohibited during the two weeks of therapy.

After 2 weeks the patient continued therapy by applying Traumeel ointment 3 times a day to the affected area.

At 3 weeks, there was a reduction in overall pain (Visual Analogue Scale score reduced from 7 to 2). Pain was not interfering with his training schedule anymore and topped limiting participation in his athletic profession. Traumeel provided an effective and well-tolerated treatment of pain related to overload damage of the quadriceps aponeurosis.

The second case was a 35-year-old male international body-builder who had complained for many months of pain during exertion on both sides of the patella in an anterior direction from the patella base. On palpation, he had pain at the base of the patella. He had a normal range of movement of the knee joint, which was stable and without exudation. The patella showed normal shifting and an undisturbed movement path and meniscus tests were negative. Radiological examination of the knee joint was normal. Ultrasound examination showed thickening of the quadriceps aponeurosis at the attachment to the base of the patella (10 mm compared with the normal mean value on extension of 6.5 mm, and 8.5 mm for tendons with an inflammatory reaction) (Figure 22).

![Figure 22: Ultrasound of the affected area](image)

The diagnosis was Enthesopathy and overload inflammation of the quadriceps aponeurosis.

The treatment consisted of Traumeel injections into the aponeurosis region: 1 ampoule every 3 days for 2 weeks. As an adjuvant therapy the patient took one Traumeel tablet (OTC) three time a day and stopped his training for the 2 weeks of therapy. After the initial two weeks, tablets and injections were stopped and the patient applied 3 times a day Traumeel ointment (OTC) to the affected area.

At 3 weeks, there was a reduction in overall pain (Visual Analogue Scale score reduced from 8 to 2) that allowed the patient to start training again.
6.7 A case of achilles tendon pain

Dr Marcin Domżalski, Dr Z. Radliński’s Provincial Center of Orthopedics and Rehabilitation, Łódź, Poland
(Unpublished report)

A 24-year-old female track-and-field athlete who had complained for several weeks of pain in the area around the Achilles tendon. The pain disappeared for two days after physical therapy but returned with training. On palpation, she had pain at the site of tendon attachment to the calcaneal tuber and on pressure to the tendon, particularly about 2 cm below the calcaneal tuber. A tendon pressure test was positive only during maximum plantar bending in the ankle, suggesting that the pain originated in the mid-tendon. She also complained of pain during standing and walking on tip-toe. Ultrasound examination showed thickening of the Achilles tendon, with a visible tissue reaction near the tendon sheath. Fibrous tissue proliferation had altered the tendon architecture, particularly about 2 cm below the calcaneal tuber.

Examinations using doppler and a B-flow coded ultrasound technique revealed significant proliferation of blood vessels within the Achilles tendon, indicating an advanced degenerative process and chronic inflammatory reaction.

The final diagnosis was overload damage, with resulting degeneration of the Achilles tendon.

The treatment consisted of Traumeel injection at the most painful site beneath the Achilles tendon: 1 ampoule every 2 days for three weeks. Adjuvant Ionotherapy with Traumeel ointment in the Achilles tendon area: 1 application per day. The athlete was suspended from training for the course of the treatment.

Follow-up at 4 weeks after the athlete had resumed training revealed: reduction in overall pain (Visual Analogue Scale score reduced from 7 to 3). Reduction in pain on palpation of the Achilles tendon and no pain on power and movement exercises on the toes. Because of the detected degenerative changes, continued monitoring was recommended.

Traumeel Injection Solution provided effective and well-tolerated treatment of pain associated with overload damage to the Achilles tendon. Pain was rapidly reduced, enabling training to be resumed after 3 weeks.

6.8 Complex strain injury involving an intercostal hematoma in a professional baseball player


An elite, left-handed Major League Baseball player originally experienced mild, right-sided thoracic “soreness” after swinging a bat. There was mild tenderness at the anterolateral 10th intercostal space. The athlete experienced slight exacerbation of pain during deep inspiration with no discomfort with active or passive rotation.

These clinical findings were consistent with an intercostal strain. The patient was not initially restricted from athletic participation. Two days later, again while batting, he immediately experienced severe and “sharp” pain in the right, lower thoracic region. During examination, a tender, palpable mass was noted at the anterolateral 10th intercostal space. In addition to more severe pain during inspiration, the discomfort was also exacerbated by rotation and side-bending, which limited his ability to participate in athletic activities for nearly 1 month. Initial chest radiographs were negative. There was negligible improvement with
conservative measures (rest, anti-inflammatory medication, ultrasound, iontophoresis) during this convalescent period, which lasted 30 days.

Magnetic resonance imaging (MRI) of the chest was ordered because of the athlete’s delayed recovery despite measures that would typically be considered adequate for a simple strain. This study revealed signal-intensity changes within the right internal intercostal muscle between the tip of the 11th rib and the 10th costal cartilage, suggestive of a focal tear of the intercostal muscle with hematoma. There was also signal-intensity change (without organized hematoma) in the right internal oblique muscle just inferior to the intercostal injury, which represented concomitant muscle strain.

Four weeks following the initial injury, the patient opted for an alternative therapy and received an intralesional injection into the involved intercostal space with Traumeel injections solution. The hematoma was not aspirated.

Within 3 days following injection, he was capable of returning to unrestricted activity and has remained painfree without limitations or recurrent injury after 3 years.

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Figure 23: Ultrasound picture of the affected and the healthy side.
A professional dancer presented with pain in the right plantar heel that she had for two weeks and right posterior heel pain deep in the Achilles tendon area that she had experienced for approximately four weeks. The plantar and posterior heel areas were both sore and achy in nature, and aggravated by increased activities and dancing in the morning and after prolonged sitting. The Achilles had been sore for a longer timeframe and at times the ankle felt “jammed” and “stiff with full relevé and plié positions.” The patient denied any ecchymosis, warmth or neurological type pain or symptoms. There was no swelling plantarly but slight fullness in the posterior heel area along the anterior border of the Achilles tendon.

The patient was dancing every day, typically in ballet slippers or barefoot, which aggravates both areas of pain. There was some previous and current lateral leg muscular soreness along both muscle bellies. She noted she had some relief of these issues with massages and strengthening exercises. A physical therapist had treated the patient at the dance studio with ultrasound, massage and various taping methods.

The physical exam revealed pain with palpation at the medial plantar heel with no swelling, color or warmth. The patient’s initial treatment after thorough differential diagnosis was a corticosteroid injection into plantar heel. In order to address both pain locations, a combination of strapping with a dancer’s pad was applied, as well as the use of heel cups with heeled shoes, stretching, ice, physical therapy modalities and massage to the lateral and medial extrinsic foot musculature. In regard to dance modification, the patient was advised to limit jumping and had her wear jazz shoes or dance gym shoes with padding/heel cups and/or tape.

Due to the patient's work travel and performance schedule, the first follow-up was at 12 weeks. The patient had full plantar heel pain resolution due to exceptional adherence. The posterior heel/Achilles area was still painful to palpation with persistent minimal swelling in the retrocalcaneal bursa area. She felt much better in heeled shoes and any flat shoes or barefoot dancing were painful as the posterior heel pain was re-aggravated, even with various persistent treatments.

In addition to repeating the aforementioned treatments, the patient also received a Traumeel injection into the posterior heel/bursa/Achilles area. The use of diagnostic ultrasound revealed the following findings: A mild increase in caliber to the Achilles tendon, watershed area and distally posterior to the calcaneus, a small focal deficit (4 mm x 4 mm x 2 mm) to the anterior fibers of the Achilles at the posterior superior corner of the calcaneus, a prominent posterior superior border of the calcaneus with some impingement of the anterior fibers of the Achilles with dynamic evaluation. There was also hypertrophy of the retrocalcaneal bursa with increased fluid observed, as well as a slight extension of the peroneus brevis muscle belly distal to the inferior aspect of the lateral malleolus with significantly hypertrophy.

The treatment continued with a series of Traumeel injections into damaged tissues: Bimonthly injections in combination with deep tissue work, ultrasound, heat, heeled shoes and modified dancing with some form of heel padding. In addition to performing continued strengthening exercises, the patient also ensured proper warm up and cool down periods. Although this dancer has a “posterior” condition, she felt best with some slight heel height in her street shoes but excessive relevé and plié positions were uncomfortable.

The physician focused on repairing the Achilles tendon and reducing inflammation of the bursa via conservative needling. By applying a series of injections into damaged tissues the inflammatory cascade can be stimulated to
induce reorganization of the disorganized collagen type III into proper type I collagen, creating the best linear mechanical strength for the tendon. The bimonthly injection of Traumeel created stability while still allowing mobility of the tendon, which is paramount to proper regeneration. These injections encourage the continual recruitment of fibroblasts to allow the tissues to go through more controlled inflammatory, proliferative and remodeling stages. Although these patients should ideally emphasize relative rest for the duration of the treatment protocol, this would be difficult for a professional dancer. This regimen affords the best outcomes with little to no downtime for the dancer's schedule with only minor compromises and alterations.

6.10 A case of Morton's neuroma


A 70-year-old woman presented complaining of severe and constant pain in the ball of her foot, particularly when walking (Visual Analogue Scale score 8 out of 10). She had been seen previously by podiatrists and received a cortisone injection and a series of alcohol sclerosing injections, none of which were effective. Surgery was scheduled. On examination, a swelling could be felt between the metatarsal heads. There was obvious splaying of the second and third phalanges, which worsened with weight bearing. On palpation, there was pain, swelling and tenderness.

A positive "Mulder Click" (popping sound and sensation) was reproduced with lateral compression. Normal range of motion of the metatarsal-phalangeal joints was observed that did not cause pain. X-rays were negative for fracture and arthritis. Ultrasound was performed using an 18 MHz linear probe in B-mode with gray scale imaging. Both real-time and static images were taken. The final diagnosis was Morton's neuroma.

Ultrasound guided Traumeel injections were administered: 1 ampoule of Traumeel mixed with 1.5 cc of 0.25% marcaine (total fluid volume approximately 5 cc) given 10 times over 2 weeks. In addition, the patient was fitted for biomechanical orthotics (shoe inserts) and advised to limit activities.

The patient is free of pain and was able to continue with her normal activities. Use of Traumeel Injection Solution, ultrasound and shoe inserts avoided the need for surgery for Morton's neuroma. Traumeel injections can be used as required, unlike corticosteroid injections which should not be given on more than 3 to 4 occasions per year.
7. Pharmaceutical information

1 Indications and Usage
1.1 Treatment of injuries and various conditions of the musculoskeletal system.

- Traumeel Injection Solution is a homeopathic drug product indicated for the treatment of injuries, inflammatory and degenerative conditions of the musculoskeletal system and for the relief of associated symptoms such as pain.

1.2 Co-administration Therapy with Zeel® Injection Solution for the treatment of inflammatory and degenerative conditions of the musculoskeletal system.

- Traumeel Injection Solution is a homeopathic drug product indicated, in combination with Zeel® Injection Solution, for the treatment of inflammatory and degenerative conditions of the musculoskeletal system, such as arthrosis/osteoarthritis and/or rheumatic joint diseases, and for the relief of symptoms including pain, swelling, and joint stiffness.

2 Dosage and Administration
2.1 General Considerations

- The dosage schedules listed below can be used as a general guide for the administration of Traumeel Injection Solution.
- Traumeel Injection Solution may be administered s.c., i.d., i.m., i.a. or i.v.
- The interval between injections is left to the discretion of the HCP, but should not exceed 1 ampoule in 24 hours.
- Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Draw up the contents of the ampoule into the syringe. Discard half or one third of the contents, depending on the required dosage, before administering.

2.2 Standard Dosage - for the treatment of injuries, inflammatory and degenerative conditions of the musculoskeletal system and for the relief of associated symptoms such as pain.

- Adults and children 12 years and older: 1 ampoule 1 to 3 times per 7 days
- Children 6 to 11 years: ½ of an ampoule 1 to 3 times per 7 days
- Children 2 to 5 years: ½ ampoule 1 to 3 times per 7 days

2.3 Acute Dosage – for the treatment of injuries, inflammatory and degenerative conditions of the musculoskeletal system and for the relief of associated symptoms such as pain.

- Adults and children 12 years and older: 1 ampoule daily, and then continue with standard dosage.
- Children 6 to 11 years: ½ of an ampoule daily, and then continue with standard dosage.
- Children 2 to 5 years: ½ ampoule daily, and then continue with standard dosage.

2.4 Co-administration therapy with Zeel® Injection Solution – for the treatment of inflammatory and degenerative conditions of the musculoskeletal system, such as arthrosis/osteoarthritis and/or rheumatic joint diseases, and for the relief of symptoms including pain, swelling, and joint stiffness.

- In the treatment of musculoskeletal conditions, if co-administration with another homeopathic medicinal product is desired, Traumeel Injection Solution may be mixed in a ratio of 1:1 with Zeel® Injection Solution.
- For convenience, the daily dose of Traumeel Injection Solution may be administered at the same time as a Zeel® Injection Solution, according to the dosing recommendations for each medication.

2.5 Instructions for Opening Glass Ampoule

- Cutting open the glass ampoule is not necessary. Hold the ampoule head up at an angle, and tap/shake down the solution contained in the ampoule head. Then break off the ampoule head by
applying pressure away from the color dot. Discard unused solution.

3 Dosage Forms and Strength
- One ampoule containing 2.2 ml each containing the active ingredients in the strengths listed under Description (10)

4 Contraindications
- Traumeel Injection Solution is contraindicated in patients with known hypersensitivity to Traumeel or any of its ingredients.
- When Traumeel Injection Solution is co-administered with Zeel® Injection Solution, refer to the Contraindications section of the respective Zeel® Injection Solution labeling.

5 Warnings and Precautions
- Keep out of reach of children.

6 Adverse Reactions
6.1 Post-marketing Experience
- The following adverse events have been identified during post-marketing use of Traumeel Injection Solution. Because these events are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.
- Adverse event rates observed in Monotherapy use of Traumeel Injection Solution: Allergic (hypersensitivity) reactions (e.g. skin allergies, redness/swelling at the injection site, even up to anaphylaxis) may occur in isolated cases. Adverse event rates observed in the Monotherapy use of Zeel® Injection Solution: Allergic (hypersensitivity) skin reactions may occur in isolated cases.

7 Drug Interactions
- No interactions have been reported, and none are expected due to the homeopathic dilutions.

8 Use in Specific Populations
8.1 Pregnancy
8.1.1 Teratogenic effects
- Pregnancy Category C. Some ingredients in Traumeel Injection Solution have been shown to be teratogenic in various animal species when given in doses several thousand times the human dose.
- There are no adequate and well-controlled studies in pregnant women. Traumeel Injection Solution should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
- When Traumeel Injection Solution is administered with Zeel® Injection Solution in a woman of childbearing age, refer to the pregnancy category and product labelling for Zeel® Injection Solution.
8.1.2 Non-teratogenic effects
- No known non-teratogenic effects.

8.2 Labor and Delivery
- No recognized use in labor or delivery.

8.3 Nursing Mothers:
- It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Traumeel Injection Solution is administered to a nursing woman.

8.4 Pediatric Use
- Safety and effectiveness in pediatric patients have not been established. However, traditional homeopathic use of the ingredients in Traumeel Injection Solution has not identified differences in responses between adults and pediatric patients.

8.5 Geriatric Use
- Safety and effectiveness in geriatric patients have not been established. However, traditional homeopathic use of the of the ingredients in Traumeel Injection Solution has not identified differences in responses between adults and geriatric patients.
9 Overdosage
- No negative effects of an overdose have been reported and none are expected due to the homeopathic dilutions.

10 Description

10.1 Ingredients
- Each 2.2 ml ampoule contains:

<table>
<thead>
<tr>
<th>Active Ingredients:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ingredient name</td>
</tr>
<tr>
<td>Aconitum napellus</td>
</tr>
<tr>
<td>Arumica montana, radix</td>
</tr>
<tr>
<td>Bellis perennis</td>
</tr>
<tr>
<td>Bellidonna</td>
</tr>
<tr>
<td>Caledula officinalis</td>
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<tr>
<td>Chamaomilla</td>
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<tr>
<td>Echinacea</td>
</tr>
<tr>
<td>Echinacea purpurea</td>
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<tr>
<td>Hamamelis virginiana</td>
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<tr>
<td>Hyper sulphuris calcureum</td>
</tr>
<tr>
<td>Hypericum perforatum</td>
</tr>
<tr>
<td>Mercurius solubilis</td>
</tr>
<tr>
<td>Millefolium</td>
</tr>
<tr>
<td>Symphytum officinale</td>
</tr>
</tbody>
</table>

Inactive Ingredients:
- Water for injection 2,179.10 μl
- Sodium Chloride 19.40 μl

10.2 Pharmaceutical Form
- Injection Solution

10.3 Route of Administration
- Parenteral: s.c., i.d., i.m., i.a or i.v

11 Clinical Pharmacology

11.1 Mechanism of Action
- The exact mechanism of Traumeel Injection Solution is not fully understood.

11.2 Pharmacodynamics
- Not applicable for homeopathic medicinal products.

12 References
- Homeopathic Pharmacopeia of the United States Revision Service

13 How Supplied / Storage and handling

13.1 Dosage forms and package sizes
- 1 ampoule of 2.2 ml in packs of 10 ampoules
- NDC 50114-7004-1

13.2 Storage and handling
- Store at room temperature. Protect from light.
Other available injections that can be combined with Traumeel®:

**Zeel** Injection Solution is indicated for the treatment of arthritis/osteoarthritis, and/or rheumatic joint diseases and for the relief of symptoms such as pain and joint stiffness.

**Neuralgo-Rheum** Injection Solution is indicated for the treatment of nerve pain, soft tissue neuritis and symptoms of disc protrusion.

**Spascupreel** Injection Solution is indicated for the relief of spasms of the smooth musculature of the gastrointestinal and the urogenital tract as well as general muscle spasms.

**Lymphomyosot** Injection Solution is indicated for improvement of lymphatic drainage, the non-specific immune defense, and conditions such as benign hypertrophy of lymph nodes, chronic tonsillitis, tonsillar hypertrophy and lymphatic edema.

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

### Product Availability

Our injections are available nationwide through the following distributors:

- McKesson Medical-Surgical/PSS: (866) 625-2679
- Emerson Ecologics (Most states): (800) 654-4432
- Acu-Market (Florida, Pennsylvania, and California): (866) 440-7703
- Natural Partners: (Arizona): (888) 633-7620
References


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