# The Safer Alternative to NSAIDs

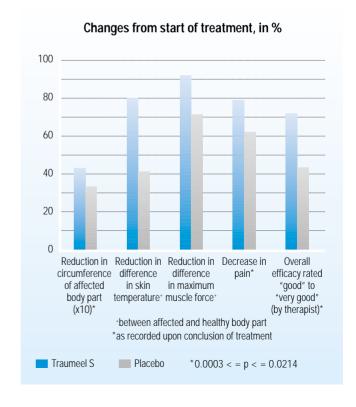
# Effective at the Point of Impact



A placebo-controlled, randomized double-blind study of 102 patients compared the efficacy of **Traumeel S ointment** to that of the ointment base (placebo)<sup>2)</sup>. For 15 days, the affected body part was covered twice daily with ointment, an occlusive dressing, and a cold compress.

In comparison to placebo, Traumeel S was found to work faster and produce greater improvements in all measured criteria. Traumeel patients resumed their sports activities after only 12.1 days in comparison to 13.5 days for patients in the placebo group.

- / No GI toxicity
- Does not inhibit platelet aggregation
- No sodium and fluid retention
- No adverse renal, hepatic, cardiovascular, or CNS side effects reported
- Not contraindicated during pregnancy and lactation
- Over 4.5 million packages sold worldwide in 2002



# Traumeel <sup>®</sup>S

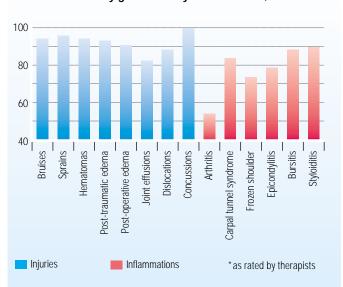
### **Systemic Relief**

A prospective study of 1.359 patients treated with either **Traumeel S tablets** or **Traumeel S drops**, assessed efficacy, tolerability, and dosage of the medication. The majority of patients took the standard recommended dosage (10 drops or 1 tablet 3 times per day).

The physicians rated the therapeutic outcome "good" to "very good" for more than 80% of the cases involving injuries and for 54–90% of inflammatory conditions<sup>5)</sup>.

Both Traumeel S drops and tablets were well tolerated; no adverse events occured during the study.

#### Good to very good efficacy of Traumeel S, in %\*



## **Pharmacological Aspects**

Current research indicates that the constituents of Traumeel S modulate a number of different cellular and biochemical pathways and that the effects of Traumeel S are not due to inhibition of cyclooxygenase or lipoxygenase as is the case with nonsteroidal anti-inflammatory drugs (NSAIDs). Traumeel S does not inhibit the arachidonic acid pathway of prostaglandin synthesis. Instead, it seems to work by modulating the generation of reactive oxygen by activated neutrophils and by inhibiting the release of inflammatory mediators and neuropeptides.<sup>6</sup>

In studies of whole blood cultures, certain plant ingredients of Traumeel S have been found to elevate levels of TGF-B, an anti-inflammatory cytokine, indicating that the immunological bystander reaction may play a role in the action of Traumeel S.<sup>7)</sup>

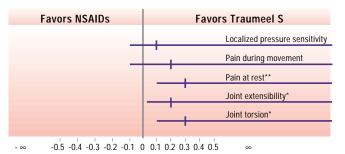
*In vitro* studies have shown that the ingredients of Traumeel S are noncytotoxic to granulocytes, lymphocytes, platelets, and endothelial cells, which indicates that the defensive functions of these cells are preserved during treatment with Traumeel S.<sup>8)</sup>

Placebo-controlled studies, drug monitoring studies, and *in vivo* experimental models including the carrageenan-induced edema test and the adjuvant arthritis test have all demonstrated the anti-inflammatory, anti-edematous, and anti-exudative effects of Traumeel S.<sup>2-5, 8-10)</sup>

# Traumeel®S

## **Treatment of Epicondylitis**

In an observational study, 163 patients suffering from epicondylitis were treated either with Traumeel or with NSAIDs (primarily diclofenac). Overall results of therapy were rated "very good" or "good" in 71 percent of patients in the Traumeel group in comparison to only 44 percent of the NSAID group. Tolerability was rated "very good" in 87.7 percent of the Traumeel group and only 44.9 percent of the NSAID group. For all evaluated criteria (localized pressure sensitivity, pain during movement, pain at rest, joint extensibility, joint torsion), the efficacy of Traumeel therapy was comparable or even slighty superior to NSAID therapy<sup>11)</sup>.



Mean difference between symptom scores after two weeks for patients treated with NSAIDs (n = 77) and Traumeel S (n = 86).

- \* indicates statistically significant superiority of Traumeel S
- \*\* indicates significant superiority of Traumeel S
- Anti-inflammatory
- Anti-edematous
- Anti-exudative

#### References

- 1) Linde K, et al. Are the Clinical Effects of Homeopathy Placebo Effects? A Meta-Analysis of
- Placebo-Controlled Trials. The Lancet 1997; 350: 834-843

  Böhmer D, Ambrus P. Treatment of Sports Injuries with Traumeel Ointment: A Controlled Double-Blind Study. Biological Therapy 1992; Vol X No. 4: 290-300
- Study. Bollogical Thetapy 1992; Vol X IV. at: 290-300
  3 Zell J. et al. Treatment of Acute Sprains of the Ankle: A Controlled Double-Blind Trial to Test the Effectiveness of a Homeopathic Ointment. Biological Therapy 1989; Vol VII No.1: 1-6
  4) Thiel W, Borho B. The Treatment of Recent Traumatic Blood Effusions (Hematomas) of the Knee Joint. Biological Therapy 1994; Vol XII No. 4: 242-248
  5) Zenner S, Weiser M. Oral Treatment of Traumatic, Inflammatory, and Degenerative Conditions with a

- Homeopathic Remedy. Biomedical Therapy 1997: Vol XV No. 1: 22-26

  Wagner H. Untersuchungsbericht über immunologische und enzym-chemische Wirknachweise durchgeführt mit dem Injektionspräparat Traumeel. Data on file, Heel GmbH, Baden-Baden, Germany

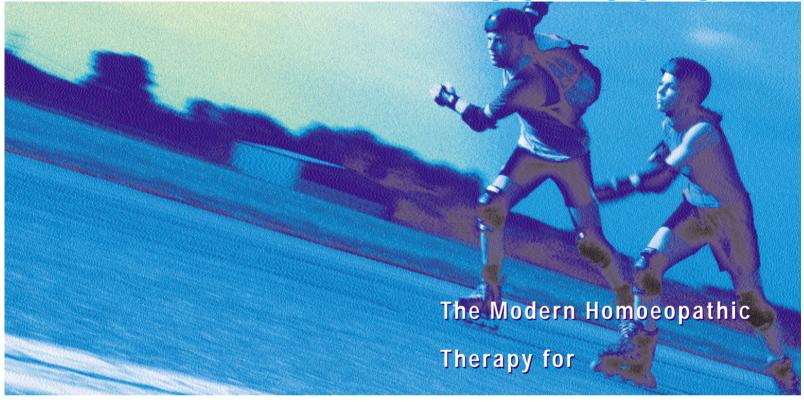
  Heine H, Schmolz M. Induction of the Immunological Bystander Reaction by Plant Extracts. Biomedical
- Therapy 1998: Vol XVI No. 3: 224-226
- Conforti A., et al. Experimental Studies on the Anti-Inflammatory Activity of a Homeopathic Preparation. Biomedical Therapy 1997: Vol XV No. 1: 28-31
   Zener S, Metelmann H. Application Possibilities of Traumeel S Injection Solution: Results of a Multicentric Drug Monitoring Trial Conducted on 3,241 Patients. Biomedical Therapy 1992; Vol X No. 4:
- 10) Oberbaum M. Randomized, Controlled Clinical Trial of the Homeopathic Medication Traumeel S in the Treatment of Chemotherapy-Induced Stomatitis in Children Undergoin Stem Cell Transplantation. Cancer 2001, Vol 92 No.3, 684-690

### 11) Publication in preparatio

### Drops – Tablets – Injection solution – Ointment

Composition: Drops: 100 g cont.: Arnica montana D2, Calendula officinalis D2, Hamamelis virginiana D2, Achillea millefolium D3 5 g each: Atropa belladonna D4 25 g: Aconitum napellus D3, Mercurius solubilis Hahnemanni D8, Hepar sulfuris D8 10 g each: Chamomilla recutita D3, Symphytum officinale D8 8g each; Bellis perennis D2, Echinacea angustifiol D2, Echinacea purpurea D2 og each: Hypericum perforatum D2 1 g. Contains 35 vol.—48 action. Tablets: 1 tablet cont.: Arnica montana D2, Calendula officinalis D2, Hamamelis virginiana D2, Achillea millefolium D3 15 mg each; Atropa belladonna D4 75 mg: Aconitum napellus D3. Mercurius solubilis Hahnemanni D8. Hepar sulfuris D8 30 mg each: Chamo ladonna D4 75 mg; Aconitum napellus D3, Mercurius solubilis Hahnemanni D8, Hepar sulfuris D8 30 mg each: Chamenilla recutita D3, Symphytum officinale D8 24 mg each; Bellis perennis D2, Echinacea angustifolia D2, Echinacea purpurea D2 6 mg each; Hypericum perforatum D2 3 mg. Injection solution: 2.2 ml cont.: Arnica montana D2, Calendula officinalis D2, Chamomilla recutita D3, Symphytum officinale D6, Achillea millefolium D3, Atropa belladonna D2 2.2 deach; Aconitum napellus D2 1.32 µl; Bellis perennis D2 1.1 µl; Hypericum perforatum D2 0.66 µl; Echinacea angustifolia D2, Echinacea purpurea D2 0.55 µl each; Hamamelis virginiana D1 0.22 µl; Mercurius solubilis Hahnemanni D6 1.1 mg, Hepar sulfuris D6 2.2 µl. Ointment: 100 g cont.: Arnica montana D3 1.5 g: Calendula officinalis Ø, Hamamelis virginiana Ø 0.45g each; Echinacea angustifolia Ø, Echinacea purpurea Ø, Chamomilla recutita Ø 0.15 g each; Symphytum officinale 04, Bellis perennis Ø 0.1g each; Hypericum perforatum D6, Achillea millefolium Ø 0.09 g each; Aconitum napellus D1, Atropa belladonna D1 0.05 g each; Mercurius solubilis Hahnemanni D6 0.04 g; Hepar sulfuris D6 0.025 g, Ointment base: Hydrophilic ointment, preserved with 12.5 vol.-% ethanol. Indications: Drops, tables, injection solution: Injuries such as sprains, dislocations, contusions, effusions of blood and effusions into a joint, fractures; post-operative and post-traumatic oedema and swelling of the soft tissues; inflammatory processes and degenerative processes associated with inflammation on the various organs and tissues, including, in particular, on the support and mobility apparatus (tendovaginitis, styloiditis, epicondylitis, bursitis, scapulohumeral periarthritis, etc.); arthrosis of the hip, knee and small joints. commotio cerebri acuta. Ointment: Injuries of all kinds (sports, accidents), such as sprains, dislocations, contusions, effusions of blood and effusions into a joint, fractures, etc.; inflammatory processes and degenerative processes association with inflammation on the various organs and tissues (e.g. periodontitis, suppuration of the gingival pockets, periodontics, springly, including, in particular, on the support and mobility apparatus (tendovaginitis, bursitis, scapulohumeral periarthritis), arthrosis of the hip, knee and small joints. Contraindications: Hypersensitivity to botanicals of the Compositae fami 15, Side effects: Drops, tablets, injection solution: In isolated cases, hypersensitivity reactions may occur. In rare cases, increased flow of saliva may occur after taking this medication. If this happens, the therapist should be consulted. Ointent: In isolated cases, hypersensitivity reactions may occur. Local allergic reactions (skin inflammation) have been reported. Dosage: Drops: In general 10 drops 3 times daily; for swelling of the soft tissues 30 drops 3 times daily. Tablets: In general, 1 tablet to be dissolved in the mouth 3 times daily. Injection solution: in acute disorders daily, otherwise 3-1 times weekly 1-2 ampoules i.m., s.c., i.d. (in the case of wheals), i.v., intra-articular or periarticular. Warning: In rare cases after intra-articular administration of Traumenel 5 (injection solution), temporary painful joint partiation may occur, possibly with sterile effusions. Administration of anti-inflammatory medication is appropriate palliative treatment in such cases. Ointment: Apply to the affected parts and rub in, morning and evening, or if necessary, more often, possibly also applying an olintment dressing. Warning: Avoid prolonged application of the ointment to large areas. Package sizes: *Drops*: Drop bottles containing 30 and 100 ml. *Tablets*: Packs containing 50 and 250 tablets. *Injection solution*: Packs containing 5, 10, 50 and 100 ampoules of 2.2 ml. *Ointment*: Tubes containing 50 and 100 g of ointment.





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**Acute Traumatic Injuries** 

Inflammation

**Arthritis** 





-Heel



