ARE YOUR PATIENTS FRUSTRATED by KNEE PAIN?

Do they suffer from diabetes, heart disease or hypertension?

Time for A SAFE AND EFFECTIVE APROACH!

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

54% of patients do not get adequate pain relief with oral and topical pain medication[1]

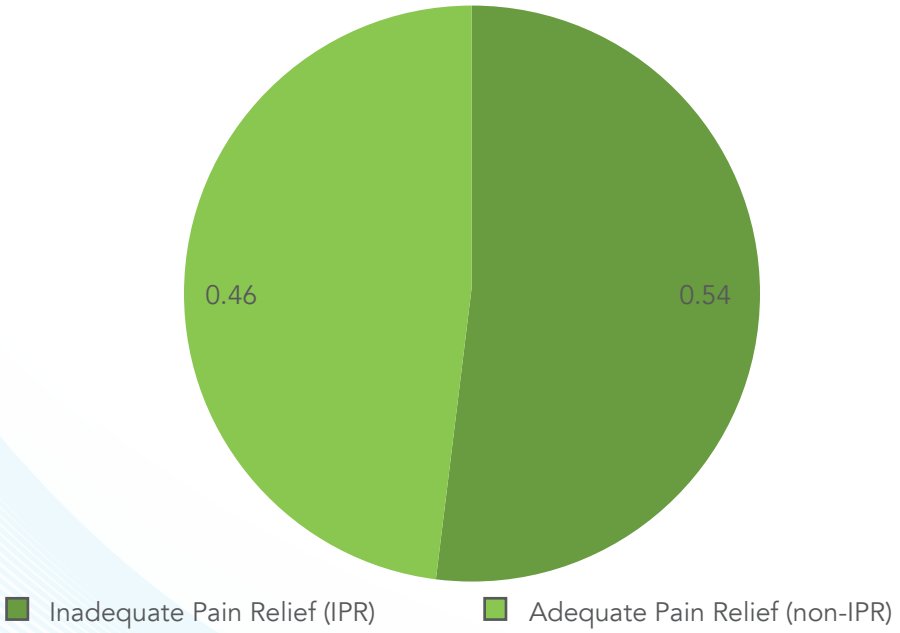


Fig 1: The fact that 54% of patients in this real-world setting had persistent moderate to severe pain suggests that currently prescribed pain treatments for knee OA are not meeting the needs of the majority of patients. The most commonly prescribed analgesic medications reported by patients were NSAIDs, followed by paracetamol and opioid-containing medications.[1]

Especially patients with moderate to severe pain report inadequate pain relief[1]

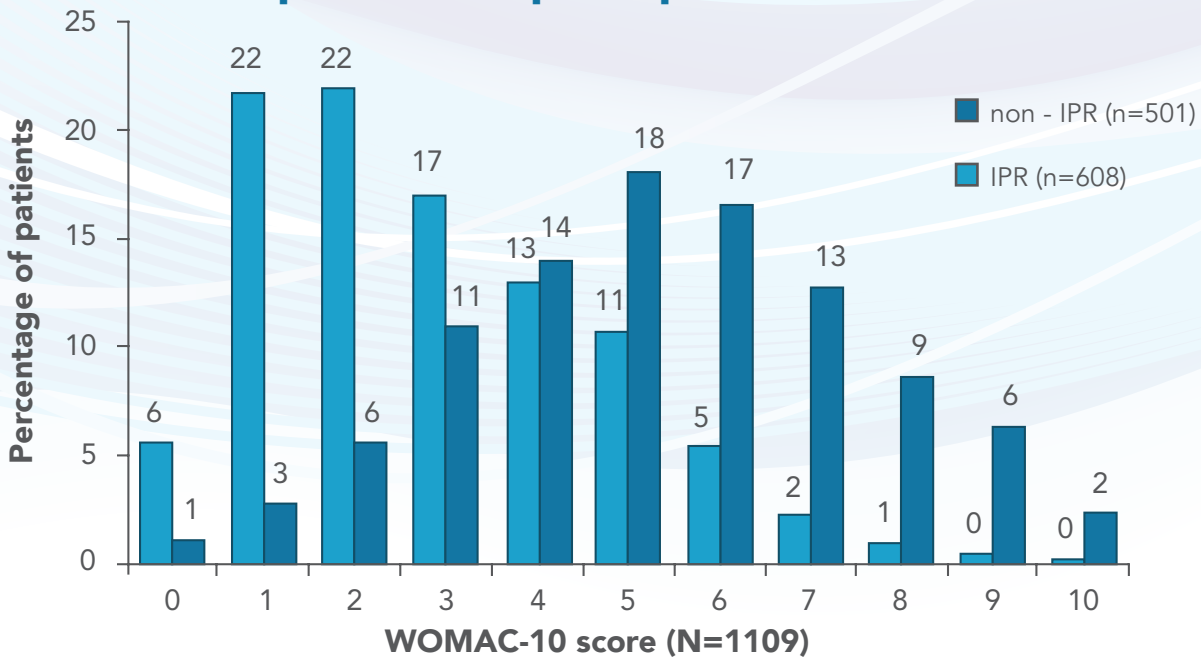


Fig 2: Inadequate pain relief and large functional loss among patients (n=1109) with knee osteoarthritis: evidence from a prospective multinational longitudinal study of osteoarthritis real-world therapies.[1]

Source
1 Rheumatology 2015;54:270-277

New Clinical Evidence – The MOZArt Study

Presented at the 2014 meeting of the American College of Rheumatology (ACR) in Boston by Carlos Lozada[1] and Roland W. Moskowitz[4].

Abstract Number: 2896 - **Session**: Osteoarthritis - Clinical Aspects II: Osteoarthritis Risk Factors and Therapies

Background/Purpose:

Tr14 & Ze14 is a combination of dilute biological and mineral extracts administered IA for painful knee OA. In response to clinician impressions of positive outcomes, a db-RCT to assess efficacy and safety compared to IA saline was deployed in the US.

Methods:

Pts with moderate-to-severe chronic knee OA were randomized to 3 weekly IA injections of either Tr14 & Ze14 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 subscores 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 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 Tr14 & Ze14, n=119, All Placebo, n=113; Intention-to-Treat (ITT) Tr14 & Ze14, n=117, Placebo, n= 111). Treatment arms were well balanced across demographic and baseline characteristics. Tr14 & Ze14 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 ($p=0.0686$). 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. Tr14 & Ze14 was significantly different ($p<0.05$) on all subsequent days except Day 29 (approached significance, $p=0.0599$, Figure 1). 50' walk pain was similarly discriminating as was the physician global assessment. Total WOMAC and subscores 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.

CONCLUSION

Combined IA injections of Traumeel® and 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

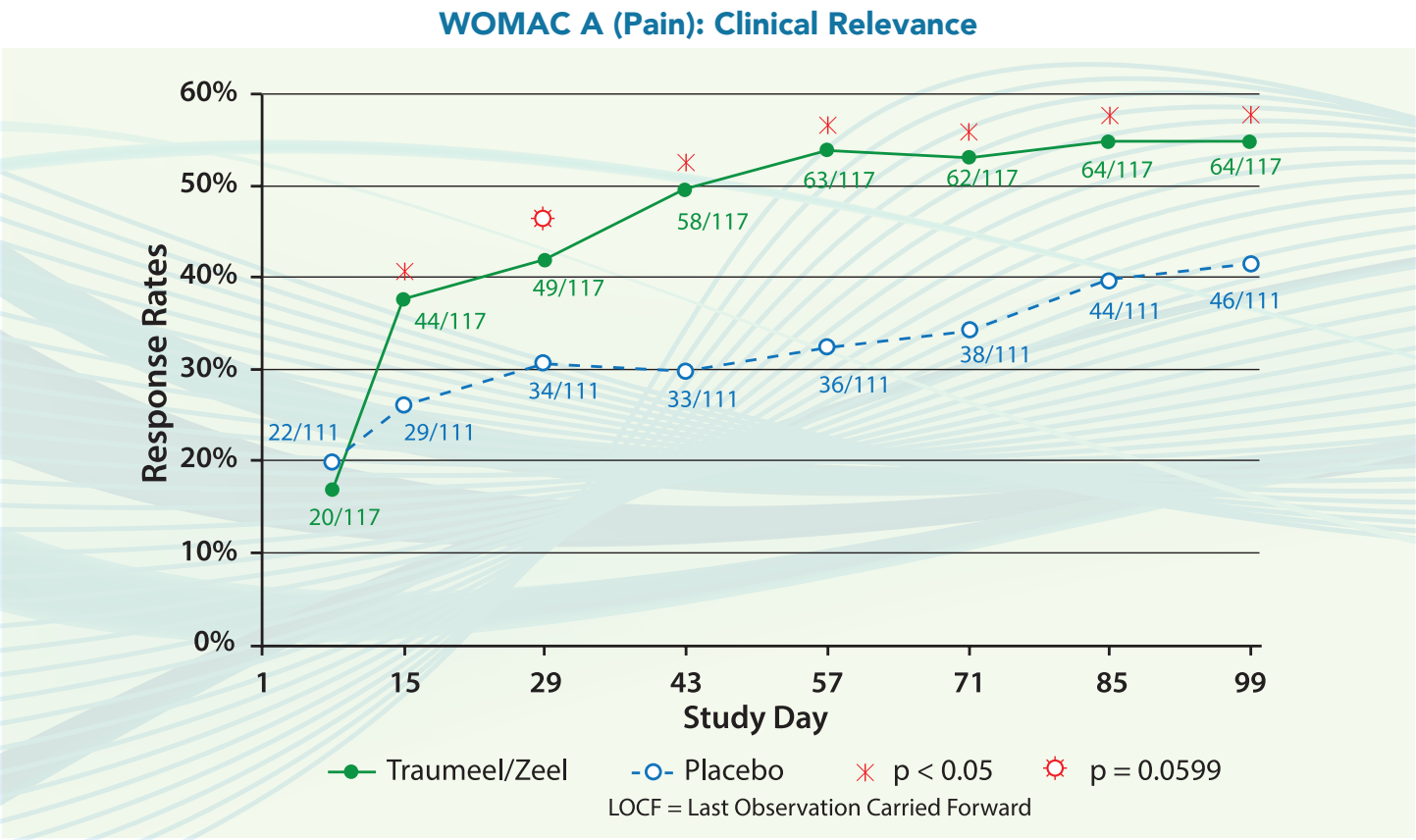


Fig 1: Proportions of Patients Meeting Validated Criterion for Response on WOMAC Subscale A: ITT population with LOCF; Minimally Important Difference (MID) from Baseline = -32.6mm

OA-K Treatment protocol according to Mozart study:
One intra-articular injection of combined Traumeel® Injection Solution (2.2ml = 1 ampule) and Zeel® Injection Solution (2.0ml = 1 ampule) into the affected knee under aseptic conditions per week for 3 consecutive weeks.

Excellent Safety Profile

Traumeel® and Zeel® Injection Solutions were developed by physicians in Europe and have been available globally, for more than sixty years. Using very low doses of plant and mineral extracts, Traumeel® and Zeel® Injection Solutions help manage the pain, inflammation and joint degeneration of arthritis and osteoarthritis while exhibiting an excellent safety profile.

Table 1: Overview of typical precautions and warnings for Traumeel® Injections Solution, Corticosteroid injections and oral NSAIDs. Sources: Package inserts of Traumeel® Injection Solution[A], betamethasone (Corticosteroid injection)[B] and naproxen (NSAID oral)[C]

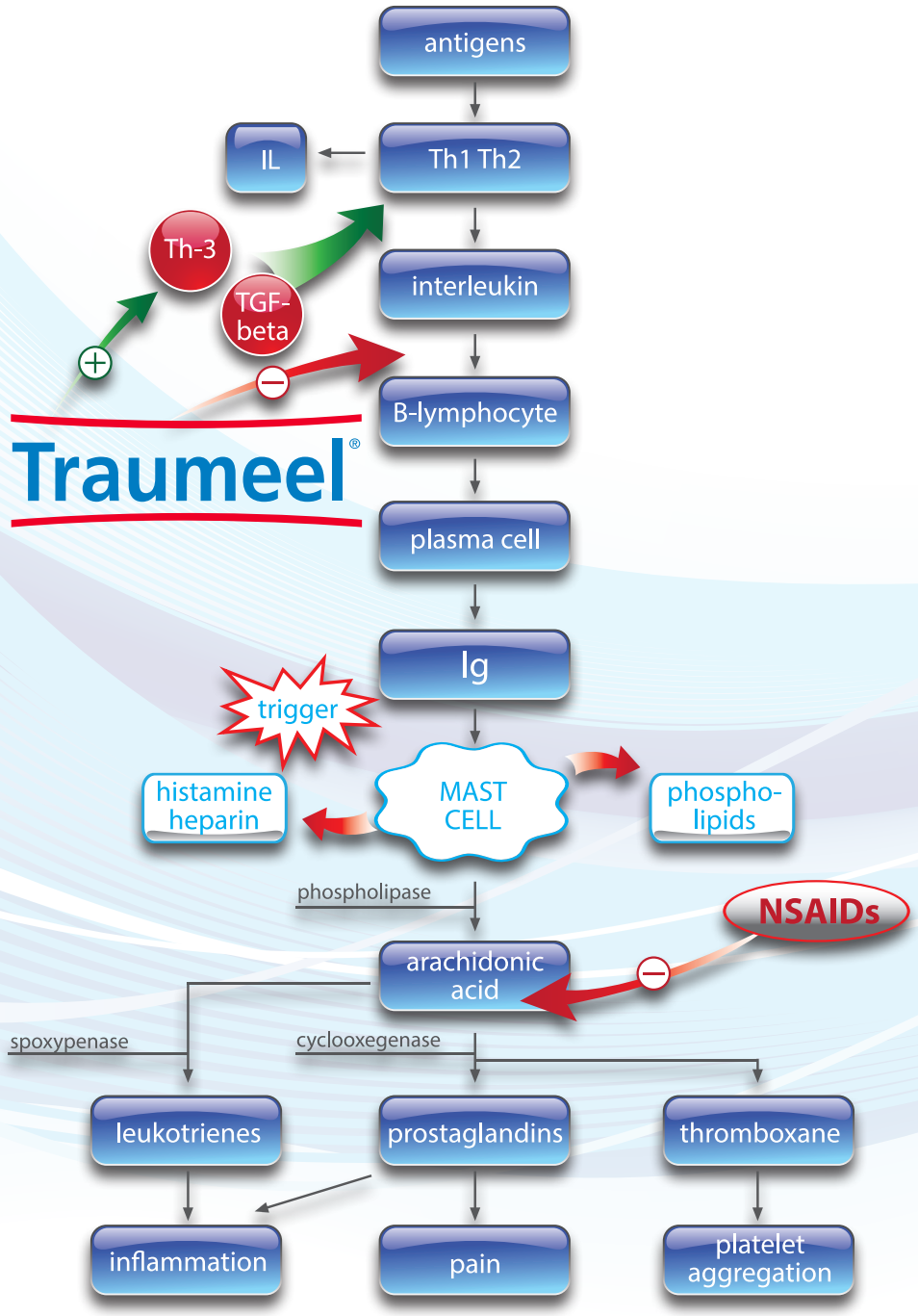
Precautions/warnings related to	Traumeel® Injection Solution[A]	Corticosteroid Injection (Betamethasone)[B]	NSAID Oral (Naproxen)[C]
Patients at increased cardiovascular risk	No known related AEs or disease interactions	Corticosteroids should be used with caution in patients with congestive heart failure, hypertension, or renal insufficiency	Naproxen, like other NSAIDs, may cause serious CV side effects, such as MI or stroke, which may result in hospitalization and even death
Patients with uncontrolled diabetes	No known related AEs or disease interactions	Corticosteroids may increase blood glucose concentrations. Therapy with corticosteroids should be administered cautiously in patients with diabetes mellitus, glucose intolerance, or a predisposition to hyperglycemia.	No known direct effects on blood glucose levels. However, in patients with diabetic nephropathy NSAIDs can cause a significant drop in GFR, particularly when used with angiotensin-blocking agents[D]
Patients under polypharmacy	No known drug-to-drug interactions	A total of 694 drugs (3032 brand and generic names) are known to interact with betamethasone	A total of 437 drugs (1685 brand and generic names) are known to interact with naproxen
Disease interactions	No known disease interactions	There are 22 known disease interactions with betamethasone	There are 20 known disease interactions with naproxen
Toxicity to joint tissue	No known detrimental effects on joint tissue	Intra-articular injection may result in damage to joint tissues	Not applicable
Injections near to tendons and tendon structures	No known detrimental effects on tendons or tendon structures	Potential risk of tendon ruptures	Not applicable
Patients who are hypersensitive to any components of the product	Contraindicated	Contraindicated	Contraindicated

Sources:
[A] https://www.drugs.com/drp/traumeel-injection-solution.html
[B] http://www.drugs.com/pro/celestone-soluspan.html
[C] http://www.drugs.com/pro/naproxen-tablets.html
[D] http://www.clevelandclinicmeded.com/medicalpubs/diseasemanagement/nephrology/diabetic-nephropathy/

Traumeel® Injection Solution Mechanism of Action

Traumeel® Injection Solution

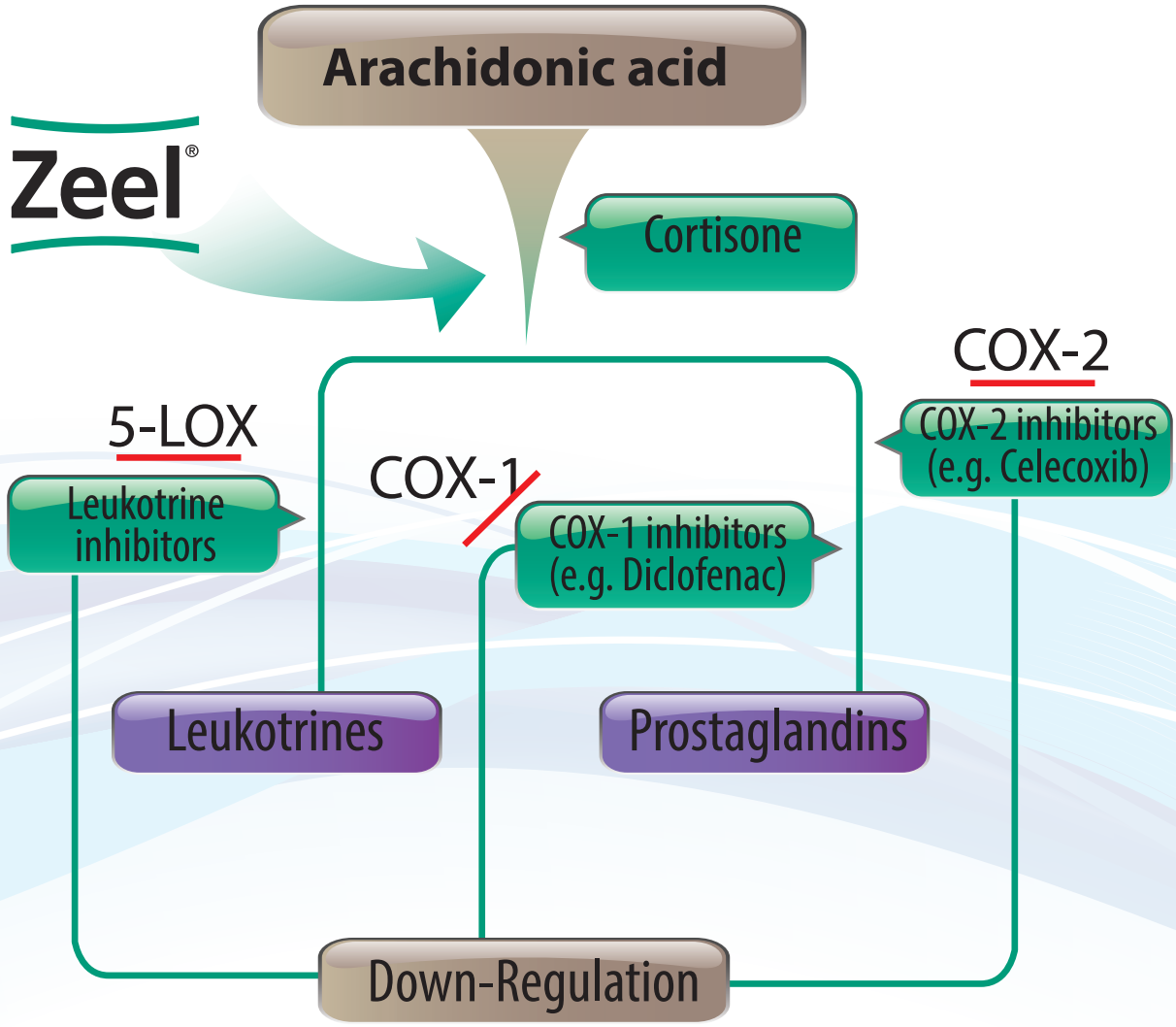
Although the exact mechanism of action is not fully understood, in-vitro studies show that Traumeel® Injection Solution inhibits IL-1β, TNF-α, and IL-8. Inhibiting these physiological messengers modulates the inflammatory response and so helps relieve pain.[1]



Source: 1 Porozov, S., Cahalon, L.,Weiser,M., Branski,D.,Lider,O., and Oberbaum, M. Inhibition of IL-β and TNF- α Secretion from Resting and Activated Human Immunocytes by the Homeopathic Medication Traumeel® Injection Solution S. Clinical and Developmental Immunology June 2004 Vol. 11 (2) pp 143-149.

Zeel® Injection Solution Mechanism of Action

Zeel® Injection Solution is thought to initiate changes to improve the synovial fluid surrounding the arthritic joint. This leads to improved joint function and less joint stiffness. Zeel® Injection Solution is also thought to slow down the production of physiological messengers that promote pain and inflammation within connective tissue and cartilage.[1]



- Distinct modulating effects on COX-1, COX-2, and 5-LOX activity
- The dual concomitant inhibition of LOX and COX eszymes in an advantageous pharmacological profile. Reference Souce [2]

Sources: 1 Gottwald R, Weiser M. Treatment of Osteoarthritis of the Knee with Zeel® Injection Solution T. Medicina Biologica 2000; Vol. 13 No. 4: 109-113.

2 Orlandini, A., Rossi, M., Setti, M., The Effectiveness of Zeel® Injection Solution and new Research Methods in Rheumatology. Biologische Medizin. Vol. 26 (4) 1997, 164-165.

Safe & Effective Pain Relief

- Available by prescription only
- Established efficacy and safety data in multiple clinical trials that also include studies under "real life" conditions and several published case-reports[1, 2]
- Non-Narcotic, Non-Addictive, Non-NSAID, Non-Steroid
- No known drug interactions - Easy to combine with other medications
- Excellent safety profile (see table 1)

Traumeel® Injection Solutions have been used to reduce pain and inflammation in multiple indications as a standalone medication or in combination with other injections: [1]

- **Intra-articular injections** for moderate to severe pain related to osteoarthritis (in combination with Zeel® Injection Solution)
- **Trigger point injections** for **back pain and other musculoskeletal conditions** (often in combination with Spascupreel or Neuralgo-Rheum)
- **Tender point injections** alone or in combination with Spascupreel for pain related to **Fibromyalgia**
- Injection of Traumeel® Injection Solution into the subacromial/subdeltoid bursal space for pain related to **rotator cuff syndrome**
- Pain related to **carpal tunnel syndrome**
- Injection therapy of pain related to **Tendinitis/Epicondylitis**
- **Sport injuries** such as ankle sprains and strains
- **Podiatric indications** such as **Morton's Neuroma, Plantar fasciitis, Achilles tendon injuries,** and others

Sources: 1 Heel Inc. Traumeel Injection Solution Product Monograph, 2014

2 Heel Inc. Zeel Injection Solution Product Monograph, 2014

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

Highlights of Prescribing Information

Traumeel® Injection Solution, Parenteral Use Rx Only

These highlights do not include all the information needed to use Traumeel® Injection Solution safely and effectively.
See full prescribing information for Traumeel® Injection Solution.

Traumeel® Injection Solution, Parenteral Use Rx Only

-----INDICATIONS AND USAGE-----

Traumeel® Injection Solution is a homeopathic drug 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. (1.1)
- 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. (1.2)

-----DOSAGE AND ADMINISTRATION------

- Standard Dosage:
  Adults and children 12 years and older:
  1 ampule 1 to 3 times per 7 days
  Children 6 to 11 years:
  ⅔ of an ampule 1 to 3 times per 7 days
  Children 2 to 5 years:
  ½ ampule 1 to 3 times per 7 days (2.2)
- Acute Dosage:
  Adults and children 12 years and older:
  1 ampule daily, and then continue with standard dosage.
  Children 6 to 11 years: ⅔ of an ampule daily, and then continue with standard dosage.
  Children 2 to 5 years: ½ ampule daily, and then continue with standard dosage. (2.3)
- When co-administered with Zeel® Injection Solution, the two products may be mixed 1:1.

-----DOSAGE FORM AND STRENGTH-----

- 1 ampule containing 2.2 ml each containing the active ingredients in the strengths listed under Description. (3)

------CONTRAINDICATIONS-----

- Traumeel® Injection Solution is contraindicated in patients with known hypersensitivity to Traumeel® Injection Solution or any of its ingredients. (4)

-----WARNINGS AND PRECAUTIONS-----

- Keep out of reach of children. (5)

-----ADVERSE REACTIONS------

- Allergic (hypersensitivity) reactions, (e.g. skin allergies, redness/swelling at the injection site, even up to anaphylaxis) may occur in isolated cases. (6)

- **To report SUSPECTED ADVERSE REACTIONS, contact MediNatura at 1.844.633.4628 or info@medinatura.com or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch**.

-----DRUG INTERACTIONS-----

- None known (7)

-----USE IN SPECIFIC POPULATIONS-----

- No studies have been conducted with Traumeel® Injection Solution on pregnant or lactating women, children, or elderly. (8)

Revised 12/2014

FULL PRESCRIBING INFORMATION: CONTENTS*

** Sections or subsections omitted from the full prescribing information are not listed.*

FULL PRESCRIBING 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.
- If co-administration with a local anesthetic is desired, Traumeel® Injection Solution may be mixed with lidocaine or similar agents at the discretion of the physician.
- 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 ampule 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 ampule into the syringe. Discard half or one third of the contents, depending on the required dosage, before administering.
- Only licensed practitioners with sufficient expertise in injecting drugs, including the

respective route of administration, should administer the product.

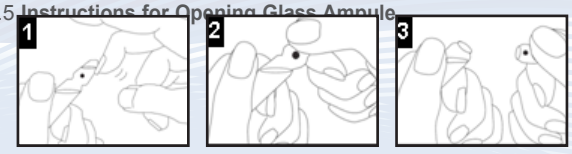
2.2 **Standard Dosage** - for the treatment of injuries, inflammatory and degenerative conditions of the musculoskeletal system and for the relief of associated symptoms such as pain.
Adults and children 12 years and older:
1 ampule 1 to 3 times per 7 days
Children 6 to 11 years:
⅔ of an ampule 1 to 3 times per 7 days
Children 2 to 5 years:
½ ampule 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 ampule daily, and then continue with standard dosage.
Children 6 to 11 years:
⅔ of an ampule daily, and then continue with standard dosage.
Children 2 to 5 years:
½ ampule 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 Ampule**



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

3 Dosage Forms and Strength

One ampule containing 2.2 ml each containing the active ingredients in the strengths listed under Description. (11)

4 Contraindications

- Traumeel® Injection Solution is contraindicated in patients with known hypersensitivity to Traumeel® Injection Solution 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

None.

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 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.

Traumeel® Injection Solution

10 Overdosage

No negative effects of an overdose have been reported and none are expected due to the homeopathic dilutions.

11 Description

11.1 **Ingredients**

• Each 2.2 ml ampule contains:

Active Ingredients:			
Ingredient name	Potency	Quantity	Final dilution
Aconitum napellus	2X	1.32 µl	5.22X
Arnica montana, radix	2X	2.20 µl	5.00X
Bellis perennis	2X	1.10 µl	5.30X
Belladonna	2X	2.20 µl	5.00X
Calendula officinalis	2X	2.20 µl	5.00X
Chamomilla	3X	2.20 µl	6.00X
Echinacea	2X	0.55 µl	5.60X
Echinacea purpurea	2X	0.55 µl	5.60X
Hamamelis virginiana	1X	0.22 µl	5.00X
Hepar sulphuris calcareum	6X	2.20 µl	9.00X
Hypericum perforatum	2X	0.66 µl	5.52X
Mercurius solubilis	6X	1.10 µl	9.30X
Millefolium	3X	2.20 µl	6.00X
Symphytum officinale	6X	2.20 µl	9.00X

Inactive Ingredients:

Water for injection 2,179.10 µl
Sodium Chloride 19.40 µl

11.2 **Pharmaceutical Form**

• Injection solution

11.3 **Route of Administration**

• Parenteral: s.c., i.d., i.m., i.a. or i.v

13 Clinical Pharmacology

13.1 **Mechanism of Action**

The exact mechanism of Traumeel® Injection Solution is not fully understood.

13.2 **Pharmacodynamics**

Not applicable for homeopathic medicinal products.

15 References

• Homeopathic Pharmacopeia of the United States Revision Service

16 How Supplied / Storage and handling

16.1 **Dosage forms and package sizes**

• 1 ampule of 2.2 ml in packs of 10 ampules
• NDC 50114-7004-1

16.2 **Storage and handling**

• Store at room temperature. Protect from light.

Highlights of Prescribing Information

Zeel® Injection Solution, Parenteral Use Rx Only

These highlights do not include all the information needed to use Zeel® Injection Solution safely and effectively. See full prescribing information for Zeel® Injection Solution.

-----INDICATIONS AND USAGE-----

Zeel® Injection Solution is a homeopathic drug indicated:

- As a mono-therapy, for the treatment of arthrosis/osteoarthritis, and/or rheumatic joint diseases and for the relief of symptoms such as pain and joint stiffness. (1.1)
- In combination with Traumeel® 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. (1.2)

-----DOSAGE AND ADMINISTRATION-----

- Standard Dosage:
  Adults and children 12 years and older:
  1 ampule 1 to 3 times per 7 days
  Children 6 to 11 years:
  ⅔ of an ampule 1 to 3 times per 7 days (2.2)
- Acute Dosage:
  Adults and children 12 years and older:
  1 ampule daily, and then continue with standard dosage.
  Children 6 to 11 years:
  ⅔ of an ampule daily, and then continue with standard dosage. (2.3)
- When co-administered with Traumeel® Injection Solution, the two products may be mixed 1:1.

-----DOSAGE FORM AND STRENGTH-----

- 1 ampule containing 2.0 ml each containing the active ingredients in the strengths listed under Description. (10.3)

-----CONTRAINDICTIONS-----

- Zeel® Injection Solution is contraindicated in patients with known hypersensitivity to Zeel® Injection Solution or any of its ingredients. (4)

-----WARNINGS AND PRECAUTIONS-----

- Keep out of reach of children. (5)

-----ADVERSE REACTIONS-----

- Allergic (hypersensitivity) skin reactions may occur in isolated cases. (6)

- **To report SUSPECTED ADVERSE REACTIONS, contact MediNatura. at 1.844.633.4628 or info@medinatura.com or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch**.

-----DRUG INTERACTIONS-----

- None known (7)

-----USE IN SPECIFIC POPULATIONS-----

- No studies have been conducted with Zeel® Injection Solution on pregnant or lactating women, children, or elderly. (8)

Revised 12/2014

FULL PRESCRIBING INFORMATION: CONTENTS*

** Sections or subsections omitted from the full prescribing information are not listed.*

FULL PRESCRIBING INFORMATION

1 Indications and Usage

1.1 **Treatment of arthrosis/osteoarthritis, and/or rheumatic joint diseases**

- Zeel® Injection Solution is a homeopathic drug product indicated for the treatment of arthrosis/ osteoarthritis, and/or rheumatic joint diseases and for the relief of symptoms such as pain and joint stiffness.

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

- Zeel® Injection Solution is a homeopathic drug product indicated, in combination with Traumeel® 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 Zeel® Injection Solution.
- If co-administration with a local anesthetic is desired, Zeel® Injection Solution may be mixed with lidocaine or similar agents at the discretion of the physician.
- Zeel® 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 ampule 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 ampule into the syringe. Discard half or one third of the contents, depending on the required dosage, before administering
- Only licensed practitioners with sufficient expertise in injecting drugs, including the respective route of administration, should administer the product.

Zeel® Injection Solution

2.2 **Standard Dosage** - for the treatment of arthrosis/osteoarthritis, and/or rheumatic joint diseases and for the relief of symptoms such as pain and joint stiffness.
Adults and children 12 years and older:
1 ampule 1 to 3 times per 7 days
Children 6 to 11 years:
⅔ of an ampule 1 to 3 times per 7 days

2.3 **Acute Dosage** – for the treatment of arthrosis/osteoarthritis, and/or rheumatic joint diseases and for the relief of symptoms such as pain and joint stiffness.
Adults and children 12 years and older:
1 ampule daily, and then continue with standard dosage.
Children 6 to 11 years:
⅔ of an ampule daily, and then continue with standard dosage.

2.4 **Co-administration therapy with Traumeel® 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, Zeel® Injection Solution may be mixed in a ratio of 1:1 with Traumeel® Injection Solution.
- For convenience, the daily dose of Zeel® Injection Solution may be administered at the same time as a Traumeel® Injection Solution, according to the dosing recommendations for each medication.

2.5 **Instructions for Opening Glass Ampule**

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

3 Dosage Forms and Strength

One ampule containing 2.0 ml each containing the active ingredients in the strengths listed under Description. (11)

4 Contraindications

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

5 Warnings and Precautions

None.

6 Adverse Reactions

6.1 Post-marketing Experience

- The following adverse events have been identified during post-marketing use of Zeel® 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 Zeel® Injection Solution: Allergic (hypersensitivity) skin reactions may occur in isolated cases.
- 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.

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 Zeel® 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. Zeel® Injection solution should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

When Zeel® Injection Solution is administered with Traumeel® Injection Solution in a woman of childbearing age, refer to the pregnancy category and product labelling for Traumeel® 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 Zeel® 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 Zeel® 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 ingredients in Zeel® Injection Solution has not identified differences in responses between adults and geriatric patients.

10 Overdosage

No negative effects of an overdose have been reported and none are expected due to the homeopathic dilutions.

11 Description

11.1 **Ingredients**

• Each 2.0 ml ampule contains:

Active Ingredients:			
Ingredient name	Potency	Quantity	Final dilution
a-Lipoicum acidum	8X	2.0 µl	10.99X
Arnica montana, radix	4X	200.0 µl	5.00X
Cartilago suis	6X	2.0 µl	9.00X
Coenzyme A	8X	2.0 µl	10.99X
Dulcamara	3X	10.0 µl	5.30X
Embryo totalis suis	6X	2.0 µl	9.00X
Funiculus umbilicalis suis	6X	2.0 µl	9.00X
Nadidum	8X	2.0 µl	10.99X
Natrum oxalaceticum	8X	2.0 µl	10.99X
Placenta suis	6X	2.0 µl	9.00X
Rhus toxicodendron	2X	10.0 µl	4.30X
Sanguinaria canadensis	4X	3.0 µl	6.82X
Sulphur	6X	3.6 µl	8.74X
Symphytum officinale	6X	10.0 µl	8.30X

Inactive Ingredients:

Water for injection 1,747.4 µl

Sodium chloride 17.6 µl

11.2 **Pharmaceutical Form**

• Sterile injection solution

11.3 **Route of Administration**

• Parenteral: s.c., i.d., i.m., i.a. or i.v

12 Clinical Pharmacology

12.1 **Mechanism of Action**

The exact mechanism of Zeel® Injection Solution is not fully understood.

12.2 **Pharmacodynamics**

Not applicable for homeopathic medicinal products.

13 References

• Homeopathic Pharmacopeia of the United States Revision Service

14 How Supplied / Storage and handling

14.1 **Dosage forms and package sizes**

• 1 ampule of 2.0 ml in packs of 10

• NDC 50114-7030-1

14.2 **Storage and handling**

• Store at room temperature. Protect from light.

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