

Traumeel®

Tablets • Oral drops • Oral vials • Gel • Ointment • Ear drops • Injection solution (Rx)

INGREDIENTS:

Tablets: Each 300 mg tablet contains as active ingredients: Belladonna 4X 75 mg; Arnica montana, radix 3X 40 mg; Aconitum napellus 3X 30 mg; Chamomilla 3X, Symphytum officinale 8X, 24 mg each; Calendula officinalis 2X, Hamamelis virginiana 2X, Millefolium 3X, Hepar sulphuris calcareum 8X, Mercurius solubilis 8X, 15 mg each; Hypericum perforatum 3X 8 mg; Bellis perennis 2X, Echinacea angustifolia 2X, Echinacea purpurea 2X, 6 mg each in a lactose base.

Oral drops: Each 100 ml contains: Arnica montana, radix 3X 10 ml; Aconitum napellus 3X, Chamomilla 3X, Belladonna 4X, Symphytum officinale 8X, 5 ml each; Bellis perennis 2X, Calendula officinalis 2X, Echinacea angustifolia 2X, Echinacea purpurea 2X, Hamamelis virginiana 2X, Hypericum perforatum 3X, Millefolium 3X, Hepar sulphuris calcareum 8X, Mercurius solubilis 8X, 2 ml each. Contains 35% ethyl alcohol by volume.

Oral vials: Each 100 ml contains: Arnica montana, radix 3X, 1.0 ml; Belladonna 3X 1.0 ml; Aconitum napellus 3X 0.6 ml; Hypericum perforatum 3X 0.3 ml; Calendula officinalis 2X 0.1 ml; Chamomilla 3X 0.1 ml; Millefolium 3X 0.1 ml; Hepar sulphuris calcareum 6X 0.1 ml; Symphytum officinale 6X 0.1ml; Bellis perennis 2X 0.05 ml; Mercurius solubilis 6X 0.05 ml; Echinacea angustifolia 2X 0.025 ml; Echinacea purpurea 2X 0.025 ml; Hamamelis virginiana 1X 0.01 ml.

Ointment: Each 100 g contains.: Calendula officinalis 1X, Hamamelis virginiana 1X, Arnica montana, radix 3X, 1.50 g each; Aconitum napellus 3X, Belladonna 3X, 1.00 g each; Bellis perennis 1X, Chamomilla 1X, Echinacea angustifolia 1X, Echinacea purpurea 1X, 0.50 g each; Millefolium 1X 0.30 g; Hepar sulphuris calcareum 8X 0.25 g; Mercurius solubilis 8X 0.12 g; Symphytum officinale 4X 0.10 g; Hypericum perforatum 6X 0.09 g. Inactive ingredients: Purified water, paraffin, white petrolatum, ethanol, and cetylstearyl alcohol.

Gel: Each 100 g of gel contains: Calendula officinalis 1X, Hamamelis virginiana 1X, Arnica montana, radix 3X, 1.50 g each; Aconitum napellus 3X, Belladonna 3X, 1.00 g each; Bellis perennis 1X, Chamomilla 1X, Echinacea angustifolia 1X, Echinacea purpurea 1X, 0.50 g each; Millefolium 1X 0.30 g; Hepar sulphuris calcareum 8X 0.25 g; Mercurius solubilis 8X 0.12 g; Symphytum officinale 4X 0.10 g; Hypericum perforatum 6X 0.09 g. Inactive ingredients: Purified water, ethanol, carbopol 980, and sodium hydroxide.

Ear drops: Each vial (0.45ml) contains: Arnica montana, radix 3X, Belladonna 3X, Calendula officinalis 2X, Chamomilla 3X, Hepar sulphuris calcareum 6X, Millefolium 3X, Symphytum officinale 6X 0.99 µl each; Aconitum napellus 3X 0.954 µl each; Bellis perennis 2X, Mercurius solubilis 6X 0.495 µl each; Hypericum perforatum 2X 0.297 µl each; Echinacea angustifolia 2X, Echinacea purpurea 2X 0.247 µl each; Hamamelis virginiana 1x 0.099 µl in an isotonic sodium chloride solution.

Injection solution (Rx): Each ampule of 2.0 ml contains: Hepar sulphuris calcareum 8X 200.0 µl; Belladonna 3X, Calendula officinalis 3X, Chamomilla 4X, Millefolium 4X, 20.0 µl each; Aconitum napellus 3X 12.0 µl; Bellis perennis 3X 10 µl; Hypericum perforatum 3X 6.0 µl; Echinacea angustifolia 3X, Echinacea purpurea 3X, 5.0 µl each; Arnica montana, radix 2X, Hamamelis virginiana 2X, Symphytum officinale 6X 2.0 µl.

INDICATIONS:

For the temporary relief of symptoms, including mild to moderate pain, associated with inflammatory, exudative and degenerative processes due to acute trauma, repetitive or overuse injuries, or arthritic conditions.

Ear drops: For the temporary relief of symptoms including minor ear inflammation, ear pain, stuffiness in ears and swimmer's ear.

Injection solution (Rx): For the temporary relief of symptoms, including mild to moderate pain, associated with inflammatory, exudative and degenerative processes due to acute trauma, repetitive or overuse injuries, or arthritic conditions. See product insert for full prescribing information. (Interactions with other medications: None known.)

SIDE EFFECTS/CONTRAINDICATIONS:

Hypersensitivity to Traumeel or any of its ingredients. Do not apply directly to open wounds.

Ointment/Gel: In rare cases, hypersensitivity to one or more ingredients may result in allergic skin reactions.

Warning: Do not apply Traumeel ointment or gel over large surfaces of the body.

HOW SUPPLIED:

Traumeel® Tablets: Bottle containing 100 tablets.

Traumeel® Oral drops: Dropper bottle containing 50 ml.

Traumeel® Oral vials: Pack containing 10 vials of 2.2 ml.

Traumeel® Ointment: Tube containing 50 or 100 grams of ointment.

Traumeel® Gel: Tube containing 50 or squeeze bottle containing 250 grams of gel.

Traumeel® Ear drops: Pack containing 10 vials of 0.45 ml.

Traumeel® Injection solution (Rx): Pack containing 10 ampules of 2.0 ml.

Zeel® and Traumeel® Protocol to supplement current treatment with Glucosamine/Chondroitin products

Weeks 1 and 2:

- **Traumeel® tablets*:** 1 tablet 3-5 times per day
- **Zeel® tablets**:** 1 tablet 3-5 times per day
- **Traumeel® ointment:** apply locally 2-5 times per day

Weeks 3-4-5:

- **Zeel® ointment:** apply locally 3-5 times per day
- **Zeel® tablets**:** 1 tablet 3-5 times per day

* or Traumeel® oral vials: 1 oral vial per day

** or Zeel® oral vials: 1 oral vial per day

Why should you use/recommend Traumeel®?

- An effective anti-inflammatory/analgesic
- For acute trauma, injuries (sports, accidents) and temporary relief of arthritic pain
- No adverse renal, hepatic, cardiovascular, gastrointestinal or CNS side effects
- No known adverse drug interactions
- Over 60 years of worldwide therapeutic use
- Compatible with conventional medications
- Compatible with local anesthesia
- Safe alternative to NSAIDs
- Safe for children

Scientific Bio-Logics
Huntington Beach, CA. 92647
Tel: (714)847-9355 • Fax: (714)848-8311
Web: www.sblogics.com
Email: info@sblogics.com

-Heel

Dosage and Administration

The dosage schedules listed below can be used as a general guide for the administration of Traumeel®. The dosage for each patient should be individualized according to the patient's response to therapy. See package insert for complete dosage information.

Traumeel® Tablets:

Adults and children above 6 years: 1 tablet sublingually or dissolved completely in mouth 3 times daily or as directed by a physician. *Infants and children to 6 years:* 1/2 the adult dosage.

Traumeel® Oral Drops:

Adults and children above 11 years: 10 to 30 drops orally 3 times daily. Due to alcohol content (Ethyl alcohol 25% by volume), a physician should be consulted before using in children under 12 years of age.

Traumeel® Oral vials:

Adults and children above 6 years: In general, 1 vial 1-3 times daily. Children to 6 years: 1/2 the adult dosage. Note: Unused portion of open vials should be discarded. Not for Injection.

Traumeel® Ointment/Gel:

Adults, children and infants: Apply generously to affected areas 2 to 3 times daily. Traumeel® should be rubbed gently into the skin. Traumeel® may be applied using mild compression bandaging and/or occlusive bandaging. Sufficient gel or ointment should be applied to cover the affected area, but should not be applied over large areas, over broken skin or directly into open wounds. For external use only.

Traumeel® Ear drops:

Adults and children above 6 years: In general, 1 vial 1-3 times daily. Pour the contents of one vial directly into the affected ear. *Infants and children up to 6 years:* 1/2 the adult dosage.

Traumeel® Injection Solution (Rx):

Adults: One ampule daily in acute disorders, otherwise 1 to 2 ampules 1 to 3 times weekly i.m., s.c. i.v. i.d. (in the case of wheals), or periarticular. *Children ages 2 to 6:* 1/2 the adult dosage.



Traumeel®



Proven safe and effective for:

- ***Bruising***
- ***Sports injuries***
- ***Inflammation***
- ***Muscular pain***

-Heel

Traumeel®

Pharmacological aspects

In-vitro and in-vivo studies have demonstrated that Traumeel modulates the release of oxygen radicals by activating the neutrophil granulocytes,¹ and also suppresses inflammatory mediators.² The components of Traumeel do not have a cytotoxic effect on granulocytes, lymphocytes, blood platelets or endothelial cells. The defense mechanisms of these cells are not impaired by Traumeel.

Pharmacological description

Traumeel is made up of a combination of 12 botanical and 2 mineral active ingredients. (Injection solution has only 1 mineral ingredient)

Traumeel causes no adverse renal, hepatic, cardiovascular, gastrointestinal or CNS side effects. Traumeel is compatible with conventional medications and local anesthesia.

Traumeel is safe for children.

Traumeel has no restrictions with regard to patient age or condition.

Traumeel is generally well-tolerated and is suitable for long-term treatment.

Traumeel has a broad spectrum of therapeutic activity.

Traumeel® vs NSAIDs*

	Traumeel®	NSAIDs
Effective anti-inflammatory/analgesic	yes	yes
Established history of clinical experiences	yes	yes
Gastro-intestinal side effects	no	yes
Platelet aggregation inhibition	no	yes
Adverse drug interactions	no	yes
Sodium and fluid retention	no	yes



Over 60 years of therapeutic use and sold in more than 60 countries

References

- 1) Wagner A. Report on findings from immunologic and enzyme research documents as accomplished with Traumeel Injection Solution. Not published. Data on file at Heel GmbH, Baden-Baden, Germany.
- 2) Conforti A et al. Experimental Studies on the Anti-Inflammatory Activity of a Homeopathic Preparation. Biomedical Therapy. XV (1) 1997: 28-31.

* Non-steroidal anti-inflammatory drugs

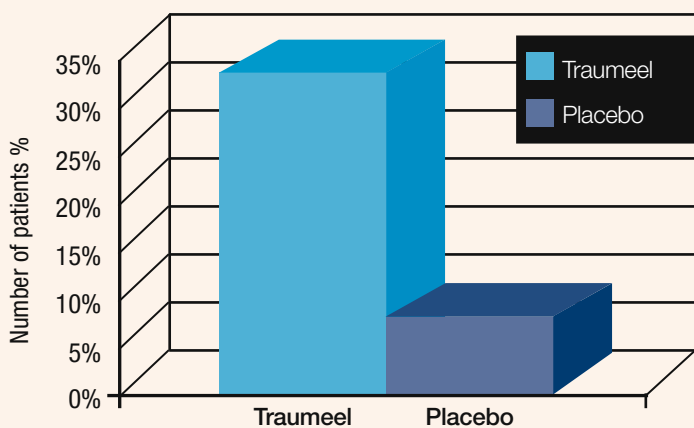
Clinically Tested

Traumeel® is supported by dozens of scientific and clinical studies

Ingredients:

Aconitum napellus:	Numbness and tingling of extremities; arms feel lame and bruised; inflammatory rheumatism.
Arnica montana, radix:	Sore, lame, bruised feeling; after traumatic injuries; muscular tonic.
Belladonna:	Shooting pain along limbs; cold extremities; stiff neck.
Bellis perennis:	Bruised feeling in pelvic region; boils; forearm pain; muscular soreness.
Calendula officinalis:	Analgesic; promotes granulation; lacerated wounds; healing agent when used locally.
Chamomilla:	Lumbago; slow healing wounds; neck stiffness.
Echinacea angustifolia:	General aching all over with exhaustion; anti-inflammatory.
Echinacea purpurea:	Anti-inflammatory and anti-infection.
Hamamelis virginiana:	Bruised soreness; rheumatism of scapula; chest tightness.
Hepar sulphuris calcareum:	Tendency to suppuration; painful limbs and joints; knee swelling.
Hypericum perforatum:	Nerve injuries; pressure over sacrum; puncture wounds.
Mercurius solubilis:	Suppurations; wrist swelling; bruised pain in back and shoulders.
Millefolium:	Hemorrhages; piercing pain in limbs; wounds bleed profusely.
Symphytum officinale:	Eye pain due to injury; sprains; injuries to sinews and tendons; specific for healing of fractures.

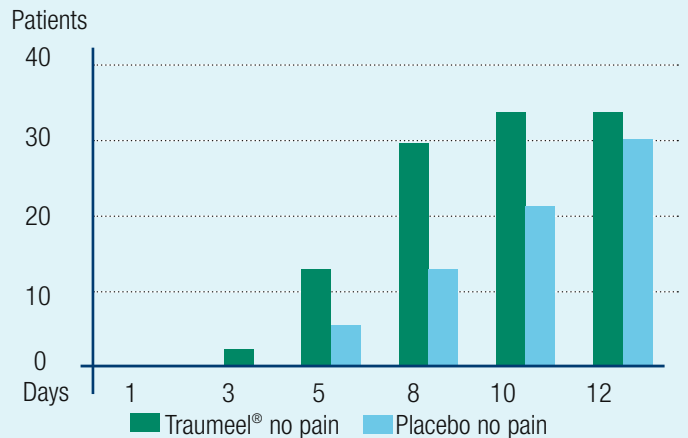
Traumeel Use and No Development of Stomatitis



In a randomized, placebo-controlled, double-blind clinical trial, oral administration of Traumeel in a saline base, was shown to have a significant and clinically-relevant impact on chemotherapy induced stomatitis in children. Clinically there is little effective treatment for chemotherapy-induced stomatitis and due to the increasingly intense treatments, the stomatitis is often a dose limiting factor in the treatment regime. The conclusion in this study indicates that Traumeel may reduce the severity and duration of stomatitis induced by chemotherapy.¹

Effectiveness of Traumeel ointment for sports-related ankle sprains.**

A placebo-controlled, randomized double-blind study



Patients without pain within two weeks from beginning of therapy with Traumeel ointment, compared with placebo (n = 33 for Traumeel; n = 36 for placebo; p = 0.015).

The number of patients no longer in pain after 10 days of treatment (p ≤ 0.0003).

Group	Success		n total
	no	yes	
Traumeel®	5	28	33
Placebo	23	13	36

Within the Traumeel group, the additional effects of the active ointment constituents accelerated recovery.**

In both groups, the basic treatment improved joint mobility. Considerably more so for the Traumeel patients (p = 0.03) than for the placebo group.**

**Source: Zell 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, VII, 1, pp. 1-6.

Study Summaries

A multicenter prospective study was carried out in three European countries to document indications, therapeutic efficacy and tolerance of Traumeel tablets and drops. Among the 1359 patients suffering from various injuries such as bruises, sprains, hematomas as well as degenerative and inflammatory conditions such as arthritis, frozen shoulder and carpal tunnel syndrome, 83% reported 'good' and 'very good' therapeutic results. No cases of adverse drug reactions were reported.²

Drug surveillance was conducted to investigate the effectiveness, patient tolerance and most frequently employed routes of administration of Traumeel as an ointment. A total of 378 physicians took part in this study. The most frequent application of the ointment was for sprains. Therapeutic results for 48% of the 3422 treated cases were graded 'very good' while therapy for 98% of the patients was considered 'very good', 'good' or 'satisfactory.' Patient tolerance to Traumeel ointment was excellent.³

References

- 1) Oberbaum M et al. Treating chemotherapy-induced stomatitis with Traumeel. Cancer. 92 (3) 2001 Aug 1: 684-690.
- 2) Zenner S and Weiser M. Oral Treatment of Traumatic, Inflammatory and Degenerative Conditions with a Homeopathic Remedy. Biomedical Therapy. XV (1) 1997: 22-26
- 3) Zenner S and Metelmann H. Therapy Experience with a Homeopathic Ointment. Biological Therapy. XII (3) 1994: 204-211.