

## TRAUMEEL

### (Information sheet from Drugs.com)

TRAUMEEL® Injection Solution is an anti-inflammatory, anti-edematous, anti-exudative combination formulation of 12 botanical substances and 1 mineral substance. TRAUMEEL® Injection Solution is officially classified as a **homeopathic** combination remedy (1).

1. Botanical ingredients: ☐ Arnica montana, radix (mountain arnica)  
☐ Calendula officinalis (marigold) ☐ Hamamelis virginiana (**witch hazel**)  
☐ Millefolium (milfoil) ☐ Belladonna (deadly nightshade) ☐ Aconitum napellus (monkshood) ☐ Chamomilla (chamomile) ☐ Symphytum officinale (comfrey) ☐ Bellis perennis (daisy) ☐ **Echinacea** angustifolia (narrow-leaved cone flower) ☐ Echinacea purpurea (purple cone flower) ☐ Hypericum perforatum (St. John's wort)
2. Mineral ingredients: ☐ Hepar sulphuris calcareum (**calcium** sulfide)

**Injection Solution:** Each 2.0 ml ampule contains as active ingredients: Hepar sulphuris calcareum 8X 200.0 µl; Belladonna 3X 20.0 µl; Calendula officinalis 3X 20.0 µl; Chamomilla 4X 20.0 µl; Millefolium 4X 20.0 µl; Aconitum napellus 3X 12.0 µl; Bellis perennis 3X 10.0 µl; Hypericum perforatum 3X 6.0 µl; Echinacea angustifolia 3X 5.0 µl; Echinacea purpurea 3X 5.0 µl; Arnica montana, radix 2X 2.0 µl; Hamamelis virginiana 2X 2.0 µl; Symphytum officinale 6X 2.0 µl. Each 2.0 ml ampule contains as an inactive ingredient: Sterile isotonic **sodium** chloride solution.

## CLINICAL PHARMACOLOGY

The exact mechanism of action of TRAUMEEL® Injection Solution is not fully understood. Various cellular and biochemical pathways appear to be modulated by the product ingredients. The mechanism of action of TRAUMEEL® Injection Solution does not appear to be the result of cyclooxygenase or lipoxygenase enzyme inhibition, as is the case with nonsteroidal anti-inflammatory drugs (NSAIDs). TRAUMEEL® Injection Solution does not inhibit the arachidonic acid pathway of prostaglandin synthesis. Instead, the mechanism of action of TRAUMEEL® Injection Solution appears to be the result of modulation of the release of oxygen radicals from activated neutrophils, and inhibition of the release of inflammatory mediators (possibly interleukin-1 from activated macrophages) and neuropeptides (2).

*In vitro* studies show that the ingredients in TRAUMEEL® Injection Solution are noncytotoxic to granulocytes, lymphocytes, platelets, and endothelia, which indicates that the defensive functions of these cells are preserved during treatment with TRAUMEEL® Injection Solution (3).

The anti-inflammatory, anti-edematous, and anti-exudative effects of TRAUMEEL® Injection Solution have been demonstrated in **clinical trials** as well as in *in vivo* experimental models including the carrageenin-induced edema test and the adjuvant **arthritis** test (3).

## INDICATIONS AND USAGE

TRAUMEEL® Injection Solution is indicated for the treatment of symptoms associated with inflammatory, exudative, and degenerative processes due to acute trauma (such as contusions, lacerations, fractures, sprains, post-operative wounds, etc.), repetitive or overuse injuries (such as tendonitis, bursitis, epicondylitis, etc.), and for minor aches and pains associated with such conditions. TRAUMEEL® Injection Solution is also indicated for the treatment of minor aches and pains associated with backache, muscular aches, and the minor pain from **rheumatoid arthritis**, osteoarthritis, gouty arthritis, and ankylosing spondylitis.

## CONTRAINDICATIONS

TRAUMEEL® Injection Solution is contraindicated in patients with a known hypersensitivity to TRAUMEEL® Injection Solution or any of its ingredients (see **ADVERSE REACTIONS** ).

## WARNINGS

If pain persists or worsens, if new symptoms occur, or if redness or swelling is present, the patient should be carefully re-evaluated because these could be signs of a serious condition.

## PRECAUTIONS

### General:

Adverse effects with TRAUMEEL® Injection Solution are extremely rare. TRAUMEEL® Injection Solution exhibits no known adverse renal, hepatic, cardiovascular, gastrointestinal or central nervous system effects.

### Information for Patients:

No harmful or potentially hazardous side effects such as central nervous system depression are known. TRAUMEEL® Injection Solution is generally well-tolerated. However, if symptoms persist or worsen, a physician should be consulted (see **WARNINGS** ).

### Drug Interactions:

TRAUMEEL® Injection Solution is not known to interact with other medications. Furthermore, the administration of TRAUMEEL® Injection Solution can be safely augmented by the application of a topical dosage form of TRAUMEEL®.

### Drug/Laboratory Test Interactions:

TRAUMEEL® Injection Solution is not known to interact with any laboratory tests.

### Carcinogenesis:

No studies have been performed to evaluate the carcinogenicity of TRAUMEEL® Injection Solution. In world-wide post-marketing surveillance studies no evidence of carcinogenicity has been found (2).

## **Pregnancy:**

**Pregnancy** Category C. In general, medications such as TRAUMEEL® Injection Solution that are classified as homeopathic are not known to cause direct or indirect harm to the fetus. However, animal reproduction studies have not been performed and there are no well-controlled studies in **pregnant women**. In cases of pregnancy or suspected pregnancy, TRAUMEEL® Injection Solution should be used only if potential benefits justify potential risks to the fetus.

## **Nursing Mothers:**

It is not known whether any of the ingredients in TRAUMEEL® Injection Solution are excreted in human milk. However, because many drugs are excreted in human milk, TRAUMEEL® Injection Solution should be administered with caution to nursing mothers.

## **Pediatric Use:**

TRAUMEEL® Injection Solution can be safely administered to children as young as 2 years (see **DOSAGE AND ADMINISTRATION** ).

## **ADVERSE REACTIONS**

In rare cases, patients with hypersensitivity to botanicals of the Compositae **family** may experience an allergic reaction after the administration of TRAUMEEL® Injection Solution including anaphylactic reaction. TRAUMEEL® Injection Solution ingredients of the Compositae family are:

Arnica montana, radix (mountain arnica)

Calendula officinalis (marigold)

Millefolium (milfoil)

Chamomilla (chamomile)

Bellis perennis (daisy)

Echinacea angustifolia (narrow-leafed cone flower)

Echinacea purpurea (purple cone flower)

## **OVERDOSAGE**

Due to the low concentration of active ingredients in homeopathic preparations such as TRAUMEEL® Injection Solution, adverse reactions following overdosage are extremely unlikely. However, care must be taken not to exceed the recommended dosage.

## **DOSAGE AND ADMINISTRATION**

The dosage schedules listed below can be used as a general guide for the administration of TRAUMEEL® Injection Solution. TRAUMEEL® Injection Solution shows individual differences in clinical response. Therefore, the dosage for each patient should be individualized according to the patient's response to therapy. For best results, treatment with TRAUMEEL® Injection Solution should be initiated immediately following injury or at the first sign of symptoms. TRAUMEEL® Injection Solution may be administered until symptoms disappear.

TRAUMEEL® Injection Solution:

*Adults and children above 6 years:* 1 ampule daily for acute disorders, or 1 to 2 ampules 1 to 3 times weekly.

*Children (2 to 6 years):* Half the adult dosage. Discard unused solution.

TRAUMEEL® Injection Solution may be administered intravenously, intramuscularly, subcutaneously or intradermally. TRAUMEEL® Injection Solution is indicated for peri-articular administration, and for intra-articular aseptic conditions. If administration with a local anesthetic is desired, TRAUMEEL® Injection Solution may be mixed in a 1:1 ratio with 1% or 2% lidocaine hydrochloride. Similar local anesthetics may also be used. The required dose of TRAUMEEL® Injection Solution is first withdrawn from the ampule into the syringe. The local anesthetic is then withdrawn into the syringe, and the syringe is then shaken briefly. Normally, about 0.5 to 1.0 milliliters of each drug is withdrawn into the syringe.

TRAUMEEL® Injection Solution should be administered using a narrow gauge needle (e.g., 22 to 30 gauge). **Note:** Parenteral drug products like TRAUMEEL® Injection Solution should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit. TRAUMEEL® Injection Solution is a clear, colorless solution. Discolored solutions should be discarded.

## HOW SUPPLIED

TRAUMEEL® Injection Solution in 2.0 ml ampules:

Packs of 10: NDC 50114-7000-1.

Avoid freezing and excessive heat. Store at room temperature. Protect from light.

**CAUTION: Rx only.**

## REFERENCES

1. The Homeopathic Pharmacopoeia of the United States (HPUS), 8<sup>th</sup> edition, Falls Church, Virginia, 1979; and the Homeopathic Pharmacopoeia of the United States Revision Service (HPRS), 1988.
2. Data on file, Heel GmbH, Baden-Baden, Germany.
3. Conforti A, *et al* . Experimental Studies on the Anti-inflammatory Activity of a Homeopathic Preparation. *Biomedical Therapy XV* No.1:28-31, 1997.

This full prescribing information has been compiled in accordance with the Code of Federal Regulations (CFR), 21 sections 201.56 and 201.57.