

## HIGHLIGHTS OF PRESCRIBING INFORMATION: Traumeel® Tablets, Oral, Rx Only

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

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

Traumeel® Tablets is an analgesic anti-inflammatory homeopathic drug indicated for the treatment of injuries, inflammation and degenerative conditions of the musculoskeletal system and for the relief of associated symptoms such as pain. (1)

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

#### • Standard Dosage:

Adults and children 12 years and older:

- 2 tablets every 4 hours. Do not exceed 12 tablets per 24 hours. (2.2)

Children under 12 years:

- 1 tablet every 4 hours. Do not exceed 6 tablets per 24 hours. (2.2)

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

- 300 mg tablets each containing the active ingredients in the strengths listed under description. (3)

### -----CONTRAINDICATIONS-----

- Traumeel® Tablets are contraindicated for patients with known hypersensitivity to Traumeel® or any of its ingredients. (4)

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

- Do not use if known sensitivity to Traumeel® or and of its ingredients exists. (5)

### -----ADVERSE REACTIONS-----

- No adverse events with a casual relationship to Traumeel® have been reported(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® Tablets on pregnant or lactating women, children or elderly. (8)

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

## FULL PRESCRIBING INFORMATION

1. Indications and Usage
  - (1.1) Traumeel® Tablets are an analgesic / anti-inflammatory 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.
2. Dosage and Administration
  - (2.1) General Considerations
    - The dosage schedule below can be used as a general guide for the administration of Traumeel® Tablets.
  - (2.2) Standard Dosage:
    - **Adults and children 12 years and older:** 2 tablets every 4 hours. Do not exceed 12 tablets per 24 hours.
    - **Children under 12 years:** 1 tablet every 4 hours. Do not exceed 6 tablets per 24 hours.
3. Dosage Forms and Strength
  - (3.1) 300 mg tablets each containing the active ingredients in the strengths listed under Description. (11)
4. Contraindications
  - (4.1) Traumeel® Tablets are contraindicated in patients with known hypersensitivity to Traumeel® or any of its ingredients.
5. Warnings and Precautions
  - (5.1) Do not use if known sensitivity to Traumeel® or any of its ingredients exists.
6. Adverse Reactions
  - (6.1) No adverse events with a causal relationship to Traumeel have been reported.
7. Drug Interactions
  - (7.1) Due to the homeopathic dilutions, no interactions have been reported, and none are expected.
8. Use in Specific Populations
  - (8.1) **Pregnancy**
    - (8.1.1) **Teratogenic Effects**
      - Some ingredients in Traumeel tablets 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® tablets should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

(8.1.2) **Non-teratogenic Effects**

- No known non-teratogenic effects.

(8.2) **Labor and Delivery**

- Not 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 tablets are 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® tablets 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 Traumeel® tablets has not identified differences in responses between adults and geriatric patients.

**11. Description**

(11.1) **Ingredients** - Each 300 mg tablet contains:

<b>Active Ingredients:</b>			
<b>Ingredient Name</b>	<b>Potency</b>	<b>Quantity</b>	<b>Final Dilution</b>
Aconitum napellus	3X	30 mg	4X
Arnica montana, radix	2X	15 mg	3.3X
Belladonna	4X	75 mg	4.6X
Bellis perennis	2X	6 mg	3.7X
Calendula officinalis	2X	15 mg	3.3X
Chamomilla	3X	24 mg	4.1X
Echinacea	2X	6 mg	3.7X
Echinacea purpurea	2X	6 mg	3.7X
Hamamelis virginiana	2X	15 mg	3.3X
Hepar sulphuris calcareum	8X	30 mg	9X
Hypericum perforatum	2X	3 mg	4X
Mercurius solubilis	8X	30 mg	9X
Millefolium	3X	15 mg	4.3X
Symphytum officinale	8X	24 mg	9.1X
<b>Inactive Ingredients:</b>			
Lactose		6 mg	
Magnesium stearate		1.5 mg	

(11.2) **Pharmaceutical Form**

- Tablet

(11.3) **Route of Administration**

- Oral

**12. Clinical Pharmacology**

(12.1) **Mechanism of Action**

- The exact mechanism of Traumeel® Tablets is not fully understood.

(12.2) **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**

- Bottle with 90 tablets
- NDC 50114-9483-2

(16.2) **Dosage forms and package sizes**

- Store at room temperature. Protect from light.
- Keep this and all medicines out of the reach of children