

HIGHLIGHTS OF PRESCRIBING INFORMATION

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

Traumeel® Tablets, Oral, Rx Only

-----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 patients with known hypersensitivity to Traumeel or any of its ingredients. (4)

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

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

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

- No adverse events with a causal 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)

Revised 06/2016

FULL PRESCRIBING INFORMATION: CONTENTS*

1 Indications and Usage

2 Dosage and Administration

- 2.1 General Considerations
- 2.2 Standard Dosage

3 Dosage Form and Strength

4 Contraindications

5 Warnings and Precautions

6 Adverse Reactions

- 6.1 Post-marketing Experience

7 Drug Interactions

8 Use in Specific Populations

- 8.1 Pregnancy
- 8.2 Labor and Delivery
- 8.3 Nursing Mothers
- 8.4 Pediatric Use
- 8.5 Geriatric Use

11 Description

- 11.1 Ingredients
- 11.2 Pharmaceutical Form
- 11.3 Route of Administration

12 Clinical Pharmacology

- 12.1 Mechanism of Action
- 12.2 Pharmacodynamics

15 References

16 How Supplied / Storage and Handling

* 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:

Active Ingredients:			
Ingredient name	Potency	Quantity	Final dilution
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

Inactive Ingredients:

Description	Quantity
Lactose	6.0 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 Storage and handling

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