

HIGHLIGHTS OF PRESCRIBING INFORMATION: Traumeel® Ointment, Topical, Rx Only

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

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

Traumeel® Ointment 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, children, and infants:

- Apply generously to affected areas 2 to 3 times daily, or as needed. Massage thoroughly into the skin. Traumeel® may be applied using mild compression bandaging and/or occlusive bandaging. (2.2)

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

- Topical ointment containing the active ingredients in the strengths listed under description. (3)

-----CONTRAINDICATIONS-----

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

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

- For external use only. Cetylstearyl alcohol may cause local skin reactions, i.e. contact dermatitis. Do not apply over large areas of the body. Do not apply over open wounds or broken skin. If symptoms persist or worsen, or if a rash develops, a physician should be consulted. (5)

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

- In rare cases, allergic skin reactions may develop. Do not use if known sensitivity to Traumeel® or any of its ingredients exists. (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 ointment 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® Ointment is 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® Ointment.

- (2.2) Standard Dosage:

- **Adults, children, and infants:** Apply generously to affected areas 2 to 3 times daily, or as needed. Massage thoroughly into the skin. Traumeel® may be applied using mild compression bandaging and/or occlusive bandaging.

3. Dosage Forms and Strength

- (3.1) One tube containing 100 g containing the active ingredients in the strengths listed under Description. (11)

4. Contraindications

- (4.1) Traumeel® Ointment is contraindicated in patients with known hypersensitivity to Traumeel® or any of its ingredients.

5. Warnings and Precautions

For external use only. Do not apply over large areas of the body. Do not apply over open wounds or broken skin. If symptoms persist or worsen, or if a rash develops, a physician should be consulted.

6. Adverse Reactions

Hypersensitivity reactions or local allergic reactions (cutaneous inflammation, redness, swelling and pruritis) can occur in very rare cases, in which case use of the product should be discontinued. Do not use if known sensitivity to Traumeel® ointment or any of its ingredients exists.

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® Ointment 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® Ointment 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**

- 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® Ointment 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® Ointment 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® Ointment has not identified differences in responses between adults and geriatric patients.

11. Description

(11.1) Ingredients - Each 100 g ointment contains:

| Active Ingredients: | | | |
|---|----------------|-----------------|-----------------------|
| Ingredient Name | Potency | Quantity | Final Dilution |
| Aconitum napellus | 1X | 0.050 g | 4.3X |
| Arnica montana, radix | 3X | 1.500 g | 4.82X |
| Belladonna | 1X | 0.050 g | 4.3X |
| Bellis perennis | MT | 0.100 g | 3X |
| Calendula officinalis | MT | 0.450 g | 2.34X |
| Chamomilla | MT | 0.150 g | 2.82X |
| Echinacea | MT | 0.150 g | 2.82X |
| Echinacea purpurea | MT | 0.150 g | 2.82X |
| Hamamelis virginiana | MT | 0.450 g | 2.34X |
| Hepar sulphuris calcareum | 6X | 0.025 g | 9.6X |
| Hypericum perforatum | 6X | 0.090 g | 9.04X |
| Mercurius solubilis | 6X | 0.040 g | 9.39X |
| Millefolium | MT | 0.090 g | 3.04X |
| Symphytum officinale | 4X | 0.100 g | 7.2X |
| Inactive Ingredients: | | | |
| Paraffin, liquid | | 9.342 g | |
| Cetostearyl alcohol (type A), emulsifying | | 8.007 g | |
| Paraffin, white soft | | 9.342 g | |
| Water, purified | | 60.579 g | |
| Ethanol (96%) | | 9.335 g | |

(11.2) Pharmaceutical Form

- Ointment

(11.3) Route of Administration

- Topical, Occlusive Dressing Technique

12. Clinical Pharmacology

(12.1) Mechanism of Action

- The exact mechanism of Traumeel® ointment 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

- Tube of 100g ointment
- NDC 50114-9482-8

(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.