TRAUMEEL- arnica montana root, atropa belladonna, calendula officinalis flowering top, matricaria recutita, achillea millefolium, calcium sulfide, comfrey root, aconitum napellus, bellis perennis, mercurius solubilis, hypericum perforatum, echinacea, unspecified, echinacea purpurea and hamamelis virginiana root bark/stem bark injection
Medinatura

Disclaimer: This homeopathic product has not been evaluated by the Food and Drug Administration for safety or efficacy. FDA is not aware of scientific evidence to support homeopathy as effective.

Traumeel 2.2ml Injection

Description

Active Ingredients:

Ingredient name	Potency	Quantity	Final dilution
Aconitum napellus	2X	1.32 µl	5.22X
Arnica montana, radix	2X	2.20 µl	5.00X
Bellis perennis	2X	1.10 µl	5.30X
Belladonna	2X	2.20 µl	5.00X
Calendula officinalis	2X	2.20 µl	5.00X
Chamomilla	3X	2.20 µl	6.00X
Echinacea	2X	0.55 µl	5.60X
Echinacea purpurea	2X	0.55 µl	5.60X
Hamamelis virginiana	1X	0.22 µl	5.00X
Hepar sulphuris calcareum	6X	2.20 µl	9.00X
Hypericum perforatum	2X	0.66 µl	5.52X
Mercurius solubilis	6X	1.10 µl	9.30X
Millefolium	3X	2.20 µl	6.00X
Symphytum officinale	6X	2.20 µl	9.00X

INDICATION AND USAGE

Treatment of injuries and various conditions of the musculoskeletal system.

• Traumeel® Injection Solution is a 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

Co-administration Therapy with Zeel® Injection Solution for the treatment of

inflammatory and degenerative conditions of the musculoskeletal system.

• Traumeel ® Injection Solution is a homeopathic drug product indicated, in combination with Zeel® Injection Solution, for the treatment of inflammatory and degenerative conditions of the musculoskeletal system, such as arthrosis/osteoarthritis and/or rheumatic joint diseases, and for the relief of symptoms including pain, swelling, and joint stiffness.

DOSAGE AND ADMINISTRATION

General Considerations

- The dosage schedules listed below can be used as a general guide for the administration of Traumeel® Injection Solution.
- If co-administration with a local anesthetic is desired, Traumeel® Injection Solution may be mixed with lidocaine or similar agents at the discretion of the physician.
- Traumeel® Injection Solution may be administered s.c., i.d., i.m., i.a. or i.v.
- The interval between injections is left to the discretion of the HCP, but should not exceed 1 ampule in 24 hours.
- Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Draw up the contents of the ampule into the syringe. Discard half or one third of the contents, depending on the required dosage, before administering.
- Only licensed practitioners with sufficient expertise in injecting drugs, including the respective route of
  administration, should administer the product.

Standard Dosage - for the treatment of injuries, inflammatory and degenerative conditions of the musculoskeletal system and for the relief of associated symptoms such as pain.

Adults and children 12 years and older:

1 ampule 1 to 3 times per 7 days

Children 6 to 11 years:

2/3 of an ampule 1 to 3 times per 7 days

Children 2 to 5 years:

1/2 ampule 1 to 3 times per 7 days

Acute Dosage - for the treatment of injuries, inflammatory and degenerative conditions of the musculoskeletal system and for the relief of associated symptoms such as pain.

Adults and children 12 years and older:

1 ampule daily, and then continue with standard dosage

Children 6 to 11 years:

2/3 of an ampule daily, and then continue with standard dosage

Children 2 to 5 years:

1/2 ampule daily, and then continue with standard dosage

Co-administration therapy with Zeel® Injection Solution - for the treatment of inflammatory and degenerative conditions of the musculoskeletal system, such as arthrosis/osteoarthritis and/or rheumatic joint diseases, and for the relief of symptoms including pain, swelling, and joint stiffness.

- In the treatment of musculoskeletal conditions, if co-administration with another homeopathic medicinal product is desired, Traumeel® Injection Solution may be mixed in a ratio of 1:1 with Zeel® Injection Solution.
- For convenience, the daily dose of Traumeel® Injection Solution may be administered at the same time as a Zeel® Injection Solution, according to the dosing recommendations for each medication.

CONTRAINDICATIONS

- Traumeel® Injection Solution is contraindicated in patients with known hypersensitivity to Traumeel® or any of its ingredients.

WARNINGS AND PRECAUTIONS

None

ADVERSE REACTIONS

Post-marketing Experience

• The following adverse events have been identified during post-marketing use of Traumeel® Injection Solution. Because these events are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

• Adverse event rates observed in Monotherapy use of Traumeel® Injection Solution: Allergic (hypersensitivity) reactions (e.g. skin allergies, redness/swelling at the injection site, even up to anaphylaxis) may occur in isolated cases.

• Adverse event rates observed in the Monotherapy use of Zeel® Injection Solution: Allergic (hypersensitivity) skin reactions may occur in isolated cases.

•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.

OVERDOSAGE

No negative effects of an overdose have been reported and none are expected due to the homeopathic dilutions.

CLINICAL PHARMACOLOGY

Mechanism of Action

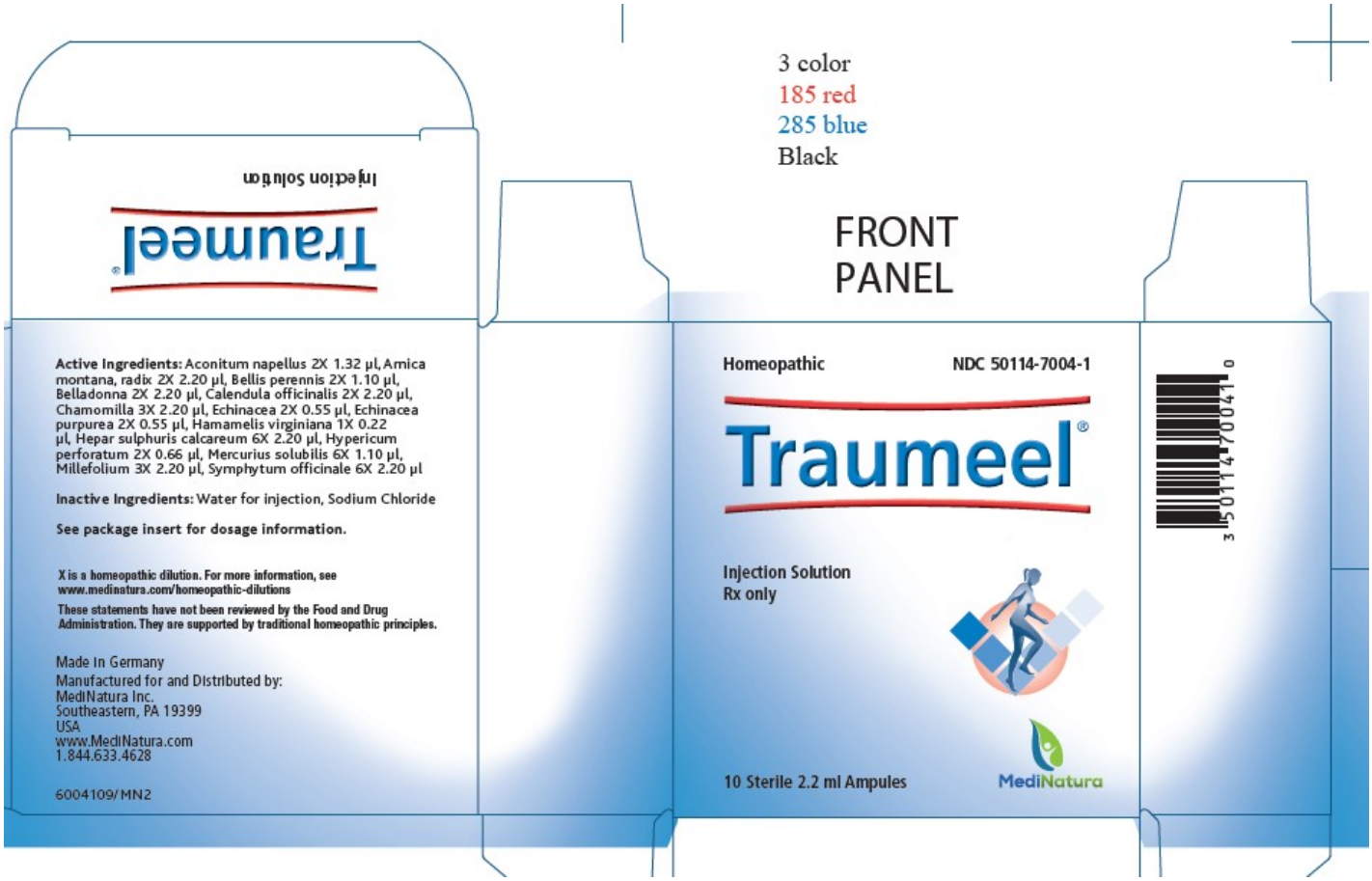
The exact mechanism of Traumeel® Injection Solution is not fully understood.

Pharmacodynamics

Not applicable for homeopathic medicinal products.

DOSAGE

One ampule containing 2.2 ml each containing the active ingredients in the strengths listed under Description.



TRAUMEEL

arnica montana root, atropa belladonna, calendula officinalis flowering top, matricaria recutita, achillea millefolium, calcium sulfide, comfrey root, aconitum napellus, bellis perennis, mercurius solubilis, hypericum perforatum, echinacea, unspecified, echinacea purpurea and hamamelis virginiana root bark/stem bark injection

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:50114-7004
Route of Administration	INTRADERMAL, INTRAVENOUS, INTRAMUSCULAR, SUBCUTANEOUS, INTRA-ARTICULAR		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ARNICA MONTANA ROOT (UNII: MUE8Y11327) (ARNICA MONTANA ROOT - UNII:MUE8Y11327)	ARNICA MONTANA ROOT	2 [hp_X] in 2.2 mL
ATROPA BELLADONNA (UNII: WQZ3G9PF0H) (ATROPA BELLADONNA - UNII:WQZ3G9PF0H)	ATROPA BELLADONNA	2 [hp_X] in 2.2 mL
CALENDULA OFFICINALIS FLOWERING TOP (UNII: 18E7415PXQ) (CALENDULA OFFICINALIS FLOWERING TOP - UNII:18E7415PXQ)	CALENDULA OFFICINALIS FLOWERING TOP	2 [hp_X] in 2.2 mL
MATRICARIA RECUTITA (UNII: G0R4UBI2ZZ) (MATRICARIA RECUTITA - UNII:G0R4UBI2ZZ)	MATRICARIA RECUTITA	3 [hp_X] in 2.2 mL
ACHILLEA MILLEFOLIUM (UNII: 2FXJ6SW4PK) (ACHILLEA MILLEFOLIUM - UNII:2FXJ6SW4PK)	ACHILLEA MILLEFOLIUM	3 [hp_X] in 2.2 mL
CALCIUM SULFIDE (UNII: 1MBW07J51Q) (CALCIUM SULFIDE - UNII:1MBW07J51Q)	CALCIUM SULFIDE	6 [hp_X] in 2.2 mL
COMFREY ROOT (UNII: M9VVZ08EKQ) (COMFREY ROOT - UNII:M9VVZ08EKQ)	COMFREY ROOT	6 [hp_X] in 2.2 mL
ACONITUM NAPELLUS (UNII: U0NQ8555JD) (ACONITUM NAPELLUS - UNII:U0NQ8555JD)	ACONITUM NAPELLUS	2 [hp_X] in 2.2 mL
BELLIS PERENNIS (UNII: 2HU33I03UY) (BELLIS PERENNIS - UNII:2HU33I03UY)	BELLIS PERENNIS	2 [hp_X] in 2.2 mL
MERCURIUS SOLUBILIS (UNII: 324Y4038G2) (MERCURIUS SOLUBILIS - UNII:324Y4038G2)	MERCURIUS SOLUBILIS	6 [hp_X] in 2.2 mL
HYPERICUM PERFORATUM (UNII: XK4IUX8MNB) (HYPERICUM PERFORATUM - UNII:XK4IUX8MNB)	HYPERICUM PERFORATUM	2 [hp_X] in 2.2 mL
ECHINACEA, UNSPECIFIED (UNII: 4N9P6CC1DX) (ECHINACEA, UNSPECIFIED - UNII:4N9P6CC1DX)	ECHINACEA, UNSPECIFIED	2 [hp_X] in 2.2 mL
ECHINACEA PURPUREA (UNII: QI7G114Y98) (ECHINACEA PURPUREA - UNII:QI7G114Y98)	ECHINACEA PURPUREA	2 [hp_X] in 2.2 mL
HAMAMELIS VIRGINIANA ROOT BARK/STEM BARK (UNII: T7S323PKJS) (HAMAMELIS VIRGINIANA ROOT BARK/STEM BARK - UNII:T7S323PKJS)	HAMAMELIS VIRGINIANA ROOT BARK/STEM BARK	1 [hp_X] in 2.2 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50114-7004-1	10 in 1 CARTON	05/09/2007	12/31/2024
1		2.2 mL in 1 AMPULE; Type 0: Not a Combination Product		
2	NDC:50114-7004-2	3 in 1 CARTON	05/09/2007	12/31/2024
2		2.2 mL in 1 AMPULE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		05/09/2007	12/31/2024

Labeler - Medinatura (102783016)

Establishment

Name	Address	ID/FEI	Business Operations
Biologische Heilmittel Heel		315635359	manufacture(50114-7004)

Establishment

Name	Address	ID/FEI	Business Operations
Hameln Pharma GmbH		315869123	manufacture(50114-7004)

Revised: 10/2021 Medinatura