#### 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.

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# **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 calcar	eum 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<sup>®</sup> 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<sup>®</sup> Injection Solution for the treatment of inflammatory and degenerative conditions of the musculoskeletal system.

• Traumeel <sup>®</sup> Injection Solution is a homeopathic drug product indicated, in combination with Zeel<sup>®</sup> 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**

- IThe dosage schedules listed below can be used as a general guide for the administration of Traumeel<sup>®</sup> Injection Solution.
- If co-administration with a local anesthetic is desired, Traumeel<sup>®</sup> Injection Solution may be mixed with lidocaine or similar agents at the discretion of the physician.
- Traumeel<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> Injection Solution may be mixed in a ratio of 1:1 with Zeel<sup>®</sup> Injection Solution.
- For convenience, the daily dose of Traumeel<sup>®</sup> Injection Solution may be administered at the same time as a Zeel<sup>®</sup> Injection Solution, according to the dosing recommendations for each medication.

# CONTRAINDICATIONS

• Traumeel<sup>®</sup> Injection Solution is contraindicated in patients with known hypersensitivity to Traumeel<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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**

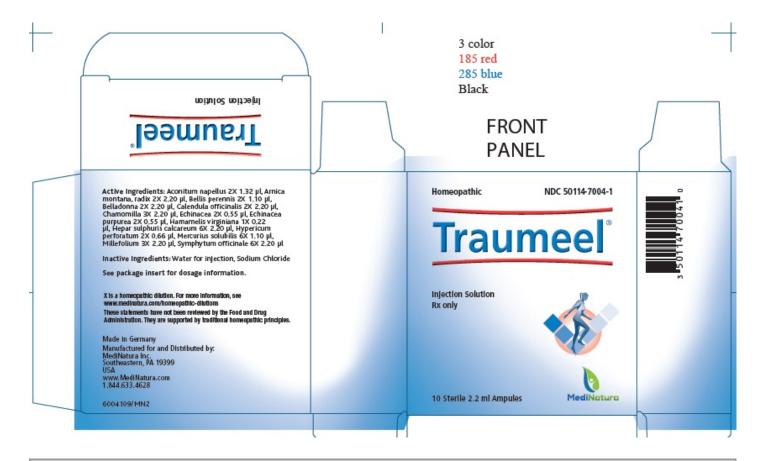
The exact mechanism of Traumeel<sup>®</sup> Injection Solution is not fully understood.

#### 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 Type       HUMAN PRESCRIPTION DRUG       (Source)       7004         Route of Administration       INTRADERMAL, INTRAVENOUS, INTRAMUSCULAR, SUBCUTANEOUS, INTRA-ARTICULAR       (Source)       7004         Active Ingredient/Active Moiety       Ingredient Name       Basis of Strength       Strength       Strength         Active Ingredient/Active Moiety       Ingredient Name       Basis of Strength       Strength       2 [hg in 2         Arnica MONTANA ROOT (UNII: MUE8 Y11327) (ARNICA MONTANA ROOT - UNIE/MUE8 Y11327)       ARNICA MONTANA ROOT - ARNICA MONTANA ROOT       2 [hg in 2         Atropa Bell Adonna (UNII: WQZ3G9PF0H) (ATROPA BELLADONNA - UNII: WQZ3G9PF0H)       Atropa Bell Adonna       2 [hg in 2         CALENDULA OFFICINALIS FLOWERING TOP (UNII: 18E7415PXQ) (CALENDULA OFFICINALIS FLOWERING TOP - UNII: 18E7415PXQ)       CALENDULA OFFICINALIS FLOWERING TOP - UNII: 18E7415PXQ)       3 [hg in 2         Matricaria Recutita (UNII: GOR4/UB12Z)       Matricaria Recutita - UNII: GOR4/UB12Z)       Achillefolium (UNII: 2FXJ6SW4PK) (ACHILLEA MILLEFOLIUM - UNII: 2FXJ6SW4PK)       Achillefolium (UNII: 3 [hg in 2         Commerey Root (UNII: 1MBW07J51Q)       CALCIUM SULFIDE - UNII: 1MBW07J51Q)       CALCIUM SULFIDE       6 [h]					
Product Type       HUMAN PRESCRIPTION DRUG       (Source)       70.04         Route of Administration       INTRADERMAL, INTRAVENOUS, INTRAMUSCULAR, SUBCUTANEOUS, INTRA-ARTICULAR       Subcutaneous, INTRA-ARTICULAR       Subcutaneous, INTRA-ARTICULAR         Active Ingredient/Active Moieturaneous, INTRA-ARTICULAR       Basis of Strength       Strength         Active Ingredient/Active Moieturaneous, INTRA-ARTICULAR       Basis of Strength       Strength         Active Ingredient/Active Moieturaneous (UNII: MUES Y11327) (ARNICA MONTANA ROOT -       ARNICA MONTANA ROOT (UNII: WQZ3G9PF0H) (ATROPA BELLADONNA -       ARNICA MONTANA ROOT       2 [hr]         ATROPA BELLADONNA (UNII: WQZ3G9PF0H) (ATROPA BELLADONNA -       ATROPA BELLADONNA       2 [hr]       1 2         CALENDULA OFFICINALIS FLOWERING TOP (UNII: 18E7415PXQ) (CALENDULA       CALENDULA OFFICINALIS FLOWERING TOP - UNII: 18E7415PXQ)       CALENDULA OFFICINALIS       2 [hr]         MATRICARIA RECUTITA (UNII: SUZZ) (MATRICARIA RECUTITA -       MATRICARIA RECUTITA (UNII: SIZZ) (MATRICARIA RECUTITA -       3 [hr]       3 [hr]         MATRICARIA RECUTITA (UNII: SIZZ) (MATRICARIA RECUTITA -       ACHILLEA MILLEFOLIUM (UNII: 2FXJ6SW4PK) (ACHILLEA MILLEFOLIUM -       3 [hr]       3 [h	<b>Product Information</b>				
Route of Administration       SUBCUTANEOUS, INTRA-ARTICULAR         SUBCUTANEOUS, INTRA-ARTICULAR       SUBCUTANEOUS, INTRA-ARTICULAR         Active Ingredient/Active Moiety       Subcuraneous, Intra-articular         Active Ingredient/Active Moiety       Basis of Strength       Strength         Arnica Montana Root (UNII: MUE8 Y11327) (ARNICA MONTANA ROOT - UNIE:MUE8 Y11327)       ARNICA MONTANA ROOT - ARNICA MONTANA ROOT (UNII: WQZ3G9PF0H) (ATROPA BELLADONNA - UNII: WQZ3G9PF0H)       Arropa Belladonna       2 [hg in 2         Calendula officinalis flowering top (UNII: 18E7415PXQ) (CALENDULA Officinalis flowering top - UNII: 18E7415PXQ) (CALENDULA Officinalis flowering top - UNII: 18E7415PXQ) (CALENDULA Officinalis flowering top - UNII: 18E7415PXQ)       Matricaria Recutifia (In 2         Matricaria Recutifia (UNII: CONTAUBIZZ) (MATRICARIA RECUTITA - UNII: GOR4UBIZZZ)       Achillefolium (UNII: 2FXJ6SW4PK) (ACHILLEA MILLEFOLIUM - UNII: SGR4UBIZZZ)       Achillefolium (UNII: 2FXJ6SW4PK) (ACHILLEA MILLEFOLIUM - UNII: 2FXJ6SW4PK)       Achillefolium - (CALCIUM SULFIDE (UNII: 1MBW07J51Q) (CALCIUM SULFIDE - UNII: 1MBW07J51Q)       CALCIUM SULFIDE         Commerey Root (UNII: MPVYZ08EKO) (COMEREY ROOt - UNII: 1MPVYZ08EKO)       COMEREY ROOt (UNII: MPVYZ08EKO) (COMEREY ROOt - UNII: 1MPVYZ08EKO)       Comerey Root (UNII: MPVYZ08EKO)       6 [h]	Product T ype	HUMAN PRESCRIPTION DRUG		nem ooue	NDC:50114- 7004
Ingredient NameBasis of StrengthStrengthARNICA MONTANA ROOT (UNII: MUE8 Y11327) (ARNICA MONTANA ROOT - UNII:MUE8 Y11327)ARNICA MONTANA ROOT - ARNICA MONTANA ROOT - ARNICA MONTANA ROOT - ATROPA BELLADONNA (UNII: WQZ3G9PF0H) (ATROPA BELLADONNA - UNII:WQZ3G9PF0H)ATROPA BELLADONNA2 [hr in 2ATROPA BELLADONNA (UNII: WQZ3G9PF0H) (ATROPA BELLADONNA - UNII:WQZ3G9PF0H)ATROPA BELLADONNA2 [hr in 2CALENDULA OFFICINALIS FLOWERING TOP (UNII: 18E7415PXQ) (CALENDULA OFFICINALIS FLOWERING TOP - UNII:18E7415PXQ)CALENDULA OFFICINALIS FLOWERING TOP - UNII: 18E7415PXQ)2 [hr in 2MATRICARIA RECUTITA (UNII: G0R4UBI2ZZ) (MATRICARIA RECUTITA - UNII:G0R4UBI2ZZ)MATRICARIA RECUTITA - MATRICARIA RECUTITA -3 [hr in 2ACHILLEA MILLEFOLIUM (UNII: 2FXJ6 SW4PK) (ACHILLEA MILLEFOLIUM - UNII:2FXJ6 SW4PK)ACHILLEA MILLEFOLIUM 3 [hr in 2CALCIUM SULFIDE (UNII: 1MBW07J51Q) (CALCIUM SULFIDE - UNII:1MBW07J51Q)CALCIUM SULFIDE6 [h] in 2COMEREY ROOT (UNII: M9YYZ08EKO) (COMEREY ROOT - UNII:M9YYZ08EKO)COMEREY ROOT6 [h] in 2	Route of Administration				
Ingredient NameBasis of StrengthStrengthARNICA MONTANA ROOT (UNII: MUE8 Y11327) (ARNICA MONTANA ROOT - UNII:MUE8 Y11327)ARNICA MONTANA ROOT - ARNICA MONTANA ROOT - ARNICA MONTANA ROOT - ATROPA BELLADONNA (UNII: WQZ3G9PF0H) (ATROPA BELLADONNA - UNII:WQZ3G9PF0H)ATROPA BELLADONNA2 [hr in 2ATROPA BELLADONNA (UNII: WQZ3G9PF0H) (ATROPA BELLADONNA - UNII:WQZ3G9PF0H)ATROPA BELLADONNA2 [hr in 2CALENDULA OFFICINALIS FLOWERING TOP (UNII: 18E7415PXQ) (CALENDULA OFFICINALIS FLOWERING TOP - UNII:18E7415PXQ)CALENDULA OFFICINALIS FLOWERING TOP - UNII:18E7415PXQ)2 [hr in 2MATRICARIA RECUTITA (UNII: G0R4UBI2ZZ) (MATRICARIA RECUTITA - UNII:G0R4UBI2ZZ)MATRICARIA RECUTITA - MATRICARIA RECUTITA -3 [hr in 2ACHILLEA MILLEFOLIUM (UNII: 2FXJ6 SW4PK) (ACHILLEA MILLEFOLIUM - UNII:2FXJ6 SW4PK)ACHILLEA MILLEFOLIUM - ACHILLEA MILLEFOLIUM3 [hr in 2CALCIUM SULFIDE (UNII: 1MBW07J51Q) (CALCIUM SULFIDE - UNII:1MBW07J51Q)CALCIUM SULFIDE6 [h] in 2COMEREY ROOT (UNII: M9YYZ08EKO) (COMEREY ROOT - UNII:M9YYZ08EKO)COMEREY ROOT6 [hr in 2					
ARNICA MONTANA ROOT (UNII: MUE8 Y11327) (ARNICA MONTANA ROOT - UNII:MUE8 Y11327)ARNICA MONTANA ROOT2 [hr in 2]ATROPA BELLADONNA (UNII: WQZ3G9PF0H) (ATROPA BELLADONNA - UNII:WQZ3G9PF0H)ATROPA BELLADONNA - 2 [hr in 2]ATROPA BELLADONNA (UNII: WQZ3G9PF0H) (ATROPA BELLADONNA - 0 [hr]ATROPA BELLADONNA (UNII: WQZ3G9PF0H) (ATROPA BELLADONNA - 2 [hr in 2]ATROPA BELLADONNA (UNII: WQZ3G9PF0H) (ATROPA BELLADONNA - 0 [hr]ATROPA BELLADONNA (UNII: WQZ3G9PF0H)2 [hr in 2]CALENDULA OFFICINALIS FLOWERING TOP (UNII: 18E7415PXQ) (CALENDULA OFFICINALIS FLOWERING TOP - UNII:18E7415PXQ)CALENDULA OFFICINALIS FLOWERING TOP2 [hr in 2]MATRICARIA RECUTITA (UNII: GOR4UBI2ZZ) (MATRICARIA RECUTITA - UNII:GOR4UBI2ZZ)MATRICARIA RECUTITA - MATRICARIA RECUTITA (UNII: 2FXJ6SW4PK) (ACHILLEA MILLEFOLIUM - UNII:2FXJ6SW4PK)ACHILLEA MILLEFOLIUM 3 [hr in 2]CALCIUM SULFIDE (UNII: 1MBW07J51Q) (CALCIUM SULFIDE - UNII:1MBW07J51Q)CALCIUM SULFIDE6 [h] in 2]COMEREY ROOT (UNII: 1MBW07J51Q) (CALCIUM SULFIDE - UNII:1MBW07J51Q)COMEREY ROOT (UNII: 00000000000000000000000000000000000	Active Ingredient/Active Mo	iety			
UNIE:MUE8 Y11327)AKNICA MONTANA ROOTin 2ATROPA BELLADO NNA (UNII: WQZ3G9PF0H) (ATROPA BELLADONNA - UNII: WQZ3G9PF0H)ATROPA BELLADONNA (UNII: WQZ3G9PF0H) (ATROPA BELLADONNA - 2 [hr in 2CALENDULA OFFICINALIS FLOWERING TOP (UNII: 18E7415PXQ) (CALENDULA OFFICINALIS FLOWERING TOP - UNII:18E7415PXQ)CALENDULA OFFICINALIS FLOWERING TOP - UNII: 18E7415PXQ)2 [hr in 2MATRICARIA RECUTITA (UNII: G0R4UBI2ZZ) (MATRICARIA RECUTITA - UNII:G0R4UBI2ZZ)MATRICARIA RECUTITA (UNII: 3 [hr in 23 [hr in 2ACHILLEA MILLEFOLIUM (UNII: 2FXJ6SW4PK) (ACHILLEA MILLEFOLIUM - UNII:2FXJ6SW4PK)ACHILLEA MILLEFOLIUM (UNII: 3 [hr in 23 [hr in 2CALCIUM SULFIDE (UNII: 1MBW07J51Q) (CALCIUM SULFIDE - UNII:1MBW07J51Q)CALCIUM SULFIDE6 [hr in 2COMEREY ROOT (UNII: M9VYZ08EKO) (COMEREY ROOT - UNII: M9VYZ08EKO)6 [hr in 2	Ing	redient Name	Basis o	of Strength	Strength
UNIE:WQZ3G9PF0H)ATROPA BELLADONNAin 2CALENDULA OFFICINALIS FLOWERING TOP (UNII: 18E7415PXQ) (CALENDULACALENDULA OFFICINALIS2 [hgOFFICINALIS FLOWERING TOP - UNII:18E7415PXQ)FLOWERING TOPin 2MATRICARIA RECUTITA (UNII: G0R4UBI2ZZ) (MATRICARIA RECUTITA - UNII:G0R4UBI2ZZ)MATRICARIA RECUTITA3 [hgACHILLEA MILLEFOLIUM (UNII: 2FXJ6SW4PK) (ACHILLEA MILLEFOLIUM - UNII:2FXJ6SW4PK)ACHILLEA MILLEFOLIUM - In 23 [hgCALCIUM SULFIDE (UNII: 1MBW07J51Q) (CALCIUM SULFIDE - UNII:1MBW07J51Q)CALCIUM SULFIDE6 [h] in 2COMEREY ROOT (UNII: M9 VVZ08EKO) (COMEREY ROOT - UNII:1M9 VVZ08EKO)COMEREY ROOT6 [h]			ARNICA MONTANA ROOT		2 [hp_X] in 2.2 mL
OFFICINALIS FLOWERING TOP - UNII:18E7415PXQ)FLOWERING TOPin 2MATRICARIA RECUTITA (UNII: G0R4UBI2ZZ) (MATRICARIA RECUTITA - UNII:G0R4UBI2ZZ)MATRICARIA RECUTITA (UNII: 3 [hr in 2ACHILLEA MILLEFOLIUM (UNII: 2FXJ6SW4PK) (ACHILLEA MILLEFOLIUM - UNII:2FXJ6SW4PK)ACHILLEA MILLEFOLIUM (UNII: 3 [hr 			ATROPA BE	LLADONNA	2 [hp_X] in 2.2 mL
UNII:G0 R4UB12ZZ)       MATRICARIA RECUTITA       in 2         ACHILLEA MILLEFOLIUM (UNII: 2FXJ6SW4PK) (ACHILLEA MILLEFOLIUM -       ACHILLEA MILLEFOLIUM (UNII: 2FXJ6SW4PK) (ACHILLEA MILLEFOLIUM -       3 [hr in 2         CALCIUM SULFIDE (UNII: 1MBW07J51Q) (CALCIUM SULFIDE - UNII:1MBW07J51Q)       CALCIUM SULFIDE (UNII: 1MBW07J51Q) (CALCIUM SULFIDE - UNII:1MBW07J51Q)       CALCIUM SULFIDE       6 [h] in 2         COMEREX ROOT (UNII: M9VVZ08EKO) (COMEREX ROOT - UNII:1M9VVZ08EKO)       COMEREX ROOT (UNII: M9VVZ08EKO)       6 [h] in 2					2 [hp_X] in 2.2 mL
UNIE:2FXJ6SW4PK)     ACHILLEA MILLEFOLIUM     in 2       CALCIUM SULFIDE (UNII: 1MBW07J51Q) (CALCIUM SULFIDE - UNII:1MBW07J51Q)     CALCIUM SULFIDE     6 [h] in 2       COMEREX ROOT (UNII: M9VVZ08EKO) (COMEREX ROOT - UNII:M9VVZ08EKO)     COMEREX ROOT     6 [h]			MATRICARIA RECUTITA		3 [hp_X] in 2.2 mL
CALCIUM SOLFIDE (UNII: IMB W07J5IQ) (CALCIUM SOLFIDE - UNII:IMB W07J5IQ)       CALCIUM SOLFIDE       in 2         in 2       in 2       in 2       in 2			ACHILLEA N	/IILLEFOLIUM	3 [hp_X] in 2.2 mL
COMEREY ROOT (IINII: MAAAAABRO) (COMEREY ROOT - IINII: MAAAABRO) COMEREY ROOT - IINII: MAAAABRO) - I COMEREY ROOT - I	CALCIUM SULFIDE (UNII: 1MBW07J5	1Q) (CALCIUM SULFIDE - UNII:1MBW07J51Q)	CALCIUM SI	ULFIDE	6 [hp_X] in 2.2 mL
in 2	<b>COMFREY ROOT</b> (UNII: M9 VVZ08EKQ) (COMFREY ROOT - UNII:M9 VVZ08EKQ)			ООТ	6 [hp_X] in 2.2 mL

ACOMPTIM MADELT HE (HMILHOMODECCID) (ACOMPTIM MADELTHE

ACONTI UM NAPELL UNII:U0NQ8555JD)	09 (UNII: UUNQ05551D) (ACONITUMINAPELLU5 -	ACONITUM N	APELLUS	<sup>2</sup> [IIP_A] in 2.2 mL
BELLIS PERENNIS (U	RENNIS (UNII: 2HU33I03UY) (BELLIS PERENNIS - UNII:2HU33I03UY) BELLIS PERE			2 [hp_X] in 2.2 mL
MERCURIUS SOLUBILIS (UNII: 324Y4038G2) (MERCURIUS SOLUBILIS - UNII: 324Y4038G2) (MERCURIUS SOLUBILIS - UNII: 324Y4038G2)			OLUBILIS	6 [hp_X] in 2.2 mL
HYPERICUM PERFORATUM (UNII: XK4IUX8MNB) (HYPERICUM PERFORATUM - UNII:XK4IUX8MNB) HYPERICUM PERFOR			ERFORATUM	2 [hp_X] in 2.2 mI
<b>ECHINACEA, UNSPE</b> UNII:4N9P6CC1DX)	CIFIED (UNII: 4N9P6CC1DX) (ECHINACEA, UNSPECIFIED	- ECHINACEA,	UNSPECIFIED	2 [hp_X] in 2.2 mL
ECHINACEA PURPUREA (UNII: QI7G114Y98) (ECHINACEA PURPUREA - UNII:QI7G114Y98) ECHINACEA PURPUREA -			URPUREA	2 [hp_X] in 2.2 mL
HAMAMELIS VIRGINIANA ROOT BARK/STEM BARK (UNII: T7S323PKJS)HAMAMELIS V(HAMAMELIS VIRGINIANA ROOT BARK/STEM BARK - UNII:T7S323PKJS)ROOT BARK/S				1 [hp_X] in 2.2 mL
Inactive Ingredi	ents			
Inactive Ingredie	ents Ingredient Name		Strer	ıgth
0	Ingredient Name		Strer	ıgth
Inactive Ingredie WATER (UNII: 059QF SODIUM CHLORIDE	<b>Ingredient Name</b> 0KO0R)		Strer	ngth
WATER (UNII: 059QF	<b>Ingredient Name</b> 0KO0R)		Strer	ıgth
WATER (UNII: 059QF SODIUM CHLORIDE	<b>Ingredient Name</b> 0KO0R)		Strer	ngth
WATER (UNII: 059QF SODIUM CHLORIDE Packaging	<b>Ingredient Name</b> 0KO0R)	Marketing Start Da		
WATER (UNII: 059QF SODIUM CHLORIDE Packaging # Item Code	Ingredient Name OKOOR) (UNII: 451W47IQ8X) Package Description	Marketing Start Da 05/09/2007		
WATER (UNII: 059QF SODIUM CHLORIDE Packaging # Item Code 1 NDC:50114-7004-1	Ingredient Name OKOOR) (UNII: 451W47IQ8X) Package Description	0		
WATER (UNII: 059QF SODIUM CHLORIDE Packaging	Ingredient Name KOOR KOOR (UNII: 451W47IQ8X)  Package Description 10 in 1 CARTON 2.2 mL in 1 AMPULE; Type 0: Not a Combination Product	0		

# **Marketing Information**

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

# 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 (50 114-70 0 4)

Revised: 3/2019