ZEEL- arnica montana root, toxicodendron pubescens leaf, solanum dulcamara top, comfrey root, sulfur, sanguinaria canadensis root, sus scrofa cartilage, sus scrofa embryo, sus scrofa umbilical cord, sus scrofa placenta, .alpha.-lipoic acid, coenzyme a, nadide and sodium diethyl oxalacetate 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.

Zeel 2.0 ml Injection

DESCRIPTION

Ingredient name	Potency	Quantity	Final dilution
a-Lipoicum acidum	8X	2.0 µl	10.99X
Arnica montana, radix	4X	200.0 µl	5.00X
Cartilago suis	6X	2.0 µl	9.00X
Coenzyme A	8X	2.0 µl	10.99X
Dulcamara	3X	10.0 µl	5.30X
Embryo totalis suis	6X	2.0 µl	9.00X
Funiculus umbilicalis suis	6X	2.0 µl	9.00X
Nadidum	8X	2.0 µl	10.99X
Natrum oxalaceticum	8X	2.0 µl	10.99X
Placenta suis	6X	2.0 µl	9.00X
Rhus toxicodendron	2X	10.0 µl	4.30X
Sanguinaria canadensis	4X	3.0 µl	6.82X
Sulphur	6X	3.6 µl	8.74X
Symphytum officinale	6X	10.0 µl	8.30

INDICATIONS AND USAGE

Treatment of arthrosis/osteoarthritis, and/or rheumatic joint diseases

- Zeel® Injection Solution is a homeopathic drug product indicated for the treatment of arthrosis/osteoarthritis, and/or rheumatic joint diseases and for the relief of symptoms such as pain and joint stiffness.

Co-administration Therapy with Traumeel® Injection Solution for the treatment of inflammatory and degenerative conditions of the musculoskeletal system.

- Zeel® Injection Solution is a homeopathic drug product indicated, in combination with Traumeel® 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 Zeel® Injection Solution.
- If co-administration with a local anesthetic is desired, Zeel® Injection Solution may be mixed with lidocaine or similar agents at the discretion of the physician.
- Zeel® 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 ampulein 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 arthrosis/osteoarthritis and/or rheumatic joint diseases and for the relief of symptoms such as pain and joint stiffness.

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

Acute Dosage - for the treatment of arthrosis/osteoarthritis and/or rheumatic joint diseases and for the relief of symptoms such as pain and joint stiffness.

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

Co-administration therapy with Traumeel® 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, Zeel® Injection Solution may be mixed in a ratio of 1:1 with Traumeel® Injection Solution.
- For convenience, the daily dose of Zeel® Injection Solution may be administered at the same time as a Traumeel® Injection Solution, according to the dosing recommendations for each medication.

CONTRAINDICATIONS

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

WARNINGS AND PRECAUTIONS

None

ADVERSERE REACTIONS

Post-marketing Experience

• The following adverse events have been identified during post-marketing use of Zeel® 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 Zeel® Injection Solution: Allergic (hypersensitivity) skin reactions may occur in isolated cases.

•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.

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 Zeel® Injection Solution is not fully understood.

Pharmacodynamics

Not applicable for homeopathic medicinal products.

DOSAGE

One ampule containing 2.0 ml each containing the active ingredients in the strengths listed under Description.

ZEEL

arnica montana root, toxicodendron pubescens leaf, solanum dulcamara top, comfrey root, sulfur, sanguinaria canadensis root, sus scrofa cartilage, sus scrofa embryo, sus scrofa umbilical cord, sus scrofa placenta, .alpha.-lipoic acid, coenzyme a, nadide and sodium diethyl oxalacetate injection

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:50114-7030
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	4 [hp_X] in 2.0 mL
TOXICODENDRON PUBESCENS LEAF (UNII: 6IO182RP7A) (TOXICODENDRON PUBESCENS LEAF - UNII:6IO182RP7A)	TOXICODENDRON PUBESCENS LEAF	2 [hp_X] in 2.0 mL
SOLANUM DULCAMARA TOP (UNII: KPS1B1162N) (SOLANUM DULCAMARA TOP - UNII:KPS1B1162N)	SOLANUM DULCAMARA TOP	3 [hp_X] in 2.0 mL
COMFREY ROOT (UNII: M9VVZ08EKO) (COMFREY ROOT - UNII:M9VVZ08EKO)	COMFREY ROOT	6 [hp_X]

COMFREY ROOT (UNII: M9VV208ERQ) (COMFREY ROOT - UNII:M9VV208ERQ)	COMFREY ROOT	in 2.0 mL
SULFUR (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)	SULFUR	6 [hp_X] in 2.0 mL
SANGUINARIA CANADENSIS ROOT (UNII: N9288CD508) (SANGUINARIA CANADENSIS ROOT - UNII:N9288CD508)	SANGUINARIA CANADENSIS ROOT	4 [hp_X] in 2.0 mL
SUS SCROFA CARTILAGE (UNII: 73ECW5WG2F) (SUS SCROFA CARTILAGE - UNII:73ECW5WG2F)	SUS SCROFA CARTILAGE	6 [hp_X] in 2.0 mL
SUS SCROFA EMBRYO (UNII: 9928MC12VO) (SUS SCROFA EMBRYO - UNII:9928MC12VO)	SUS SCROFA EMBRYO	6 [hp_X] in 2.0 mL
SUS SCROFA UMBILICAL CORD (UNII: 118OYG6W3H) (SUS SCROFA UMBILICAL CORD - UNII:118OYG6W3H)	SUS SCROFA UMBILICAL CORD	6 [hp_X] in 2.0 mL
SUS SCROFA PLACENTA (UNII: C8CV8867O8) (SUS SCROFA PLACENTA - UNII:C8CV8867O8)	SUS SCROFA PLACENTA	6 [hp_X] in 2.0 mL
.ALPHA.-LIPOIC ACID (UNII: 73Y7P0K73Y) (.ALPHA.-LIPOIC ACID - UNII:73Y7P0K73Y)	.ALPHA.-LIPOIC ACID	8 [hp_X] in 2.0 mL
COENZYME A (UNII: SAA04E81UX) (COENZYME A - UNII:SAA04E81UX)	COENZYME A	8 [hp_X] in 2.0 mL
NADIDE (UNII: 0U46U6E8UK) (NADIDE - UNII:0U46U6E8UK)	NADIDE	8 [hp_X] in 2.0 mL
SODIUM DIETHYL OXALACETATE (UNII: 6CA025Y4FG) (DIETHYL OXALACETATE - UNII:15S56468G7)	SODIUM DIETHYL OXALACETATE	8 [hp_X] in 2.0 mL

Inactive Ingredients

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50114-7030-1	10 in 1 CARTON	07/31/2014	
1		2.0 mL in 1 AMPULE; Type 0: Not a Combination Product		
2	NDC:50114-7030-2	3 in 1 CARTON	07/31/2014	
2		2.0 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		07/31/2014	

Labeler - MediNatura (102783016)

Establishment

Name	Address	ID/FEI	Business Operations
Hameln Pharma GmbH		315869123	manufacture(50114-7030)

Establishment

Name	Address	ID/FEI	Business Operations
Biologische Heilmittel Heel		315635359	manufacture(50114-7030)