

NEURALGO RHEUM- pseudognaphalium obtusifolium, causticum, colchicum autumnale bulb, citrullus colocynthis fruit pulp, iron, lithium benzoate, toxicodendron pubescens leaf and filipendula ulmaria root injection
MediNatura Inc

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.

Neuralgo-Rheum 1.1ml Injection

DESCRIPTION

Each 1.1 ml solution for injection ampule contains:

Active Ingredients:

Ingredient name	Potency	Quantity	Final dilution
Causticum	10X	1.1 µl	12.99
Causticum	30X	1.1 µl	32.99
Causticum	200X	1.1 µl	203.00
Colchicum autumnale	10X	1.1 µl	12.99
Colchicum autumnale	30X	1.1 µl	32.99
Colchicum autumnale	200X	1.1 µl	203.00
Colocynthis	10X	1.1 µl	12.99
Colocynthis	30X	1.1 µl	32.99
Ferrum metallicum	10X	1.1 µl	12.99
Ferrum metallicum	30X	1.1 µl	32.99
Gnaphalium polycephalum	6X	3.3 µl	8.52
Gnaphalium polycephalum	10X	3.3 µl	12.52
Gnaphalium polycephalum	30X	3.3 µl	32.52
Lithium benzoicum	10X	1.1 µl	12.99
Lithium benzoicum	30X	1.1 µl	32.99
Rhus toxicodendron	10X	1.1 µl	12.99
Rhus toxicodendron	30X	1.1 µl	32.99
Spiraea ulmaria	10X	1.1 µl	12.99
Spiraea ulmaria	30X	1.1 µl	32.99

List of Excipients:

Water for injection 1,072.5 µl

Sodium Chloride 10.3 µl

INDICATIONS AND USAGE

Neuralgo-Rheum® Injection Solution is a homeopathic drug product indicated for the treatment of nerve pain, soft tissue rheumatism and symptoms of disc protrusion.

DOSAGE AND ADMINISTRATION

General Considerations

The dosage schedules listed below can be used as a general guide for the administration of Neuralgo-Rheum Injection Solution.

- Neuralgo-Rheum Injection Solution may be administered s.c., i.d., i.m., or i.v..
- If co-administration with a local anesthetic is desired, Neuralgo-Rheum Injection Solution may be mixed with lidocaine or similar agents at the discretion of the physician.
- 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 required dose into syringe.
- Discard any unused ampule contents. Do not reuse ampule.
- Only licensed practitioners with sufficient expertise in injecting drugs, including the respective route of administration, should administer the product.

Standard Dosage:

Adults and children 12 years and older: 1 ml 1 to 3 times per 7 days.

Children 6 to 11 years: 0.7 ml 1 to 3 times per 7 days.

Children 2 to 5 years: 0.5 ml 1 to 3 times per 7 days.

Acute Dosage:

Adults and children 12 years and older: 1 ml daily, and then continue with standard dosage.

Children 6 to 11 years: 0.7 ml daily, and then continue with standard dosage.

Children 2 to 5 years: 0.5 ml daily, and then continue with standard dosage.

CONTRAINDICATIONS

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

WARNINGS AND PRECAUTIONS

None

ADVERSE REACTIONS

Post-marketing Experience

No adverse events have been reported with a causal relationship to Neuralgo-Rheum Injection Solution.

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 Neuralgo-Rheum Injection Solution is not fully understood.

Pharmacodynamics

Not applicable for homeopathic medicinal products.

DOSAGE

1 ampule containing 1.1 ml solution for injection each containing the active ingredients in the strengths listed under Description.



NEURALGO RHEUM

pseudognaphalium obtusifolium, causticum, colchicum autumnale bulb, citrullus colocynthis fruit pulp, iron, lithium benzoate, toxicodendron pubescens leaf and filipendula ulmaria root injection

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code	NDC:50114-
--------------	-------------------------	-----------	------------

Product Type	HUMAN PRESCRIPTION DRUG	(Source)	7070	
Route of Administration	INTRADERMAL, INTRAMUSCULAR, INTRAVENOUS, SUBCUTANEOUS			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
PSEUDOGNAPHALIUM OBTUSIFOLIUM (UNII: 36XQ854NWW) (PSEUDOGNAPHALIUM OBTUSIFOLIUM - UNII:36XQ854NWW)		PSEUDOGNAPHALIUM OBTUSIFOLIUM	6 [hp_X] in 1.1 mL	
CAUSTICUM (UNII: DD5FO1WKFU) (CAUSTICUM - UNII:DD5FO1WKFU)		CAUSTICUM	10 [hp_X] in 1.1 mL	
COLCHICUM AUTUMNALE BULB (UNII: 993QHL78E6) (COLCHICUM AUTUMNALE BULB - UNII:993QHL78E6)		COLCHICUM AUTUMNALE BULB	10 [hp_X] in 1.1 mL	
CITRULLUS COLOCYNTHIS FRUIT PULP (UNII: 23H32AOH17) (CITRULLUS COLOCYNTHIS FRUIT PULP - UNII:23H32AOH17)		CITRULLUS COLOCYNTHIS FRUIT PULP	10 [hp_X] in 1.1 mL	
IRON (UNII: E1UOL152H7) (IRON - UNII:E1UOL152H7)		IRON	10 [hp_X] in 1.1 mL	
LITHIUM BENZOATE (UNII: R9Z042Z19E) (LITHIUM CATION - UNII:8H8Z5UER66)		LITHIUM BENZOATE	10 [hp_X] in 1.1 mL	
TOXICODENDRON PUBESCENS LEAF (UNII: 6IO182RP7A) (TOXICODENDRON PUBESCENS LEAF - UNII:6IO182RP7A)		TOXICODENDRON PUBESCENS LEAF	10 [hp_X] in 1.1 mL	
FILIPENDULA ULMARIA ROOT (UNII: 997724QNDS) (FILIPENDULA ULMARIA ROOT - UNII:997724QNDS)		FILIPENDULA ULMARIA ROOT	10 [hp_X] in 1.1 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:50 114-7070-1	10 in 1 CARTON	07/08/2014	
1		1.1 mL in 1 AMPULE; Type 0: Not a Combination Product		
2	NDC:50 114-7070-2	3 in 1 CARTON	07/08/2014	
2		1.1 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		07/08/2014		

Labeler - MediNatura Inc (102783016)

Establishment

Name	Address	ID/FEI	Business Operations
Biologische Heilmittel Heel		315635359	manufacture(50114-7070)

Establishment

Name	Address	ID/FEI	Business Operations
Siegfried Hameln GmbH		3158 69 123	manufacture(50 114-70 70)

Revised: 4/2019

MediNatura Inc