

Water for injection 1,072.5 µl  
Sodium chloride 10.3 µl

- 11.2 Pharmaceutical Form**  
• Sterile Injection solution
- 11.3 Route of Administration**  
• Parenteral: s.c., i.d., i.m. or i.v
- 12 Clinical Pharmacology**  
**12.1 Mechanism of Action**  
The exact mechanism of Neuralgo-Rheum Injection Solution is not fully understood.  
**12.2 Pharmacodynamics**  
Not applicable for homeopathic medicinal products.
- 15 References**  
• Homeopathic Pharmacopeia of the United States Revision
- 16 How Supplied / Storage and Handling**  
**16.1 Dosage forms and package sizes**  
• 1 ampule of 1.1 ml solution for injection in packs of 10 ampules  
• NDC 50114-7070-1  
**16.2 Storage and Handling**  
• Store at room temperature. Protect from light.  
• Keep out of reach of children.

## HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use Neuralgo-Rheum Injection Solution safely and effectively. See full prescribing information for Neuralgo-Rheum Injection Solution.

### Neuralgo-Rheum Injection Solution, Parenteral Use Rx Only

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

Neuralgo-Rheum Injection Solution is a homeopathic drug indicated for the treatment of nerve pain, soft tissue rheumatism and symptoms of disc protrusion. (1)

#### -----DOSAGE AND ADMINISTRATION-----

- 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 (2.2)
- 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. (2.3)

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

- 1 ampule containing 1.1 ml solution for injection each containing the active ingredients in the strengths listed under Description. (3)

#### -----CONTRAINDICATIONS-----

- Neuralgo-Rheum Injection Solution is contraindicated in patients with known hypersensitivity to Neuralgo-Rheum or any of its ingredients. (4)

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

- None (5)

#### -----ADVERSE REACTIONS-----

- No adverse events have been reported with a causal relationship to Neuralgo-Rheum Injection solution. (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 Neuralgo-Rheum Injection Solution on pregnant or lactating women, children, or elderly. (8)

Revised 12/2014

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

### 2 Dosage and Administration

#### 2.1 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.

#### 2.2 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.

#### 2.3 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.

#### 2.4



- Cutting open the glass ampule is not necessary. Hold the ampule head up at an angle, and tap/shake down the solution contained in the ampule head. Then break off the ampule head by applying pressure away from the color dot. Discard unused solution.

### 3 Dosage Forms and Strength

1 ampule containing 1.1 ml solution for injection each containing the active ingredients in the strengths listed under Description. (11)

### 4 Contraindications

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

### 5 Warnings and Precautions

None

### 6 Adverse Reactions

#### 6.1 Post-marketing Experience

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

### 7 Drug Interactions

No interactions have been reported, and none are expected due to the homeopathic dilutions.

### 8 Use in Specific Populations

#### 8.1 Pregnancy

##### 8.1.1 Teratogenic effects

Pregnancy Category C. Some ingredients in Neuralgo-Rheum Injection Solution 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. Neuralgo-Rheum Injection Solution 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 Neuralgo-Rheum Injection Solution 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 Neuralgo-Rheum Injection Solution 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 Neuralgo-Rheum Injection Solution has not identified differences in responses between adults and geriatric patients.

### 10 Overdosage

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

### 11 Description

#### 11.1 Ingredients

- Each 1.1 ml ampule contains:

##### List of Excipients:

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
Colocyntsis	10X	1.1 µl	12.99
Colocyntsis	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