

**LYMPHOMYOSOT X- araneus diadematus, tribasic calcium phosphate, equisetum hyemale, ferrous iodide, fumaria officinalis flowering top, gentiana lutea root, geranium robertianum, myosotis arvensis, nasturtium officinale, sodium sulfate, pinus sylvestris leafy twig, smilax regelii root, scrophularia nodosa, teucrium scorodonia flowering top, thyroid, unspecified and veronica officinalis flowering top 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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## **Lymphomyosot X 1.1ml Injection**

### **DESCRIPTION**

<b>Ingredient name</b>	<b>Potency</b>	<b>Quantity</b>	<b>Final dilution</b>
Aranea diadema	6X	0.55 µl	9.30X
Calcarea phosphorica	12X	0.55 µl	15.30X
Equisetum hyemale	4X	0.55 µl	7.30X
Ferrum iodatum	12X	1.1 µl	15.00X
Fumaria officinalis	4X	0.55 µl	7.30X
Gentiana lutea	5X	0.55 µl	8.30X
Geranium robertianum	4X	1.1 µl	7.00X
Myosotis arvensis	3X	0.55 µl	6.30X
Nasturtium aquaticum	4X	1.1 µl	7.00X
Natrum sulphuricum	4X	0.55 µl	7.30X
Pinus sylvestris	4X	0.55 µl	7.30X
Sarsaparilla	6X	0.55 µl	9.30X
Scrophularia nodosa	3X	0.55 µl	6.30X
Teucrium scorodonia	3X	0.55 µl	6.30X
Thyroidinum	12X	0.55 µl	15.30X
Veronica officinalis	3X	0.55 µl	6.30X

### **INDICATION AND USAGE**

Lymphomyosot x<sup>®</sup> Injection Solution is a homeopathic drug product indicated for the improvement of lymphatic drainage, the non-specific immune defense, and conditions such as benign hypertrophy of lymphnodes, chronic tonsillitis, tonsillar hypertrophy and lymphatic edema.

### **DOSAGE AND ADMINISTRATION**

#### **General Consideration**

- If co-administration with a local anesthetic is desired, Lymphomyosot<sup>®</sup> X Injection Solution may be mixed with lidocaine or similar agents at the discretion of the physician.
- The dosage schedules listed below can be used as a general guide for the administration of Lymphomyosot<sup>®</sup> X Injection Solution.
- Lymphomyosot<sup>®</sup> X Injection Solution may be administered s.c., i.d., i.m., 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 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.

## **WARNINGS AND PRECAUTIONS**

Keep out of reach of children.

## **CONTRAINDICATIONS**

Lymphomyosot<sup>®</sup> X Injection Solution is contraindicated in patients with known hypersensitivity to Lymphomyosot<sup>®</sup> X or any of its ingredients.

## **OVERDOSAGE**

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

## **ADVERSE REACTIONS**

### **Post-marketing Experience**

The following adverse events have been identified during post-marketing use of Lymphomyosot<sup>®</sup> X 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

- 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.

## DOSAGE FORMS AND STRENGTH

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

## MECHANISM OF ACTION

The exact mechanism of Lymphomyosot® X injection Solution is not fully understood.



## LYMPHOMYOSOT X

araneus diadematus, tribasic calcium phosphate, equisetum hyemale, ferrous iodide, fumaria officinalis flowering top, gentiana lutea root, geranium robertianum, myosotis arvensis, nasturtium officinale, sodium sulfate, pinus sylvestris leafy twig, smilax regelii root, scrophularia nodosa, teucrium scorodonia flowering top, thyroid, unspecified and veronica officinalis flowering top injection

**Product Information**

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:50 114-8200
<b>Route of Administration</b>	INTRADERMAL, INTRAMUSCULAR, INTRAVENOUS, SUBCUTANEOUS		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>ARANEUS DIADEMATUS</b> (UNII: 6T6CO7R3Z5) (ARANEUS DIADEMATUS - UNII:6T6CO7R3Z5)	ARANEUS DIADEMATUS	6 [hp_X] in 1.1 mL
<b>TRIBASIC CALCIUM PHOSPHATE</b> (UNII: 91D9GV0Z28) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CATION	12 [hp_X] in 1.1 mL
<b>EQUISETUM HYEMALE</b> (UNII: 59677RXH25) (EQUISETUM HYEMALE - UNII:59677RXH25)	EQUISETUM HYEMALE	12 [hp_X] in 1.1 mL
<b>FERROUS IODIDE</b> (UNII: F5452U54PN) (FERROUS IODIDE - UNII:F5452U54PN)	FERROUS IODIDE	3 [hp_X] in 1.1 mL
<b>FUMARIA OFFICINALIS FLOWERING TOP</b> (UNII: VH659J61ZL) (FUMARIA OFFICINALIS FLOWERING TOP - UNII:VH659J61ZL)	FUMARIA OFFICINALIS FLOWERING TOP	4 [hp_X] in 1.1 mL
<b>GENTIANA LUTEA ROOT</b> (UNII: S72O3284MS) (GENTIANA LUTEA ROOT - UNII:S72O3284MS)	GENTIANA LUTEA ROOT	5 [hp_X] in 1.1 mL
<b>GERANIUM ROBERTIANUM</b> (UNII: R511HK0UBL) (GERANIUM ROBERTIANUM - UNII:R511HK0UBL)	GERANIUM ROBERTIANUM	4 [hp_X] in 1.1 mL
<b>MYOSOTIS ARVENSIS</b> (UNII: C73BK97H5J) (MYOSOTIS ARVENSIS - UNII:C73BK97H5J)	MYOSOTIS ARVENSIS	3 [hp_X] in 1.1 mL
<b>NASTURTIUM OFFICINALE</b> (UNII: YH89GMV676) (NASTURTIUM OFFICINALE - UNII:YH89GMV676)	NASTURTIUM OFFICINALE	4 [hp_X] in 1.1 mL
<b>SODIUM SULFATE</b> (UNII: 0YPR65R21J) (SODIUM SULFATE ANHYDROUS - UNII:36KCS0R750)	SODIUM SULFATE	4 [hp_X] in 1.1 mL
<b>PINUS SYLVESTRIS LEAFY TWIG</b> (UNII: Q1RGP4UB73) (PINUS SYLVESTRIS LEAFY TWIG - UNII:Q1RGP4UB73)	PINUS SYLVESTRIS LEAFY TWIG	4 [hp_X] in 1.1 mL
<b>SMLAX ORNATA ROOT</b> (UNII: 2H1576D5WG) (SMLAX ORNATA ROOT - UNII:2H1576D5WG)	SMLAX ORNATA ROOT	6 [hp_X] in 1.1 mL
<b>SCROPHULARIA NODOSA</b> (UNII: 7H443NUB2T) (SCROPHULARIA NODOSA - UNII:7H443NUB2T)	SCROPHULARIA NODOSA	3 [hp_X] in 1.1 mL
<b>TEUCRIUM SCORODONIA FLOWERING TOP</b> (UNII: LOK3I16O7G) (TEUCRIUM SCORODONIA FLOWERING TOP - UNII:LOK3I16O7G)	TEUCRIUM SCORODONIA FLOWERING TOP	3 [hp_X] in 1.1 mL
<b>THYROID, UNSPECIFIED</b> (UNII: 0B4FDL9I6P) (THYROID, UNSPECIFIED - UNII:0B4FDL9I6P)	THYROID, UNSPECIFIED	12 [hp_X] in 1.1 mL
<b>VERONICA OFFICINALIS FLOWERING TOP</b> (UNII: 9IH82J936J) (VERONICA OFFICINALIS FLOWERING TOP - UNII:9IH82J936J)	VERONICA OFFICINALIS FLOWERING TOP	3 [hp_X] in 1.1 mL

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
<b>WATER</b> (UNII: 059QF0KO0R)	

**Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:50 114-8200-3	3 in 1 CARTON	07/31/2014	
1		1.1 mL in 1 AMPULE; Type 0: Not a Combination Product		

2	NDC:50 114-8200-1	10 in 1 CARTON	07/31/2014	
2		1.1 mL in 1 AMPULE; Type 0: Not a Combination Product		
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>		<b>Marketing Start Date</b>	<b>Marketing End Date</b>
unapproved homeopathic			07/31/2014	

**Labeler** - MediNatura (102783016)

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Hameln Pharma GmbH		315869123	manufacture(50 114-8200)

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Biologische Heilmittel Heel		315635359	manufacture(50 114-8200)

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