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 Lymphomyosot® X Injection Solution is not fully understood.

12.2 Pharmacodynamics
Not applicable for homeopathic medicinal products.

15 References
• Homeopathic Pharmacopeia of the United States Revision Service

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 50114-8200-1

16.2 Storage and handling
• Store at room temperature. Protect from light.
• Keep out of reach of children.

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HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use Lymphomyosot® X Injection Solution safely and effectively. See full prescribing information for Lymphomyosot® X.

Lymphomyosot® X Injection Solution, Parenteral Use Rx Only

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

Lymphomyosot® X Injection Solution is a homeopathic drug indicated for improvement of lymphatic drainage, the non-specific immune defense, and conditions such as benign hypertrophy of lymph nodes, chronic tonsillitis, tonsillar hypertrophy and lymphatic edema. (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-----

• Lymphomyosot® X Injection Solution is contra-indicated in patients with known hypersensitivity to Lymphomyosot® X or any of its ingredients. (4)

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

• None (5)

-----ADVERSE REACTIONS------

• Allergic (hypersensitivity) skin reactions may occur in isolated cases. (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 Lymphomyosot® X Injection Solution on pregnant or lactating women, children, or elderly. (8)

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FULL PRESCRIBING INFORMATION: CONTENTS*

* *Sections or subsections omitted from the full prescribing information are not listed.*

FULL PRESCRIBING INFORMATION

1 Indications and Usage

1.1 Lymphomyosot® X 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 lymph nodes, chronic tonsillitis, tonsillar hypertrophy and lymphatic edema.

2 Dosage and Administration

2.1 General Considerations

- If co-administration with a local anesthetic is desired, Lymphomyosot® 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® X Injection Solution.
- Lymphomyosot® 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.

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

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

4 Contraindications

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

5 Warnings and Precautions

None

6 Adverse Reactions

6.1 Post-marketing Experience

- The following adverse events have been identified during post-marketing use of Lymphomyosot® 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.

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 Lymphomyosot® X 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. Lymphomyosot® X 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 Lymphomyosot® X 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 Lymphomyosot® X 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 Lymphomyosot® X 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:

Active Ingredients:			
Ingredient name	Potency	Quantity	Final dilution
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

Inactive Ingredients:

Water for injections	1,089.0 µl
Sodium chloride	10.3 µl