ENGYSTOL- cynanchum vincetoxicum root and sulfur 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.

Engystol 1.1ml Injection

DESCRIPTION

Ingredient name	Potency	Quantity	Final dilution
Asclepias vincetoxicum	6X	6.6 µl	8.22X
Asclepias vincetoxicum	10X	6.6 µl	12.22X
Asclepias vincetoxicum	30X	6.6 µl	32.22X
Sulphur	4X	3.3 µl	6.52X
Sulphur	10X	3.3 µl	12.52X

INDICATIONS AND USAGE

Engystol® Injection Solution is a homeopathic drug product indicated for the support of the immune system to reduce severity and duration of symptoms in viral infections, particularly in the early stages of colds and influenza-like illnesses.

DOSAGE AND ADMINISTRATION

General Considerations

• The dosage schedules listed below can be used as a general guide for the administration of Engystol® Injection Solution.

• Engystol® 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. Discard any unused ampule contents.

• 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

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

WARNINGS AND PRECAUTIONS

None

ADVERSE REACTIONS

Post-marketing Experience

• The following adverse events have been identified during post-marketing use of Engystol® 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

OVERDOSAGE

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

CLINICAL PHARMACOLOGY

Mechanism of Action

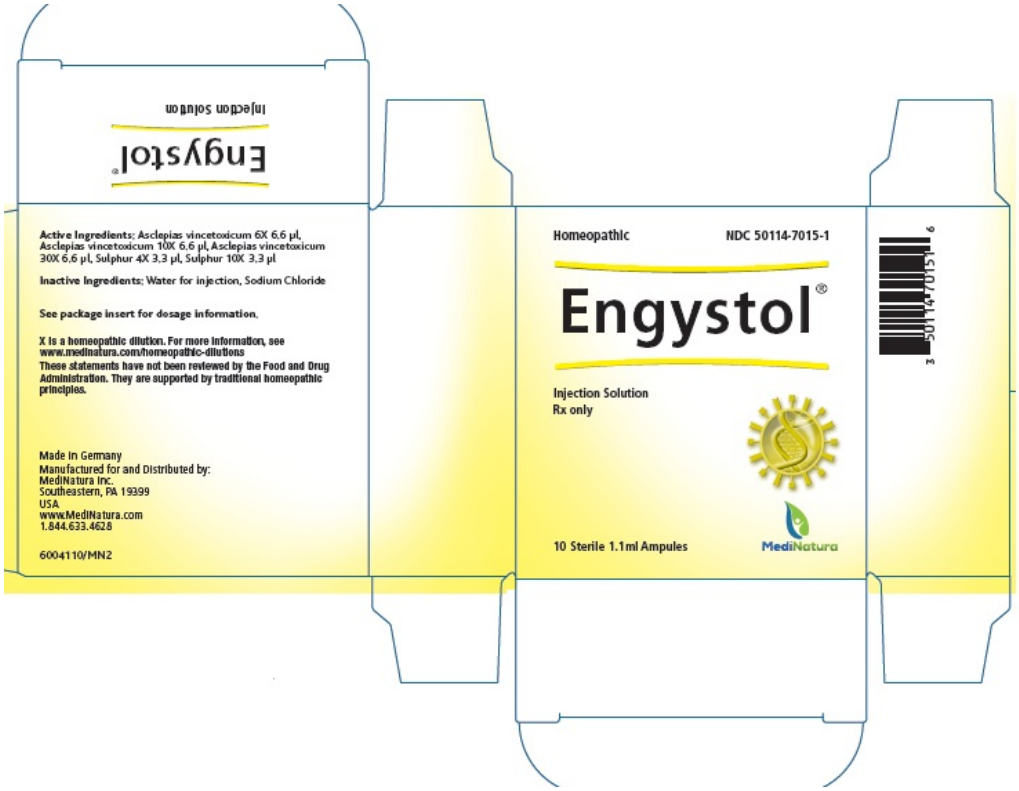
The exact mechanism of Engystol® Injection Solution is not fully understood.

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.



ENGYSTOL

cynanchum vincetoxicum root and sulfur injection

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:50114-7015
Route of Administration	INTRADERMAL, INTRAMUSCULAR, INTRAVENOUS, SUBCUTANEOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CYNANCHUM VINCETOXICUM ROOT (UNII: 9R858U917W) (CYNANCHUM VINCETOXICUM ROOT - UNII:9R858U917W)	CYNANCHUM VINCETOXICUM ROOT	6 [hp_X] in 1.1 mL
SULFUR (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)	SULFUR	4 [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:50114-7015-1	10 in 1 CARTON	05/31/2014	

1		1.1 mL in 1 AMPULE; Type 0: Not a Combination Product		
2	NDC:50114-7015-2	3 in 1 CARTON	05/31/2014	
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		05/31/2014	

Labeler - MediNatura (102783016)

Establishment

Name	Address	ID/FEI	Business Operations
Hameln Pharma GmbH		315869123	manufacture(50114-7015)

Establishment

Name	Address	ID/FEI	Business Operations
Biologische Heilmittel Heel		315635359	manufacture(50114-7015)

Revised: 3/2019 MediNatura