SPASCUPREEL- aconitum napellus, ammonium bromide, citrullus colocynthis fruit pulp, atropine sulfate, gelsemium sempervirens root, magnesium phosphate, dibasic trihydrate, veratrum album root, passiflora incarnata flowering top, matricaria recutita, amanita muscaria fruiting body and cupric sulfate 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.

Spascupreel 1.1ml Injection

DESCRIPTION

Each 1.1 ml solution for injection ampule contains:

Active Ingredients:

Ingredient name	Potency	Quantity	Final dilution
Aconitum napellus	6X	2.20 µl	8.69X
Agaricus muscarius	4X	0.55 µl	7.30X
Ammonium bromatum	4X	1.10 µl	7.00X
Atropinum sulphuricum	6X	1.10 µl	8.99X
Chamomilla	3X	0.55 µl	6.30X
Colocynthis	4X	1.10 µl	7.00X
Cuprum sulphuricum	6X	0.55 µl	9.30X
Gelsemium sempervirens	6x	1.10 µl	8.99X
Magnesia phosphorica	6X	1.10 µl	8.99X
Passiflora incarnata	2X	0.55 µl	5.30X
Veratrum album	6X	1.10 µl	8.99X

Inactive Ingredients:

Water for injection 1,089.0 µl

Sodium Chloride 10.4 µl

INDICATION AND USAGE

Spascupreel® Injection Solution is a homeopathic drug product indicated for the relief of spasms of the smooth musculature of the gastrointestinal and the urogenital tract as well as general muscle spasms.

DOSAGE AND ADMINISTRATION

General Considerations

- The dosage schedules listed below can be used as a general guide for the administration of Spascupreel® Injection Solution.
- Spascupreel® Injection Solution may be administered s.c., i.d., i.m., or i.v.
- If co-administration with a local anesthetic is desired, Spascupreel® 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. 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

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

WARNINGS AND PRECAUTIONS

Keep out of reach of children.

ADVERSE REACTIONS

Post-marketing Experience
- No adverse events have been reported with a causal relationship to Spascupreel® injection solution.
- To report SUSPECTED ADVERSE REACTIONS, contact MediNatura. at 1.844.633.4628 or info@medinatura.com or FDA at1-800-FDA-1088 or www.fda.gov/medwatch.

CLINICAL PHARMACOLOGY

Mechanism of Action

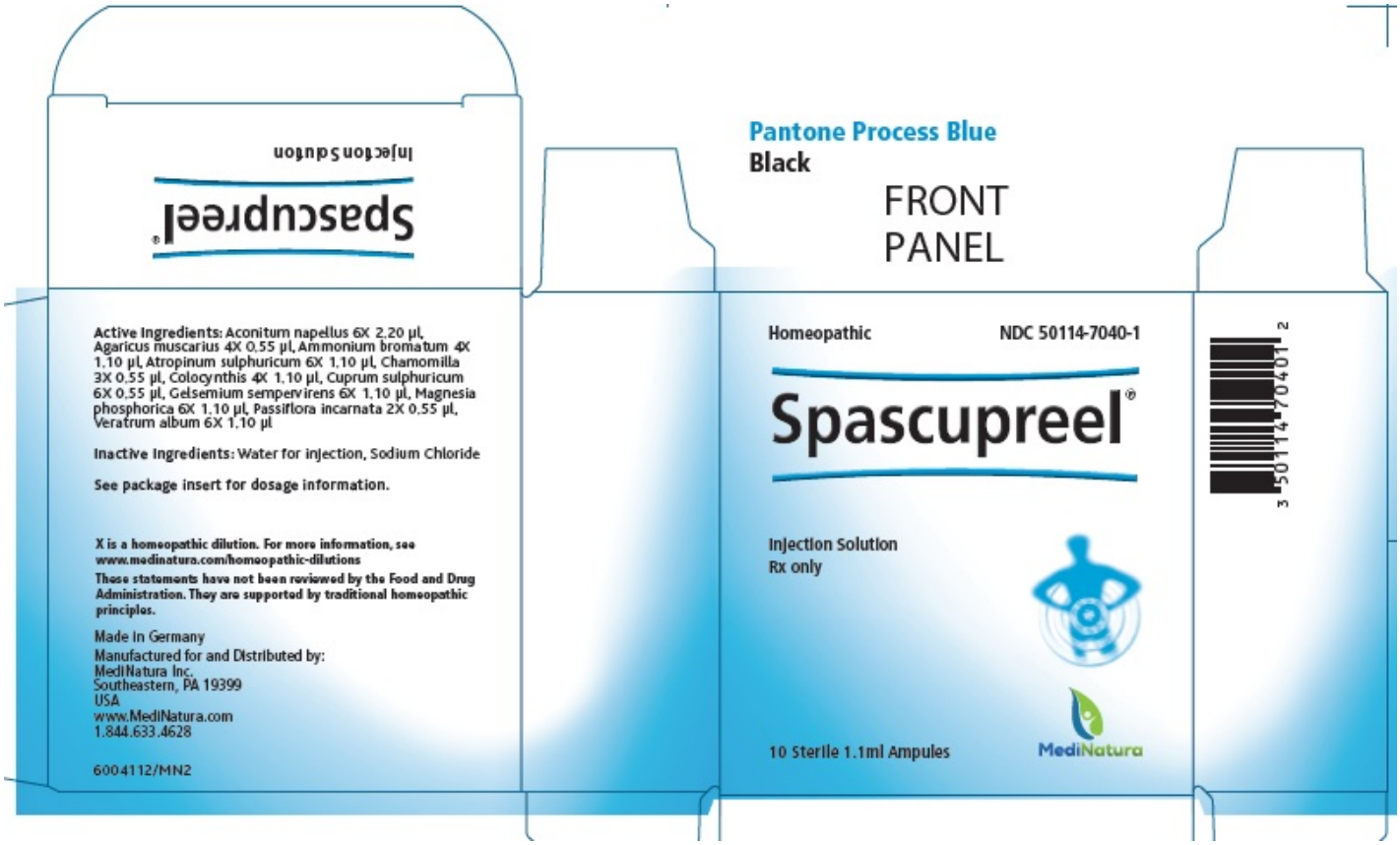
The exact mechanism of Spascupreel® Injection Solution is not fully understood.

Pharmacodynamics

Not applicable for homeopathic medicinal products.

DOSAGE

1 ampule containing 1.1 ml solution for injection.



SPASCUPREEL

aconitum napellus, ammonium bromide, citrullus colocynthis fruit pulp, atropine sulfate, gelsemium sempervirens root, magnesium phosphate, dibasic trihydrate, veratrum album root, passiflora incarnata flowering top, matricaria recutita, amanita muscaria fruiting body and cupric sulfate injection

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:50114-7040
Route of Administration	INTRADERMAL, INTRAVENOUS, INTRAMUSCULAR, SUBCUTANEOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ACONITUM NAPELLUS (UNII: U0NQ8555JD) (ACONITUM NAPELLUS - UNII:U0NQ8555JD)	ACONITUM NAPELLUS	6 [hp_X] in 1.1 mL
AMMONIUM BROMIDE (UNII: R0JB3224WS) (BROMIDE ION - UNII:952902IX06)	AMMONIUM BROMIDE	4 [hp_X] in 1.1 mL
CITRULLUS COLOCYNTHIS FRUIT PULP (UNII: 23H32AOH17) (CITRULLUS COLOCYNTHIS FRUIT PULP - UNII:23H32AOH17)	CITRULLUS COLOCYNTHIS FRUIT PULP	4 [hp_X] in 1.1 mL
ATROPINE SULFATE (UNII: 03J5ZE7KA5) (ATROPINE - UNII:7C0697DR9I)	ATROPINE SULFATE	6 [hp_X] in 1.1 mL
GELSEMIUM SEMPERVIRENS ROOT (UNII: 639KR60Q1Q) (GELSEMIUM SEMPERVIRENS ROOT - UNII:639KR60Q1Q)	GELSEMIUM SEMPERVIRENS ROOT	6 [hp_X] in 1.1 mL
MAGNESIUM PHOSPHATE, DIBASIC TRIHYDRATE (UNII: HF539G9L3Q) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM PHOSPHATE, DIBASIC TRIHYDRATE	6 [hp_X] in 1.1 mL
VERATRUM ALBUM ROOT (UNII: QNS6W5US1Z) (VERATRUM ALBUM ROOT - UNII:QNS6W5US1Z)	VERATRUM ALBUM ROOT	6 [hp_X] in 1.1 mL

PASSIFLORA INCARNATA FLOWERING TOP (UNII: CLF5YFS11O) (PASSIFLORA INCARNATA FLOWERING TOP - UNII:CLF5YFS11O)	PASSIFLORA INCARNATA FLOWERING TOP	2 [hp_X] in 1.1 mL
MATRICARIA RECUTITA (UNII: G0R4UBI2ZZ) (MATRICARIA RECUTITA - UNII:G0R4UBI2ZZ)	MATRICARIA RECUTITA	3 [hp_X] in 1.1 mL
AMANITA MUSCARIA FRUITING BODY (UNII: DIF093I037) (AMANITA MUSCARIA FRUITING BODY - UNII:DIF093I037)	AMANITA MUSCARIA FRUITING BODY	4 [hp_X] in 1.1 mL
CUPRIC SULFATE (UNII: LRX7AJ16DT) (CUPRIC CATION - UNII:8CBV67279L)	CUPRIC CATION	6 [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:50114-7040-1	10 in 1 CARTON	08/30/2014	
1		1.1 mL in 1 AMPULE; Type 0: Not a Combination Product		
2	NDC:50114-7040-2	1 in 1 CARTON	08/30/2014	
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		08/30/2014	

Labeler - MediNatura Inc (102783016)

Establishment

Name	Address	ID/FEI	Business Operations
Hameln Pharma GmbH		315869123	manufacture(50114-7040)

Establishment

Name	Address	ID/FEI	Business Operations
Biologische Heilmittel Heel		315635359	manufacture(50114-7040)

Revised: 3/2019 MediNatura Inc