

12 Clinical Pharmacology

12.1 Mechanism of Action

The exact mechanism of Spascupreel® 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 50114-7040-1

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 Spascupreel® Injection Solution safely and effectively. See full prescribing information for Spascupreel®.

Spascupreel® Injection Solution, Parenteral Use Rx Only

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

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

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

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

- None (5)

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

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

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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 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.

2 Dosage and Administration

2.1 General Considerations

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

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:

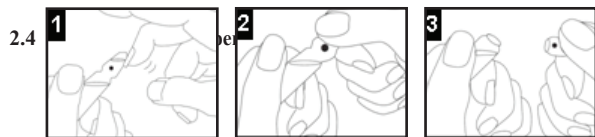
1 ml daily, and then continue with standard dosage.

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.



- 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

- Spascupreel® Injection Solution is contraindicated in patients with known hypersensitivity to Spascupreel® 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 Spascupreel® 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 Spascupreel® 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. Spascupreel® 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 Spascupreel® 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 Spascupreel® 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 Spascupreel® 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
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

11.2 Pharmaceutical Form

- Sterile Injection Solution

11.3 Route of Administration

- Parenteral: s.c., i.d., i.m., or i.v