

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use Uri-Control Tablets safely and effectively. See full prescribing information for Uri-Control.

Uri-Control Tablets, Oral Use, Rx Only

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

Uri-Control is a homeopathic drug indicated for the treatment of urinary tract infection, albuminuria, hematuria, incontinence. (1)

-----DOSAGE AND ADMINISTRATION-----

Allow tablets to dissolve completely in the mouth, do not swallow.

• Standard Dosage:

Adults and children 12 years and older:

3 tablets per day, taking 1 tablet every 4 to 6 hours.

Children under 12 years:

2 tablets per day, taking 1 tablet every 6 to 8 hours. (2.2).

• Acute Dosage:

Adults and children 12 years and older:

1 tablet every ½ to 1 hour until symptoms lessen, then continue with standard dosage. Do not exceed 12 tablets in 24 hours.

Children under 12 years:

1 tablet every ½ to 1 hour until symptoms lessen, then continue with standard dosage. Do not exceed 8 tablets in 24 hours. (2.3).

-----DOSAGE FORM AND STRENGTH-----

- 300 mg tablets each containing the active ingredients in the strengths listed under Description. (3)

-----CONTRAINDICATIONS-----

- Uri-Control is contraindicated in patients with known hypersensitivity to Uri-Control or any of its ingredients. (4)

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

- Keep out of reach of children. (5)

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

- No adverse events with a causal relationship to Uri-Control have been reported. (6)

- **To report SUSPECTED ADVERSE REACTIONS, contact MediNatura at 1.844.MediNatura (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 Uri-Control Tablets on pregnant or lactating women, children, or elderly. (8)

Revised 05/2014

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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 Uri-Control Tablets is a homeopathic drug product indicated for the treatment of urinary tract infection, albuminuria, hematuria, and incontinence.

2 Dosage and Administration

2.1 General Considerations

- The dosage schedules listed below can be used as a general guide for the administration of Uri-Control Tablets.
- Allow tablets to dissolve completely in the mouth, do not swallow.

2.2 Standard Dosage:

Adults and children 12 years and older:

3 tablets per day, taking 1 tablet every 4 to 6 hours.

Children under 12 years:

2 tablets per day, taking 1 tablet every 6 to 8 hours.

2.3 Acute Dosage:

Adults and children 12 years and older:

1 tablet every ½ to 1 hour until symptoms lessen, then continue with standard dosage.

Do not exceed 12 tablets in 24 hours.

Children under 12 years:

1 tablet every ½ to 1 hour until symptoms lessen, then continue with standard dosage.

Do not exceed 8 tablets in 24 hours.

3 Dosage Forms and Strength

300 mg tablets each containing the active ingredients in the strengths listed under Description. (10)

4 Contraindications

Uri-Control Tablets are contraindicated in patients with known hypersensitivity to Uri-Control or any of its ingredients.

5 Warnings and Precautions

Keep out of reach of children.

6 Adverse Reactions

6.1 Post-marketing Experience

- No adverse events with a causal relationship to Uri-Control have been reported.

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. There are no adequate and well-controlled studies in pregnant women. Uri-Control 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 Uri-Control 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 Uri-Control 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 Uri-Control 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 300 mg tablet contains:

| Active Ingredients: | | | |
|----------------------|---------|----------|----------------|
| Ingredient name | Potency | Quantity | Final dilution |
| Apis mellifica | 6X | 30 mg | 7X |
| Argentum nitricum | 6X | 30 mg | 7X |
| Belladonna | 4X | 30 mg | 5X |
| Cantharis | 6X | 30 mg | 7X |
| Causticum | 8X | 30 mg | 9X |
| Equisetum hyemale | 6X | 30 mg | 7X |
| Petroselinum sativum | 8X | 30 mg | 9X |
| Pulsatilla | 6X | 30 mg | 7X |
| Sarsaparilla | 6X | 30 mg | 7X |
| Terebinthina | 8X | 30 mg | 9X |

Inactive Ingredients: Lactose, Magnesium stearate

11.2 Pharmaceutical Form

- Tablets

11.3 Route of Administration

- Oral

12 Clinical Pharmacology

12.1 Mechanism of Action

The exact mechanism of Uri-Control Tablets 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

- Bottle with 100 tablets
- NDC 50114-9002-2

16.2 Storage and handling

- Store at room temperature. Protect from light and moisture.
- Keep out of reach of children