**URELLE- hyoscyamine sulfate, methenamine, methylene blue, phenyl salicylate, and sodium phosphate, monobasic, monohydrate tablet**
**Viatris Specialty LLC**

*Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.*

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**URELLE®**

**Urinary Antiseptic**

## DESCRIPTION:

Urelle® tablets for oral administration are supplied as navy blue round tablets with "A-002" debossed on one side.

Each Tablet Contains:

Hyoscyamine Sulfate 0.12 mg

Methenamine 81.0 mg

Methylene Blue 10.8 mg

Phenyl Salicylate 32.4 mg

Sodium Phosphate Monobasic 40.8 mg

## INACTIVE INGREDIENTS:

Corn Starch, Dicalcium Phosphate, FD&C Blue #2/Indigo Carmine Aluminum Lake, Magnesium Stearate, Microcrystalline Cellulose, Polyethylene Glycol, Polyvinyl Alcohol, Talc, Titanium Dioxide.

## INDICATIONS and USAGE:

Urelle® is indicated for the treatment of symptoms of irritative voiding. Indicated for the relief of local symptoms, such as inflammation, hypermotility, and pain, which accompany lower urinary tract infections. Indicated for the relief of urinary tract symptoms caused by diagnostic procedures.

## CONTRAINDICATIONS:

Hypersensitivity to any of the ingredients is possible. Risk - benefit should be carefully considered when the following medical problems exist: cardiac disease (especially cardiac arrhythmias, congestive heart failure, coronary heart disease, mitral stenosis); gastrointestinal tract obstructive disease; glaucoma; myasthenia gravis; acute urinary retention may be precipitated in obstructive uropathy (such as bladder neck obstruction due to prostatic hypertrophy).

**WARNINGS:**

**If rapid pulse, dizziness, or blurring of vision occurs, discontinue use immediately.**

Patients should be advised that urine will be colored blue when taking this medication. Do not exceed recommended dosage.

**PRECAUTIONS:**

Cross sensitivity and/or related problems - patients intolerant of belladonna alkaloids or salicylates may be intolerant of this medication also. Delay in gastric emptying could complicate the management of gastric ulcers.

Urelle® contains methylene blue. Methylene blue should generally NOT be given to patients taking serotonergic drugs.

**Drug Interactions:**

Although the exact mechanism of this drug interaction is unknown, methylene blue inhibits the action of monoamine oxidase A— an enzyme responsible for breaking down serotonin in the brain. It is believed that when methylene blue is given to patients taking serotonergic psychiatric medications, high levels of serotonin can build up in the brain, causing toxicity. This is referred to as Serotonin Syndrome. Signs and symptoms of Serotonin Syndrome include mental changes (confusion, hyperactivity, memory problems), muscle twitching, excessive sweating, shivering or shaking, diarrhea, trouble with coordination, and/or fever.

**Additional Information for Healthcare Professionals:**

Methylene blue can interact with serotonergic psychiatric medications and cause serious CNS toxicity.

In emergency situations requiring life-threatening or urgent treatment with methylene blue (as described above), the availability of alternative interventions should be considered and the benefit of methylene blue treatment should be weighed against the risk of serotonin toxicity. If methylene blue must be administered to a patient receiving a serotonergic drug, the serotonergic drug must be immediately stopped, and the patient should be closely monitored for emergent symptoms of CNS toxicity for two weeks (five weeks if fluoxetine [Prozac] was taken), or until 24 hours after the last dose of methylene blue, whichever comes first.

In non-emergency situations when non-urgent treatment with methylene blue is contemplated and planned, the serotonergic psychiatric medication should be stopped to allow its activity in the brain to dissipate. Most serotonergic psychiatric drugs should be stopped at least 2 weeks in advance of methylene blue treatment. Fluoxetine (Prozac), which has a longer half-life compared to similar drugs, should be stopped at least 5 weeks in advance.

Treatment with the serotonergic psychiatric medication may be resumed 24 hours after the last dose of methylene blue.

Serotonergic psychiatric medications should not be started in a patient receiving methylene blue. Wait until 24 hours after the last dose of methylene blue before starting

the antidepressant.

Educate your patients to recognize the symptoms of serotonin toxicity or CNS toxicity and advise them to contact a healthcare professional immediately if they experience any symptoms while taking serotonergic psychiatric medications or methylene blue.

**To report SUSPECTED ADVERSE REACTIONS, contact Meda Pharmaceuticals Inc. at 1-877-999-8402 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.**

## DOSAGE and ADMINISTRATION:

Adults – One tablet orally 4 times per day followed by liberal fluid intake.

Pediatric – Dosage must be individualized by a physician for older children. Urelle® is not recommended for use in children 6 years of age or younger.

## HOW SUPPLIED:

Urelle® tablets for oral administration are supplied in child resistant bottles of 90 tablets (NDC 0037-6321-90).

Store at controlled room temperature 20°-25°C (68°-77°F).

Dispense in a tight, light resistant container as defined in the USP.

**KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.**

Distributed by:
Meda Pharmaceuticals®
Somerset, New Jersey 08873-4120



Rx Only

IN-632110-01

Rev. 07/2014

## PRINCIPAL DISPLAY PANEL – BOTTLE LABEL

**NDC 0037-6321-90**
**90 TABLETS**

**Urelle®**
**Urinary Antiseptic**

**Rx only**

**Distributed by:**
**MEDA**
**PHARMACEUTICALS®**

**Somerset, New Jersey 08873-4120**



**Description:** Urelle® tablets for oral administration are supplied as navy blue round tablets with “A-002” debossed on one side.

**Each Tablet Contains:**
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Methenamine 81.0 mg
Methylene Blue 10.8 mg
Phenyl Salicylate 32.4 mg
Sodium Phosphate Monobasic 40.8 mg

**Dosage:** Adults - one tablet orally 4 times per day followed by liberal fluid intake. Pediatric - Dosage must be individualized by a physician for older children. Urelle® is not recommended for use in children 6 years of age or younger.

**Precaution:** Contains Methylene Blue and should NOT be taken with serotonergic psychiatric medications. For full product information see package insert.

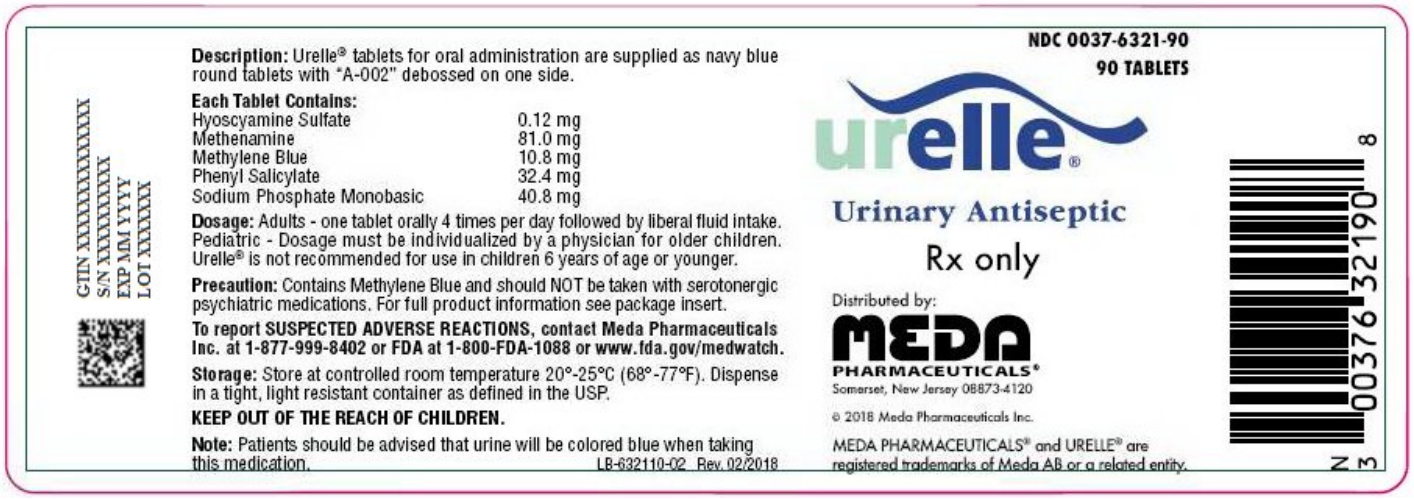
**To report SUSPECTED ADVERSE REACTIONS, contact Meda Pharmaceuticals Inc. at 1-877-999-8402 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.**

**Storage:** Store at controlled room temperature 20°-25°C (68°-77°F). Dispense in a tight, light resistant container as defined in the USP.

**KEEP OUT OF THE REACH OF CHILDREN.**

**Note:** Patients should be advised that urine will be colored blue when taking this medication.

LB-632110-02 Rev. 02/2018




## URELLE

hyoscyamine sulfate, methenamine, methylene blue, phenyl salicylate, and sodium phosphate, monobasic, monohydrate tablet

## Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN PRESCRIPTION DRUG | **Item Code (Source)** | NDC:0037-6321 |
| **Route of Administration** | ORAL | | |

## Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **HYOSCYAMINE SULFATE** (UNII: F2R8V82B84) (HYOSCYAMINE - UNII:PX44XO846X) | HYOSCYAMINE SULFATE | 0.12 mg |
| **METHENAMINE** (UNII: J50OIX95QV) (METHENAMINE - UNII:J50OIX95QV) | METHENAMINE | 81 mg |
| **METHYLENE BLUE** (UNII: T42P99266K) (METHYLENE BLUE CATION - UNII:ZMZ79891ZH) | METHYLENE BLUE | 10.8 mg |
| **PHENYL SALICYLATE** (UNII: 28A37T47QO) (PHENYL SALICYLATE - UNII:28A37T47QO) | PHENYL SALICYLATE | 32.4 mg |
| **SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE** (UNII: 593YOG76RN) (PHOSPHATE ION - UNII:NK08V8K8HR) | SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE | 40.8 mg |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **STARCH, CORN** (UNII: O8232NY3SJ) | |
| **ANHYDROUS DIBASIC CALCIUM PHOSPHATE** (UNII: L11K75P92J) | |
| **FD&C BLUE NO. 2** (UNII: L06K8R7DQK) | |
| **MAGNESIUM STEARATE** (UNII: 70097M6I30) | |
| **MICROCRYSTALLINE CELLULOSE** (UNII: OP1R32D61U) | |
| **POLYETHYLENE GLYCOL, UNSPECIFIED** (UNII: 3WQ0SDW1A) | |
| **POLYVINYL ALCOHOL, UNSPECIFIED** (UNII: 532B59J990) | |
| **TALC** (UNII: 7SEV7J4R1U) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | BLUE | **Score** | no score |
| **Shape** | ROUND | **Size** | 11mm |
| **Flavor** | | **Imprint Code** | A002 |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:0037-6321-90 | 90 in 1 BOTTLE; Type 0: Not a Combination Product | 01/12/2015 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| Unapproved drug other | | 01/12/2015 | |

## Labeler - Viatris Specialty LLC (117455616)

Revised: 1/2015 Viatris Specialty LLC