**ALL-IN-ONE UTI EMERGENCY KIT- methenamine, sodium salicylate, and phenazopyridine hydrochloride**
**UQORA INC**

*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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**Uqora All-In-One UTI Emergency Kit**

***Drug Facts***

| ***Active ingredients (in each tablet)*** | ***Purpose*** |
|---|---|
| Methenamine 162mg | Antibacterial |
| Sodium Salicylate 162.5mg (NSAID)*<br>*nonsteroidal anti-inflammatory drug | Analgesic (pain reliever) |

| ***Active ingredient (in each tablet)*** | ***Purpose*** |
|---|---|
| Phenazopyridine Hydrochloride 99.5mg | Urinary Tract Analgesic |

**Uses**

**UTI Infection Control**

Temporarily relieves:
- pain and burning
- frequency and urgency of urination

**UTI Pain Relief**

Fast relief from urinary pain, burning, urgency and frequency associated with urinary tract infections. Treatment should not exceed 2 days; see Directions.

**Warnings**

**Reye's Syndrome *(UTI Infection Control Only)***

**Reye’s syndrome:** Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this
product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye’s syndrome, a rare but serious illness.

**Stomach Bleeding Warning *(UTI Infection Control Only)***

**Stomach bleeding warning:** This product contains a nonsteroidal anti-inflammatory drug (NSAID), which may cause stomach bleeding. The chance is higher if you
- are 60 or older

- have stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing an NSAID (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

**Do Not Exceed *(UTI Pain Relief Only)***

**Do not exceed recommended dosage**

**Do Not Use**

**Do not use**:
- If you are allergic to salicylates (including aspirin) ( ***UTI Infection Control only***)
- If you have Glucose-6-Phosphate Dehydrogenase (G6PD) deficiency unless approved by your doctor ( ***UTI Pain Relief only)***

**Ask A Doctor Before Use**

**Ask a doctor before use if you have:**
- frequent, burning urination for the first time ***(UTI Infection Control only)***
- the stomach bleeding warning applying to you ***(UTI Infection Control only)***
- history of stomach problems, such as heartburn ***(UTI Infection Control only)***
- high blood pressure ***(UTI Infection Control only)***
- heart disease ***(UTI Infection Control only)***
- liver cirrhosis ***(UTI Infection Control only)***
- bleeding problems ***(UTI Infection Control only)***
- diuretic use ***(UTI Infection Control only)***
- ulcers ***(UTI Infection Control only)***
- kidney disease
- a sodium restricted diect ***(UTI Infection Control only)***
- reached age 60 or older ***(UTI Infection Control only)***
- allergies to foods, preservatives or dyes ***(UTI Pain Relief only)***
- had a hypersensitive reaction to phenazopyridine ***(UTI Pain Relief only)***

**Ask A Doctor Or Pharmacist Before Use *(UTI Infection Control Only)***

**Ask a doctor or pharmacist before use if you are:**
- taking any other drug containing an NSAID (prescription or non-prescription)
- taking a blood thinning (anticoagulant), steroid, diabetes, gout or arthritis drug

**When Using This Product**

**When using this product:**
- do not take more than the recommended dosage ***(UTI Infection Control only)***
- stomach upset may occur, taking this product with or after meals may reduce stomach upset ***(UTI Pain Relief only)***
- your urine will become reddish-orange in color. This is not harmful, but care should be taken to avoid staining clothing or other items. ***(UTI Pain Relief only)***

**Stop Use And Ask A Doctor**

**Stop use and ask a doctor if**:

- product has been used for 3 days ***(UTI Infection Control only)***
- ringing in the ears ***(UTI Infection Control only)***
- you experience any of the following signs of stomach bleeding: ■ feel faint ■ vomit blood ■ have bloody or black stool ■ have stomach pain or upset that gets worse or lasts ***(UTI Infection Control only)***
- your symptoms last for more than 2 days ***(UTI Pain Relief only)***
- you suspect you are having an adverse reaction to the medication ***(UTI Pain Relief only)***

**Long Term Administration *(UTI Pain Relief Only)***

Long-term administration of phenazopyridine hydrochloride has induced neoplasia in rats (large intestine) and mice (liver). Although
no association between phenazopyridine hydrochloride and human neoplasia has been reported, adequate epidemiological studies along these lines have not been conducted.

**If Pregnant or Breast Feeding**

UTI Infection Control

**If pregnant or breast feeding,** ask a health professional before use. It is especially important not to use this product (which contains sodium salicylate) during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

UTI Pain Relief

**If pregnant or breast feeding,** ask a health professional before use.

**Keep Out Of The Reach Of Children**

**Keep out of the reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away 1-800-222-1222

**Directions**

**UTI Infection Control**

**Adults and children 12 years and over:**

- take 2 tablets with a full glass of water 3 times a day. Drink plenty of fluids.
- **Do not use for more than a 3 day period unless directed by a doctor.**

**Children under 12 years**: ask a doctor.

**UTI Pain Relief**

**Adults and children 12 years and over:**

- take 2 tablets 3 times daily with a full glass of water, with or after meals as needed
- **Do not use for more than 2 days (12 tablets) without consulting a doctor.**

**Children under 12 years:** consult a doctor

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**Other Information**

**UTI Infection Control**

- **each tablet contains:** sodium 24.4 mg
- store at 59-86°F (15-30°C) in a cool dry place
- protect from sunlight
- Tamper evident: tablets sealed in blisters. Do not use if blister foil or seal is open or damaged

**UTI Pain Relief**

- this product may stain contact lenses
- this product can interfere with laboratory tests including urine, glucose (sugar), and ketones tests
- store at room temperature 15°-30°C (59°-86°F) in a dry place and protect from light
- Tamper evident: tablets sealed in blisters. Do not use if blister foil or seal is open or damaged

**Inactive Ingredients**

**UTI Infection Control**

benzoic acid, croscarmellose sodium, fd&c red #40, fd&c yellow #6, hypromellose, magnesium stearate, methacrylic acid-ethyl acrylate copolymer, microcrystalline cellulose, silicon dioxide, stearic acid, sodium bicarbonate, sodium lauryl sulfate, talc, titanium dioxide, triacetin, triethyl citrate

**UTI Pain Relief**

corn starch, croscarmellose sodium, hypromellose, lactose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinylpyrrolidone, pregelatinized starch, silicon dioxide, sodium starch glycolate, talc and triacetin.

Distributed by Uqora, Inc.

3043 4th Avenue, San Diego, CA 92103

support@uqora.com

For questions or concerns please contact (888) 313-1372

**Additional Items**

***2 diagnostic UTI test strips*** (Directions Enclosed)

***Other information***

- store at room temperature 59-86 F (15-30 C) out of direct sunlight. Do not

refrigerate or freeze
- For in-vitro (external) diagnostic use.

**Principal Display Panel**

uqora

Urinary Care

3-in-1 Convenience Kit

ALL-IN-ONE

UTI EMERGENCY KIT

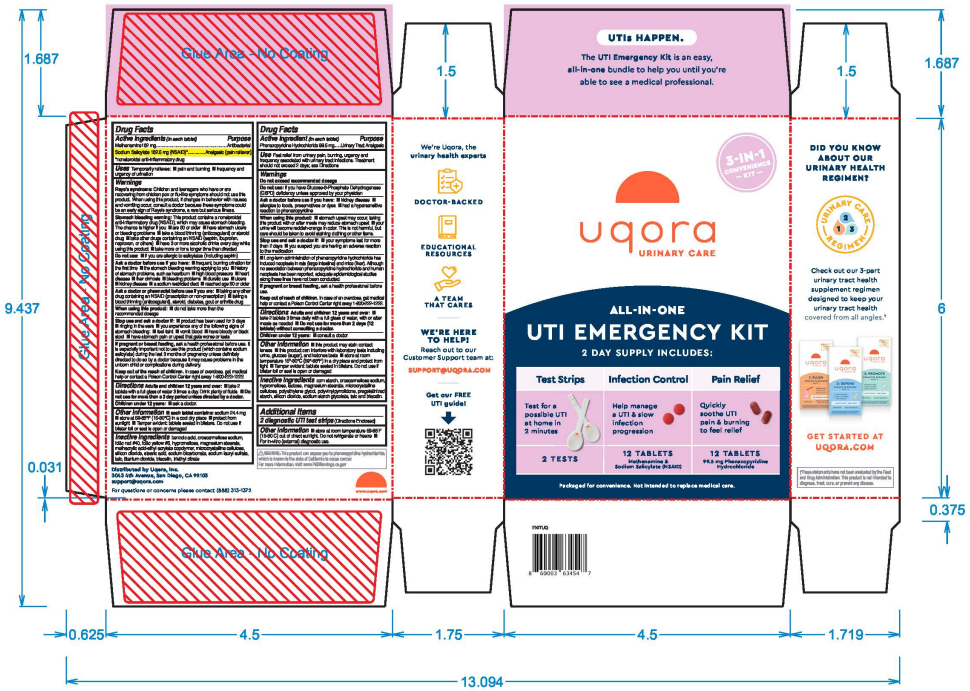
2 Day Supply Includes:

Test Strips
- Test for a possible UTI at home in 2 minutes
- 2 Tests

Infection Control
- Help manage a UTI & slow infection progress
- 12 Tablets (Methenamine & Sodium Salicylate (NSAID)

Pain Relief
- Quickly sooth UTI pain & burning to feel relief
- 12 Tablets (99.5mg Phenazopyridine Hydrochloride)

Packaged for convenience. Not intended to replace medical care.




# ALL-IN-ONE UTI EMERGENCY KIT

methenamine, sodium salicylate, and phenazopyridine hydrochloride kit

## Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:73712-500 |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:73712-500-24 | 1 in 1 CARTON; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product) | 10/17/2022 | |

## Quantity of Parts

| Part # | Package Quantity | Total Product Quantity |
|---|---|---|
| **Part 1** | 1 BLISTER PACK | 12 |
| **Part 2** | 1 BLISTER PACK | 12 |

## Part 1 of 2

# UQORA ANTIBACTERIAL PLUS URINARY PAIN RELIEF

methenamine, sodium salicylate tablet

| Product Information | |
|---|---|
| **Item Code (Source)** | NDC:73712-804 |
| **Route of Administration** | ORAL |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **METHENAMINE** (UNII: J50OIX95QV) (METHENAMINE - UNII:J50OIX95QV) | METHENAMINE | 162 mg |
| **SODIUM SALICYLATE** (UNII: WIQ1H85SYP) (SALICYLIC ACID - UNII:O414PZ4LPZ) | SODIUM SALICYLATE | 162.5 mg |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **SODIUM BICARBONATE** (UNII: 8MDF5V39QO) | |
| **TRIETHYL CITRATE** (UNII: 8Z96QXD6UM) | |
| **FD&C YELLOW NO. 6** (UNII: H77VEI93A8) | |
| **HYPROMELLOSES** (UNII: 3NXW29V3WO) | |
| **FD&C RED NO. 40** (UNII: WZB9127XOA) | |
| **BENZOIC ACID** (UNII: 8SKN0B0MIM) | |
| **CROSCARMELLOSE SODIUM** (UNII: M28OL1HH48) | |
| **MAGNESIUM STEARATE** (UNII: 70097M6I30) | |
| **METHACRYLIC ACID-ETHYL ACRYLATE COPOLYMER (1:1) TYPE A** (UNII: NX76LV5T8J) | |
| **CELLULOSE, MICROCRYSTALLINE** (UNII: OP1R32D61U) | |
| **SILICON DIOXIDE** (UNII: ETJ7Z6XBU4) | |
| **STEARIC ACID** (UNII: 4ELV7Z65AP) | |
| **SODIUM LAURYL SULFATE** (UNII: 368GB5141J) | |
| **TALC** (UNII: 7SEV7J4R1U) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |
| **TRIACETIN** (UNII: XHX3C3X673) | |

| Product Characteristics | | | |
|---|---|---|---|
| **Color** | red | **Score** | no score |
| **Shape** | ROUND | **Size** | 11mm |
| **Flavor** | | **Imprint Code** | PH061 |
| **Contains** | | | |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |

| | | | | |
|---|---|---|---|---|
| **1** | NDC:73712-804-12 | 12 in 1 BLISTER PACK; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product) | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| unapproved drug other | | 10/17/2022 | |

## Part 2 of 2

## UQORA MAXIMUM STRENGTH URINARY PAIN RELIEF

phenazopyridine hydrochloride tablet

### Product Information

| | |
|---|---|
| **Item Code (Source)** | NDC:73712-113 |
| **Route of Administration** | ORAL |

### Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **PHENAZOPYRIDINE HYDROCHLORIDE** (UNII: 0EWG668W17) (PHENAZOPYRIDINE - UNII:K2J09EMJ52) | PHENAZOPYRIDINE HYDROCHLORIDE | 99.5 mg |

### Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **POLYETHYLENE GLYCOL, UNSPECIFIED** (UNII: 3WQ0SDW1A) | |
| **CELLULOSE, MICROCRYSTALLINE** (UNII: OP1R32D61U) | |
| **HYPROMELLOSES** (UNII: 3NXW29V3WO) | |
| **MAGNESIUM STEARATE** (UNII: 70097M6I30) | |
| **SILICON DIOXIDE** (UNII: ETJ7Z6XBU4) | |
| **SODIUM STARCH GLYCOLATE TYPE A** (UNII: H8AV0SQX4D) | |
| **CROSCARMELLOSE SODIUM** (UNII: M28OL1HH48) | |
| **LACTOSE, UNSPECIFIED FORM** (UNII: J2B2A4N98G) | |
| **POVIDONE, UNSPECIFIED** (UNII: FZ989GH94E) | |
| **TALC** (UNII: 7SEV7J4R1U) | |
| **TRIACETIN** (UNII: XHX3C3X673) | |
| **STARCH, CORN** (UNII: O8232NY3SJ) | |

### Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | brown | **Score** | no score |
| **Shape** | OVAL | **Size** | 9mm |
| **Flavor** | | **Imprint Code** | p99 |

| Contains | |
|---|---|

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| 1 | NDC:73712-113-12 | 12 in 1 BLISTER PACK; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product) | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| unapproved drug other | | 10/17/2022 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| unapproved drug other | | 10/17/2022 | |

## Labeler - UQORA INC (022730893)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Pharbest | | 557054835 | manufacture(73712-500) |

Revised: 10/2022 UQORA INC