

**AZO URINARY TRACT DEFENSE ANTIBACTERIAL PROTECTION- methenamine, sodium salicylate tablet**  
**i-Health, 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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**AZO Urinary Tract Defense**

**Drug Facts**

**☐Active Ingredients (in each tablet):**

Methenamine 162 mg

Sodium Salicylate 162.5 (NSAID Nonsteroidal Anti-Inflammatory Drug)

**☐Purpose**

☐Antibacterial

Analgesic (pain reliever)

**☐Uses**☐ Temporarily relieves:

- pain & burning
- frequency and urgency of urination

**☐Warnings**

**☐Reye's syndrome:** ☐Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use 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:** ☐This product contains an NSAID, which may cause stomach bleeding. The chance is higher if you:

- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen or others)
- have 3 or more alcoholic drinks every day while using this product
- have stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- are age 60 or older
- take more or for a longer time than directed

**☐Do not use:**

- if you are on a sodium restricted diet
- if you are allergic to salicylates (including aspirin) unless directed by a doctor
- if you have stomach problems (such as heartburn, upset stomach, or stomach pain) that persist or recur, or if you have ulcers or bleeding problems unless directed by a doctor

**☐Ask a doctor before use if you have**

- frequent, burning urination for the first time
- the stomach bleeding warning applying to you
- history of stomach problems, such as heartburn
- high blood pressure
- heart disease

- liver cirrhosis
- bleeding problems
- diuretic use
- ulcers
- kidney disease
- reached age 60 or older

**Ask a doctor or pharmacist before use if you are**

- taking any other drug containing an NSAID (prescription or nonprescription)
- taking a blood thinning (anticoagulant), steroid, diabetes, gout or arthritis drug

**When using this product** do not take more than the recommended dosage

**Stop and ask a doctor if**

- product has been used for 3 days
- you experience any of the following signs of stomach bleeding: feel faint, vomit blood, have blood or black stools, have stomach pain that does not get better
- ringing in the ears or a loss of hearing occurs

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

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

**Directions:** Adults and children 12 years and over: take 2 tablets with a full glass of water 3 times a day. Drink plenty of fluids. Children under 12 years: ask a doctor.

**Other Information:**

- each tablet contains 25 mg of sodium
- store at 59-86°F (15-30°C) in a dry place
- protect from light
- Tamper evidence tablets sealed in blisters. Do not use if blister foil or seal is open or damaged.

**Inactive Ingredients:** Benzoic Acid, Cellulose, Croscarmellose Sodium, Edible black ink, FD&C Red #40 Lake, FD&C Yellow #6 Lake, Hydroxypropyl Cellulose, Hydroxypropyl Methylcellulose, Magnesium Stearate, Methacrylic Acid - Ethyl Acrylate Copolymer, Silica, Stearic Acid, Titanium Dioxide, Triethyl Citrate

AZO

Urinary Tract Defense

Antibacterial Protection\*

Antibacterial Urinary Pain Relief

Methenamine and Sodium Salicylate (NSAID)

\* Helps inhibit the progression of infection until you see your healthcare professional. AZO is not intended to replace medical care.



### Drug Facts

Active Ingredients (in each tablet):	Purpose
Methanamine 152 mg	Antibacterial
Sodium Salicylate 162.5 mg (NSAID Nonsteroidal Anti-Inflammatory Drug)	Analgesic (pain reliever)

**Uses** Temporarily relieves: pain & burning • frequency and urgency of urination

#### Warnings

**Reye's syndrome:** Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use 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.

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The chance is higher if you:

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- have 3 or more alcoholic drinks every day while using this product
- have stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- are age 60 or older
- take more or for a longer time than directed

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- if you are on a sodium restricted diet
- if you are allergic to salicylates (including aspirin) unless directed by a doctor
- if you have stomach problems (such as heartburn, upset stomach, or stomach pain) that persist or recur, or if you have ulcers or bleeding problems unless directed by a doctor

#### Ask a doctor before use if you have

- frequent, burning urination for the first time
- the stomach bleeding warning applying to you
- history of stomach problems, such as heartburn
- high blood pressure
- liver cirrhosis
- bleeding problems
- chronic use
- ulcers
- kidney disease
- reached age 60 or older

#### Ask a doctor or pharmacist before use if you are

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- taking a blood thinning (anticoagulant), steroid, diabetes, gout or arthritis drug

**When using this product:** • do not take more than the recommended dosage

#### Stop and ask a doctor if

- product has been used for 3 days
- you experience any of the following signs of stomach bleeding:
  - feel faint, vomit blood
  - have bloody or black stools
- have stomach pain that does not get better
- ringing in the ears or a loss of hearing occurs

**If pregnant or breast feeding, ask a health professional before use. Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

## Antibacterial <sup>plus</sup> Urinary Pain Relief!

# AZO

### Urinary Tract Defense™ Antibacterial Protection

#### Antibacterial Urinary Pain Relief Methanamine and Sodium Salicylate (NSAID) 4 Tablets

\*Helps inhibit the progression of infection until you see your healthcare professional. AZO is not intended to replace medical care.

#### Drug Facts (continued)

**Directions:** Adults and children 12 years and over: take 2 tablets with a full glass of water 3 times a day. Drink plenty of fluids. Children under 12 years: ask a doctor.

**Other Information:** • each tablet contains 25 mg of sodium • store at 59-86°F (15-30°C) in a dry place • protect from light • Tamper evident. Do not use if foil pouch is open or damaged.

**Inactive Ingredients:** Benzoic Acid, Cellulose Croscarmellose Sodium, Edible black ink, FD&C Red #40 Lake, FD&C Yellow #6 Lake, Hydroxypropyl Cellulose, Hydroxypropyl Methylcellulose, Magnesium Stearate, Methacrylic Acid-Ethyl Acrylate Copolymer, Silica, Stearic Acid, Titanium Dioxide, Triethyl Citrate.

Distributed by i-Health, Inc., 55 Sebethe Drive, Cromwell, CT 06416.

For questions, concerns, or to report an adverse event,

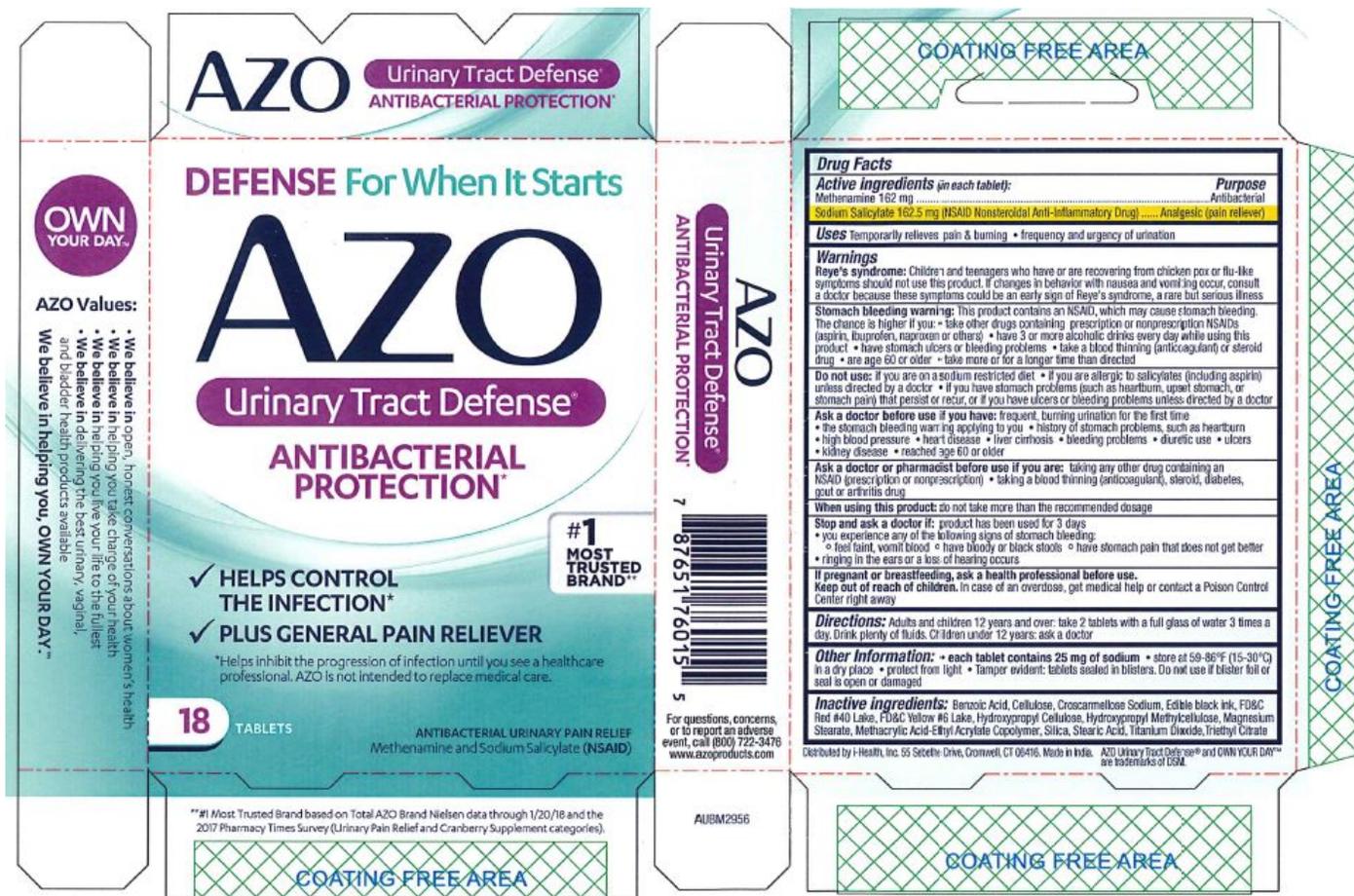
please call 1-800-722-3476 or visit [www.azoproducts.com](http://www.azoproducts.com)

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**NOT FOR RESALE**



## AZO URINARY TRACT DEFENSE ANTIBACTERIAL PROTECTION

methenamine, sodium salicylate tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:49973-011
<b>Route of Administration</b>	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
BENZOIC ACID (UNII: 8SKN0B0MIM)	
POWDERED CELLULOSE (UNII: SMD1X3XO9M)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYDROXYPROPYL CELLULOSE (1600000 WAMW) (UNII: RFW2ET671P)	

<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A</b> (UNII: NX76LV5T8J)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>TRIETHYL CITRATE</b> (UNII: 8Z96QXD6UM)	

### Product Characteristics

<b>Color</b>	red	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	10 mm
<b>Flavor</b>		<b>Imprint Code</b>	AZOUD
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49973-011-24	1 in 1 BOX	03/01/2016	
1		24 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:49973-011-18	1 in 1 BOX	04/23/2018	
2		18 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:49973-011-04	4 in 1 POUCH; Type 0: Not a Combination Product	11/06/2015	01/31/2018

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		11/06/2015	

**Labeler** - i-Health, Inc. (061427694)