

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.

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

Distributed by and Contact Information

Distributed by i-Health, Inc., 25 Bacon Road, Enfield, CT 06082
For Questions or Concerns: 800-722-3476 or Visit azoproducts.com

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.

AZO Antibacterial[®] Plus Urinary Pain Relief!
Urinary Tract Defense Antibacterial Protection

NEW from AZO! Antibacterial[®] Plus Urinary Pain Relief!

AZO

Urinary Tract Defense™
Antibacterial Protection

- HELPS CONTROL THE INFECTION*
- PLUS GENERAL PAIN RELIEVER

#1 MOST TRUSTED BRAND

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

Antibacterial Urinary Pain Relief
Methenamine and Sodium Salicylate (NSAID) **24 Tablets**

AZO is the Most Trusted Brand based on Nielsen data through 6/13/15 and the 2015 Pharmacy Times CTO Survey

COATING FREE AREA

Drug Facts (Continued)

Other Information: • Keep out of reach of children. • Do not take more than the recommended dosage. • Do not use if you are allergic to any of the ingredients. • Do not use if you are pregnant or breastfeeding. • Do not use if you are taking other NSAIDs. • Do not use if you are taking other drugs containing salicylates. • Do not use if you are taking other drugs containing methenamine. • Do not use if you are taking other drugs containing sodium salicylate. • Do not use if you are taking other drugs containing aspirin. • Do not use if you are taking other drugs containing acetaminophen. • Do not use if you are taking other drugs containing ibuprofen. • Do not use if you are taking other drugs containing naproxen. • Do not use if you are taking other drugs containing celecoxib. • Do not use if you are taking other drugs containing rofecoxib. • Do not use if you are taking other drugs containing valdecoxib. • Do not use if you are taking other drugs containing etoricoxib. • Do not use if you are taking other drugs containing meloxicam. • Do not use if you are taking other drugs containing piroxicam. • Do not use if you are taking other drugs containing tenoxicam. • Do not use if you are taking other drugs containing firocoxib. • Do not use if you are taking other drugs containing mavacoxib. • Do not use if you are taking other drugs containing lumateperone. • Do not use if you are taking other drugs containing mavacoxib. • Do not use if you are taking other drugs containing lumateperone. • Do not use if you are taking other drugs containing mavacoxib. • Do not use if you are taking other drugs containing lumateperone.

Drug Facts

Active Ingredients (in each tablet):

Active Ingredients (in each tablet):	Purpose
Methenamine, 152 mg	Antibacterial
Sodium Salicylate, 162.5mg (NSAID) (Acetaminophen 200 mg) (Ibuprofen 200 mg)	Analgesic (pain reliever)

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

Warnings:

- Flu-like symptoms: 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. 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

Stomach bleeding warning: This product contains an NSAID, which may cause stomach bleeding.

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:

- history of stomach problems, such as heartburn
- high blood pressure
- kidney disease
- liver disease
- bleeding problems
- stomach ulcers
- recent eye, ear or other surgery

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
- pregnant or breastfeeding, 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.

For questions, concerns, or to report an adverse event, call (800) 722-5376
www.azoproducts.com
AZO (Methenamine and Sodium Salicylate) is a registered trademark of Health, Inc.

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COATING FREE AREA

Drug Facts

Active Ingredients (in each tablet):	Purpose
Methanamine 150 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.

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
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- 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

- 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 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 ^{plus} 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.

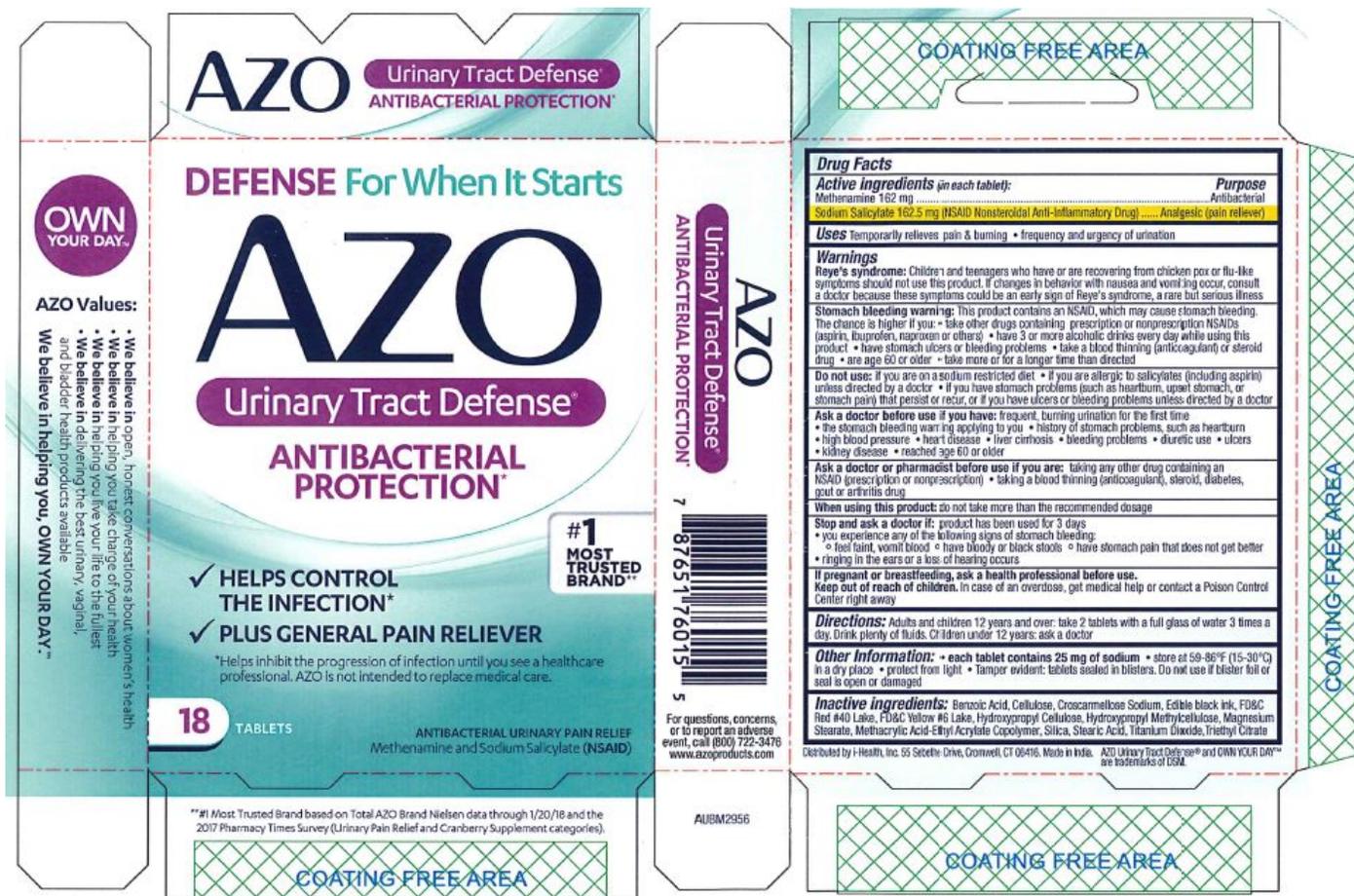
For questions, concerns, or to report an adverse event, please call 1-800-722-3476 or visit www.azoproducts.com

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NOT FOR RESALE



AZO URINARY TRACT DEFENSE ANTIBACTERIAL PROTECTION

methenamine, sodium salicylate tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49973-011
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: WQ1H85SY) (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)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	

HYDROXYPROPYL CELLULOSE (1600000 WAMW) (UNII: RFW2ET671P)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

Product Characteristics

Color	red	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	AZODU
Contains			

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
4	NDC:49973-011-48	2 in 1 BOX	12/15/2025	
4		24 in 1 BLISTER PACK; Type 0: Not a Combination Product		

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)

Establishment

Name	Address	ID/FEI	Business Operations
AMOL PHARMACEUTICALS PRIVATE LIMITED		676245969	manufacture(49973-011)