

# **QUALITY CHOICE ANTIBACTERIAL PLUS URINARY PAIN RELIEF- methenamine, sodium salicylate tablet**

## **Chain Drug Marketing Association**

*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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## **Drug Facts**

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

Methenamine 162 mg

Sodium Salicylate 162.5 mg (NSAID Nonsteroidal Anti-Inflammatory Drug)

### **Purpose**

Antibacterial

Analgesic (pain reliever)

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

**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 behaviour 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 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.**

**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

### **Inactive ingredients:**

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

**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: tablets sealed in blisters. Do not use if blister foil or seal is open or damaged.

- **HELPS CONTROL THE INFECTION\***
- **PLUS GENERAL PAIN RELIEVER**

### **Antibacterial Urinary Pain Relief**

Methenamine and Sodium Salicylate (**NSAID**)

### **Packaging**

NDC 63868-0187-24

**QC**  
QUALITY CHOICE

Compare to The Active Ingredients  
in AZO Urinary Tract Defense\*\*

## Antibacterial<sup>†</sup> Plus Urinary Pain Relief

**Antibacterial Protection<sup>†</sup>**

**Methenamine and Sodium Salicylate (NSAID)**

Helps Control the Infection  
Provides General Pain Relief

\*Helps inhibit the progression of infection until you see a healthcare professional. Not intended to replace medical care.

24

Tablets

Knockout for Expiration Date and Lot Number

6 35515 99603 8

Caution: Tablets sealed in blister. Do not use if blister is opened or damaged

Drug Facts		Purpose
<b>Active ingredients (in each tablet)</b>		Antibacterial
Methenamine 162 mg		Analgesic (pain reliever)
<b>Sodium Salicylate 162.5 mg (NSAID)*</b>		
<small>*nonsteroidal anti-inflammatory drug</small>		

  

Drug Facts (continued)	
<b>Uses</b> Temporarily relieves ■ pain and burning ■ frequency and urgency of urination	
<b>Warnings</b>	
<b>Reye's syndrome:</b> 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.	
<b>Stomach bleeding warning:</b> 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	
<b>Do not use</b> ■ if you are allergic to salicylates (including aspirin)	
<b>Ask a doctor before use if</b> ■ you have frequent, burning urination for the first time ■ stomach bleeding warning applies to you ■ you have a history of stomach problems, such as heartburn ■ you have high blood pressure, heart disease, liver cirrhosis, or kidney disease ■ you are taking a diuretic ■ you have a sodium-restricted diet	
<b>Ask a doctor before use if</b> ■ taking any other drug containing an NSAID (prescription or non-prescription) ■ taking a prescription drug for anticoagulant (blood thinning), gout, diabetes, or arthritis	
<b>When using this product</b> ■ do not take more than the recommended dosage	
<b>Stop use and ask a doctor if</b> ■ product has been used for 3 days ■ ringing in the ears ■ 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	
<b>If pregnant or breast feeding</b> 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.	
<b>Keep out of the reach of children.</b> In case of overdose, get medical help or contact a Poison Control Center right away.	
<b>Directions</b> 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.	
<b>Do not use for more than a 3 day period unless directed by a doctor.</b>	
<b>Other information</b> ■ each tablet contains 24.4mg of sodium ■ store at 59-86°F (15-30°C) in a cool dry place ■ protect from sunlight	
<b>Inactive ingredients</b> benzoic acid, croscarmellose sodium, fti&c red #40, fti&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, tracetin, triethyl citrate	
<b>Questions or comments?</b> 1-800-321-7178	

DISTRIBUTION WANTED

SATISFACTION GUARANTEED

100%

DISTRIBUTED BY C.D.M.A., Inc.®

43157 W. Nine Mile

Novi, MI 48375

www.qualitychoice.com

Questions: 248-449-9300

\*This product is not manufactured or distributed by DSM IP Assets B.V., owner of the registered trademark AZO Urinary Tract Defense®.

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QUALITY CHOICE ANTIBACTERIAL PLUS URINARY PAIN RELIEF			
methenamine, sodium salicylate tablet			
Product Information			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:63868-187
<b>Route of Administration</b>	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
<b>METHENAMINE</b> (UNII: J50OIX95QV) (METHENAMINE - UNII: J50OIX95QV)	METHENAMINE	162 mg	
<b>SODIUM SALICYLATE</b> (UNII: MQ1H85YP) (SALICYLIC ACID - UNII: O414PZ4LPZ)	SODIUM SALICYLATE	162.5 mg	
Inactive Ingredients			

Ingredient Name	Strength
<b>BENZOIC ACID</b> (UNII: 8SKN0B0MIM)	
<b>CROSCARMELOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<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>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>SODIUM BICARBONATE</b> (UNII: 8MDF5V39QO)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>TRIACETIN</b> (UNII: XHX3C3X673)	
<b>TRIETHYL CITRATE</b> (UNII: 8Z96QXD6UM)	

### Product Characteristics

<b>Color</b>	red	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	11mm
<b>Flavor</b>		<b>Imprint Code</b>	PH061
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-187-24	1 in 1 CARTON	02/22/2017	
1		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		02/22/2017	

**Labeler** - Chain Drug Marketing Association (011920774)

**Registrant** - Reese Pharmaceutical Co (004172052)

### Establishment

Name	Address	ID/FEI	Business Operations
Pharbest		557054835	manufacture(63868-187)

