

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

**Topco Associates 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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## **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**



## TOPCARE ANTIBACTERIAL PLUS URINARY PAIN RELIEF

methenamine, sodium salicylate tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:36800-314
<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: WQ1H85YP) (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: 70097M6130)
<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:36800-314-24	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** - Topco Associates LLC (006935977)

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

### Establishment

Name	Address	ID/FEI	Business Operations
Pharbest		557054835	manufacture(36800-314)