

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

**AmerisourceBergen Drug Corp**

*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**



## GOOD NEIGHBOR ANTIBACTERIAL PLUS URINARY PAIN RELIEF

methenamine, sodium salicylate tablet

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:46122-622 |
| <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: MQ1H85SYP) (SALICYLIC ACID - UNII:O414PZ4LPZ) | SODIUM SALICYLATE | 162.5 mg |

### Inactive Ingredients

| Ingredient Name                        | Strength |
|--|----------|
| <b>BENZOIC ACID</b> (UNII: 8SKNOB0MIM) |          |

|  |
|--|
| <b>CROSCARMELLOSE 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:46122-622-62 | 1 in 1 CARTON   | 11/23/2019           |                    |
| 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<br>other |  | 11/23/2019           |                    |

**Labeler** - AmerisourceBergen Drug Corp (007914906)

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

### Establishment

| Name     | Address | ID/FEI    | Business Operations    |
|----------|---------|-----------|------------------------|
| Pharbest |         | 557054835 | manufacture(46122-622) |

