

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.

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



QUALITY CHOICE ANTIBACTERIAL PLUS URINARY PAIN RELIEF

methenamine, sodium salicylate tablet

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:63868-187 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|----------|
| METHENAMINE (UNII: J5O OIX95QV) (METHENAMINE - UNII:J5O OIX95QV) | METHENAMINE | 162 mg |
| SODIUM SALICYLATE (UNII: WIQ1H85SYP) (SALICYLIC ACID - UNII:O414PZ4LPZ) | SODIUM SALICYLATE | 162.5 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| BENZOIC ACID (UNII: 8SKN0B0MM) | |
| CROSCARMELLOSE SODIUM (UNII: M28OL1HH48) | |
| FD&C RED NO. 40 (UNII: WZB9127XOA) | |
| FD&C YELLOW NO. 6 (UNII: H77VEI93A8) | |
| HYPROMELLOSES (UNII: 3NXW29V3WO) | |
| MAGNESIUM STEARATE (UNII: 70097M6B0) | |
| METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J) | |
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U) | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | |
| SODIUM LAURYL SULFATE (UNII: 368GB5141J) | |
| TALC (UNII: 7SEV7J4R1U) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |
| TRIACETIN (UNII: XHX3C3X673) | |
| TRIETHYL CITRATE (UNII: 8Z96QXD6UM) | |

Product Characteristics

| | | | |
|----------|-------|--------------|----------|
| Color | red | Score | no score |
| Shape | ROUND | Size | 11mm |
| Flavor | | Imprint Code | PH061 |
| Contains | | | |

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 |
|-------------------------|---------|-----------|--|
| Reese Pharmaceutical Co | | 004172052 | repack(63868-187) , relabel(63868-187) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|------|---------|--------|---------------------|
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Pharbest

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manufacture(63868-187)

Revised: 1/2019

Chain Drug Marketing Association