PREMIER VALUE ANTIBACTERIAL PLUS URINARY PAIN RELIEF- methenamine, sodium salicylate tablet
Chain Drug Consortium, 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.

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

PREMIER VALUE ANTIBACTERIAL PLUS URINARY PAIN RELIEF

methenamine, sodium salicylate tablet

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68016-003
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: WQ1H85SYP) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SODIUM SALICYLATE	162.5 mg

Inactive Ingredients

Ingredient Name	Strength
BENZOIC ACID (UNII: 8SKN0B0MIM)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	

FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
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:68016-003-24	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 Consortium, LLC (101668460)

Registrant - Reese Pharmaceutical Co (004172052)

Establishment

Name	Address	ID/FEI	Business Operations
Pharbest		557054835	manufacture(68016-003)