URO-PAIN DUAL ACTION ANTIBACTERIAL PROTECTION- methenamine, sodium salicylate tablet
Rising Pharma Holdings, Inc.

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.

URO-PAIN Dual Action

Drug Facts

Active ingredient (in each tablet)

Methenamine 162 mg

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

Purpose

Antibacterial

Analgesic (pain reliever)

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 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

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 breastfeeding, ask a health professional before use.

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

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

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

Inactive Ingredients: benzoic acid, cellulose, croscarmellose sodium, edible black ink, fd & c red #40 lake, fd & c yellow #6 lake, hydroxypropyl cellulose, hydroxypropyl methylcellulose, magnesium stearate, methacrylic acid-ethyl acrylate copolymer, silica, stearic acid, titanium dioxide, triethyl citrate

Questions or comments? Call 1-844-474-7464
Distributed by:

Rising Pharma Holdings, Inc.

East Brunswick, NJ 08816
Made in India
Mfg License Code:
RA/Drug/RAJ.-1750

Issued: 09/2023

Case Label NDC 57237-332-42

URO-PAIN Dual Action

Antibacterial Urinary Pain Relief

Methenamine and Sodium Salicylate (NSAID) Tablets
162 mg; 162.5 mg

* Helps inhibit the progression of infection until you see your healthcare professional. URO is not intended to replace medical care.

URO-PAIN DUAL ACTION ANTIBACTERIAL PROTECTION

methenamine, sodium salicylate tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:57237-332
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: WIQ1H85SYP) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SODIUM SALICYLATE	162.5 mg

Inactive Ingredients

Ingredient Name	Strength
BENZOIC ACID (UNII: 8SKN0B0MIM)	
POWDERED CELLULOSE (UNII: SMD1X3XO9M)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYDROXYPROPYL CELLULOSE (1600000 WAMW) (UNII: RFW2ET671P)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

Product Characteristics

Color	red	**Score**	no score
Shape	ROUND	**Size**	10mm
Flavor		**Imprint Code**	URO
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57237-332-42	1 in 1 BOX	12/06/2023	
1		24 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:57237-332-81	1 in 1 BOX	12/06/2023	
2		18 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		12/06/2023	

Labeler - Rising Pharma Holdings, Inc. (116880195)

Revised: 12/2023 Rising Pharma Holdings, Inc.