

CYSTEX PLUS- methenamine, sodium salicylate tablet
Clarion Brands, 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

Methenamine.....Antibacterial
Sodium Salicylate.....Analgesic (pain reliever)

Use 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. When using 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 a nonsteroidal anti-inflammatory drug (NSAID), which may cause stomach bleeding. The chance is higher if you

- are 60 or older
- have stomach ulcers or bleeding problems
- take a blood thinner (anticoagulant) or steroid drug
- take other drugs containing an NSAID (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

Do not use

- if you are allergic to salicylates (including aspirin) or any other pain reliever/fever reducer

Ask a doctor before use if

- you have frequent, burning urination for the first time
- stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, or kidney disease
- you are taking a diuretic
- you have a sodium-restricted diet

Ask a doctor or pharmacist before use if you are

- taking any other drug containing an NSAID (prescription or non prescription)
- taking a prescription drug for anticoagulation (blood thinning), gout, diabetes, or arthritis

When using this product

- do not take more than the recommended dosage

Stop use and ask a doctor if

- product has been used for 3 days
- ringing in the ears occurs
- you experience any of the following signs of stomach bleeding:
 - feel faint
 - vomit blood
 - have bloody or black stools
 - have stomach pain or upset that gets worse or lasts

If pregnant or breast feeding, ask a health professional before use. It is especially important not to use this product (which contains sodium salicylate) during the last three months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or problems during delivery.

Keep out of reach of children

In case of 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

- store at 59-86° F (15-30° C) in a dry place
- protect from light
- **each tablet contains: 23.7 mg sodium**

Questions?

Call 1-844-297-8394

Inactive ingredients

benzoic acid, cellulose, croscarmellose sodium, edible blank 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

PRINCIPAL DISPLAY PANEL

**CYSTEX®
Urinary Pain Relief (NSAID)**

Max Strength+

Fast relief of pain & burning plus helps control infection

40 Tablets

The Original Brand of Antibacterial Protection
Plus Pain Relief

ANTIBACTERIAL PROTECTION + PAIN RELIEF

Guaranteed Satisfaction, If you are not completely satisfied, send us a copy of your cash register receipt, UPC code # along with your full name and address and we will replace or refund your purchase. Limit one refund per household.

USE ONLY IF BLISTER UNIT IS UNBROKEN

Cystex is not intended to replace a doctor's care.

For more information on Cystex tablets or Urinary Tract infection please visit www.cystex.com or call 844-297-8394.

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The Original Brand of Antibacterial Protection
Plus Pain Relief



ANTIBACTERIAL PROTECTION

Cystex®
Urinary Pain Relief (NSAID)

Max Strength+
Fast relief of pain & burning plus
helps control infection

40 Tablets

Drug Facts continued
Number of Tablets: 40
Active Ingredients: Acetaminophen, Ibuprofen, and Phenazone.
Each tablet contains 325 mg of Acetaminophen, 200 mg of Ibuprofen, and 100 mg of Phenazone.
Other Ingredients: Cellulose, Dicalcium Phosphate Dihydrate, Hydroxypropyl Methylcellulose, Polyethylene Glycol 400, Polyethylene Glycol 600, Polyethylene Glycol 800, Polyethylene Glycol 1000, Polyethylene Glycol 1500, Polyethylene Glycol 2000, Polyethylene Glycol 3000, Polyethylene Glycol 4000, Polyethylene Glycol 6000, Polyethylene Glycol 8000, Polyethylene Glycol 10000, Polyethylene Glycol 15000, Polyethylene Glycol 20000, Polyethylene Glycol 30000, Polyethylene Glycol 40000, Polyethylene Glycol 60000, Polyethylene Glycol 80000, Polyethylene Glycol 100000.

Warnings: Do not take if you are allergic to acetaminophen, ibuprofen, or phenazone. Do not take if you have ever had a seizure. Do not take if you are pregnant or breastfeeding. Do not take if you are taking other NSAIDs. Do not take if you are taking other acetaminophen products. Do not take if you are taking other ibuprofen products. Do not take if you are taking other phenazone products. Do not take if you are taking other NSAID products. Do not take if you are taking other acetaminophen, ibuprofen, or phenazone products. Do not take if you are taking other NSAID products.

Directions: Adults and children 17 years and over: Take 2 tablets with a full glass of water 3 times a day. Child 12 years and over: Take 1 tablet with a full glass of water 3 times a day. Child 6 to 12 years: Take 1/2 tablet with a full glass of water 3 times a day. Child 2 to 6 years: Take 1/4 tablet with a full glass of water 3 times a day. Child 1 to 2 years: Take 1/8 tablet with a full glass of water 3 times a day.

Other Information: Contains 40 tablets in a blister pack. Each blister pack contains 20 tablets. Each blister pack contains 20 tablets.

Guaranteed Satisfaction, If you are not completely satisfied, send us a copy of your cash register receipt, UPC code # along with your full name and address and we will replace or refund your purchase. Limit one refund per household.

USE ONLY IF BLISTER UNIT IS UNBROKEN

CYSTEX
URINARY PAIN RELIEF TABLETS

Reye's Syndrome: Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using 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 a nonsteroidal anti-inflammatory drug (NSAID), which may cause stomach bleeding. The chance is higher if you: □ are age 60 or older □ have stomach ulcers or bleeding problems □ take a blood thinner (anticoagulant) or steroid drug □ take other drugs containing an NSAID (aspirin, ibuprofen, naproxen, or others) □ have 3 or more alcoholic drinks every day while using this product □ take more or for a longer time than directed

ATTENTION: USE ONLY IF TABLET BLISTER SEALS ARE UNBROKEN

CLARION BRANDS, LLC. 1-844-297-8394 5003



CYSTEX PLUS

methenamine, sodium salicylate tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69693-512
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)	
Fd&c Red No. 40 (UNII: WZB9127XOA)	
Fd&c Yellow No. 6 (UNII: H77VEI93A8)	
Hydroxypropyl Cellulose (160000 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	10 mm
Flavor		Imprint Code	CYSTEK
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69693-512-40	1 in 1 CARTON	05/01/2016	
1		40 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:69693-512-20	1 in 1 CARTON	05/01/2016	
2		20 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		11/01/2015	

Labeler - Clarion Brands, LLC (079742703)**Establishment**

Name	Address	ID/FEI	Business Operations
ULTRA SEAL CORPORATION		085752004	PACK(69693-512)

Establishment

Name	Address	ID/FEI	Business Operations
ULTRAtab Laboratories, Inc.		151051757	MANUFACTURE(69693-512)

Revised: 12/2020

Clarion Brands, LLC