

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)	Purposes
Methenamine 162 mg	Antibacterial
Sodium Salicylate 162.5 mg (NSAID)*	Analgesic (Pain Reliever)
* nonsteroidal anti-inflammatory drug	

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. 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 thinning (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)

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
- a sodium restricted diet
- reach age 60 or older

Ask a doctor or pharmacist before use if you are

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

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
- 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 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

Keep out of the reach of children. In case of overdose, get medical help or contact a Poison Control Center right away 1-800-222-1222.

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.

Do not use for more than a 3 day period unless directed by a doctor.

Other information

- **each tablet contains:** sodium 24.4 mg

- store at 59-86°F (15-30°C) in a cool dry place
- protect from sunlight

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 titanium dioxide, triethyl citrate

Questions or comments?

1-844-297-8394

PRINCIPAL DISPLAY PANEL

VALUE SIZE! 2x More Tablets[‡]

MAX STRENGTH

Cystex[®]

Methenamine 162 mg **ANTIBACTERIAL** | Sodium Salicylate 162.5 mg **(NSAID) PAIN RELIEVER**

UTI PAIN RELIEF

+ UTI BACTERIA CONTROL

Fast relief of pain & burning
plus helps control UTI bacteria

Maximum Strength UTI Pain Relief

Formulated without Urine Discoloring Ingredients[†]

#1 OTC Ingredient for UTI Bacteria Control^{*}

[†]Does not contain urine coloring agents as found in other leading UTI products

[‡]Compared to 2023 leading UTI Relief Brands

48 Tablets

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

TAMPER EVIDENT: TABLETS SEALED IN BLISTER. DO NOT USE IF BLISTER IS OPENED OR DAMAGED.

1000221

REV 7/23 CSTX048BRI

MAX STRENGTH

**Cystex®
Urinary Health Made Easy™**

For more information on Cystex
UTI Pain Relief, other products,
or Urinary Tract Infections (UTIs)
please visit www.cyxtex.com
or call 844-297-8394

MAX STRENGTH

**Cystex®
Urinary Health Made Easy™**

Distributed by: Cystex, LLC
811 Broad Street, Suite 600
Chattanooga, TN 37402 @2023

*Source: IRI Sales Data, 2023

P16919
48ct.

Knockout for Expiration
Date and Lot Number



Principal Display for Blister Pack

CYSTEX

Methenamine 162 mg / Sodium Salicylate 162.5 mg (NSAID)

URINARY PAIN RELIEF TABLETS

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than directed.

**ATTENTION: USE ONLY IF TABLET
BLISTER SEALS ARE UNBROKEN**

LOT: X00X000 EXP: MM/YY

CYSTEX, LLC. 1-844-297-8394

1000075

CYSTEX
Methenamine 162 mg / Sodium Salicylate 162.5 mg (NSAID)
URINARY PAIN RELIEF TABLETS

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**ATTENTION: USE ONLY IF TABLET
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LOT: X00X000 EXP: MM/YY
CYSTEX, LLC. 1-844-297-8394 1000075

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: MQ1H85SYP) (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)	
Hypromellose, Unspecified (UNII: 3NXW29V3WO)	
Magnesium Stearate (UNII: 70097M6I30)	
Methacrylic Acid And Ethyl Acrylate Copolymer (UNII: NX76LV5T8J)	
Microcrystalline Cellulose (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	10mm
Flavor		Imprint Code	CYSTEX
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		
3	NDC:69693-512-24	1 in 1 CARTON	06/01/2022	
3		24 in 1 BLISTER PACK; Type 0: Not a Combination Product		
4	NDC:69693-512-48	1 in 1 CARTON	06/01/2022	
4		48 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
Pharbest Pharmaceuticals, Inc.		557054835	manufacture(69693-512)

Revised: 12/2023

Clarion Brands, LLC