

**CYSTEX- 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.*

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**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 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****NEW Large Size!***Now 48 Tablets***MAX STRENGTH****Cystex<sup>®</sup>****Methenamine 162 mg & Sodium Salicylate 162.5 mg (NSAID)****UTI PAIN RELIEF (NSAID)****+ BACTERIA CONTROL****Fast relief of pain & burning  
plus helps control UTI bacteria****Maximum Strength****#1 OTC Ingredient for UTI Bacteria Control\***

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

**48 Tablets****TAMPER EVIDENT: TABLETS SEALED IN BLISTER. DO NOT USE IF BLISTER IS OPENED OR DAMAGED.****REV 3/22 CSTX048BRI****MAX STRENGTH****Cystex<sup>®</sup>****Urinary Health Made Easy™**

For more information on Cystex tablets or  
Urinary Tract Infections please visit  
[www.cystex.com](http://www.cystex.com) or call 844-297-8394.  
\*Source: IRI Sales Data, 2022.

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## **MAX STRENGTH**

**Cystex<sup>®</sup>**  
**Urinary Health Made Easy<sup>™</sup>**

1000069

*P16250*  
*48ct.*



## CYSTEX

Methenamine 162 mg / Sodium Salicylate 162.5 mg (NSAID)

### URINARY PAIN RELIEF TABLETS

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

LOT: X00X000 EXP: MM/YY

CYSTEX, LLC. 1-844-297-8394

1000075

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## CYSTEX

methenamine, sodium salicylate tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69693-513(NDC:69693-512)
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Methenamine</b> (UNII: J50OIX95QV) (Methenamine - UNII:J50OIX95QV)	Methenamine	162 mg
<b>Sodium Salicylate</b> (UNII: MQ1H85SYP) (Salicylic Acid - UNII:O414PZ4LPZ)	Sodium Salicylate	162.5 mg

### Inactive Ingredients

Ingredient Name	Strength
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<b>Benzoic Acid</b> (UNII: 8SKN0B0MIM)
<b>Croscarmellose Sodium</b> (UNII: M28OL1HH48)
<b>Fd&amp;c Red No. 40</b> (UNII: WZB9127XOA)
<b>Fd&amp;c Yellow No. 6</b> (UNII: H77VEI93A8)
<b>Hypromellose, Unspecified</b> (UNII: 3NXW29V3WO)
<b>Magnesium Stearate</b> (UNII: 70097M6I30)
<b>Methacrylic Acid - Ethyl Acrylate Copolymer (1:1) Type A</b> (UNII: NX76LV5T8J)
<b>Microcrystalline Cellulose</b> (UNII: OP1R32D61U)
<b>Silicon Dioxide</b> (UNII: ETJ7Z6XBU4)
<b>Stearic Acid</b> (UNII: 4ELV7Z65AP)
<b>Sodium Bicarbonate</b> (UNII: 8MDF5V39QO)
<b>Sodium Lauryl Sulfate</b> (UNII: 368GB5141J)
<b>Talc</b> (UNII: 7SEV7J4R1U)
<b>Titanium Dioxide</b> (UNII: 15FIX9V2JP)
<b>Triacetin</b> (UNII: XHX3C3X673)
<b>Triethyl Citrate</b> (UNII: 8Z96QXD6UM)

### Product Characteristics

<b>Color</b>	RED	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	10mm
<b>Flavor</b>		<b>Imprint Code</b>	CYSTEX
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69693-513-24	1 in 1 CARTON	06/01/2022	
1		24 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:69693-513-48	1 in 1 CARTON	06/01/2022	
2		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		06/01/2022	

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

### Establishment

Name	Address	ID/FEI	Business Operations
Pharbest Pharmaceuticals, Inc.		557054835	manufacture(69693-513)

Revised: 12/2023

Clarion Brands, LLC