

CYSTEX- methenamine, sodium salicylate tablet
Clarion Brands, LLC

Drug Facts

Active Ingredients

Methenamine 162 mg

Antibacterial

Sodium Salicylate 162.5 mg (NSAID*) *nonsteroidal anti-inflammatory drug.....Analgesic (pain reliever)

Purposes

Antibacterial

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 are

- 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

- 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 (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.

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, 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

PRINCIPAL DISPLAY PANEL

DUAL ACTION

Cystex®

Urinary Health

Methenamine 162 mg | Sodium Salicylate 162.5 mg **(NSAID)**

PAIN RELIEF (NSAID)

+ UTI BACTERIA CONTROL

2-in-1 Formula to Help Slow UTI Bacteria Growth and Provide General Pain Relief

Helps Control
UTI infection

Formulated for no
Urine Discoloration

#1 Ingredient for UTI BACTERIAL Control*

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

24 Tablets

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

Distributed by: Cystex, LLC 811 Broad Street
Suite 600, Chattanooga, TN 37402 ©2024
Call 844-297-8394 or visit Cystex.com

*Source: IRI Sales Data, 2023.

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

1000288
Made In India
RA/Drug/RAJ.-1750

Cystex DUAL ACTION

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Urinary Health

Methenamine 162 mg | Sodium Salicylate 162.5 mg (NSAID)

PAIN RELIEF (NSAID)

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2-in-1 Formula to Help Slow UTI Bacteria Growth and Provide General Pain Relief

- Helps Control UTI Infection
- Formulated for no Urine Discoloration*

#1 INGREDIENT for UTI BACTERIAL CONTROL²

24 tablets

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

8 89476 51024 0

Lot Code /Expiration

1000280
Made in India
RA/Drug/RAJL-1700

1

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

Drug Facts

Active ingredients	Purposes
Methenamine 162 mg	Antibacterial
Sodium salicylate 162.5 mg (NSAID) ¹	*nonsteroidal anti-inflammatory drug Analgesic (pain reliever)

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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 ■ 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 ■ sodium-restricted diet ■ reached age 60 or older

Ask a doctor or pharmacist before use if you are ■ taking any other drug containing a 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

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1

48 tablets

1000273

Cystex DUAL ACTION

Cystex DUAL ACTION
Urinary Health

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48 tablets

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8 89476 51248 0

Lot Code /Expiration

1000273
Made in India
RA/Drug/RAJL-1750

1

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CYSTEX

methenamine, sodium salicylate tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69693-518
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)	
Powdered Cellulose (UNII: SMD1X3X09M)	
Croscarmellose Sodium (UNII: M28OL1HH48)	
Fd&c Red No. 40 (UNII: WZB9127XOA)	
Fd&c Yellow No. 6 (UNII: H77VEI93A8)	
Hydroxypropyl Cellulose, Unspecified (UNII: 9XZ8H6N6OH)	
Hypromellose, Unspecified (UNII: 3NXW29V3WO)	
Magnesium Stearate (UNII: 70097M6I30)	
Methacrylic Acid And Ethyl Acrylate Copolymer (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	CYSTEX
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69693-518-24	1 in 1 CARTON	11/01/2024	
1		24 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:69693-518-48	1 in 1 CARTON	11/01/2024	
2		48 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
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Category	Citation	Date	Date
OTC Monograph Drug	505G(a)(3)	11/01/2024	

Labeler - Clarion Brands, LLC (079742703)

Revised: 12/2024

Clarion Brands, LLC