

METHENAMINE AND SODIUM SALICYLATE (NSAID)- methenamine, sodium salicylate tablet
Drug Ocean 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.

METHENAMINE AND SODIUM SALICYLATE (NSAID) TABLETS

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 1-844-200-6566

Distributed by:

Drug Ocean LLC
1 Bridge Plaza, North Central Road,
6th Floor, Suite 675,
Fort Lee, NJ 07024

Made in India

Mfg License Code:
RA/Drug/RAJ.-1750

ORG 03/2024

Carton Label

DRUG OCEAN NDC 70985- **030-11**

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

Antibacterial Urinary Pain Relief

- **Helps Control the Infection***
- **Plus General Pain Reliever**

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

18 Tablets

The image displays the packaging for Methenamine and Sodium Salicylate (NSAID) Tablets. The front panel features the Drug Ocean logo and the product name in large, bold letters. Below the name, the strengths '162 mg ; 162.5 mg' are prominently displayed. A blue banner indicates 'Antibacterial Urinary Pain Relief', followed by the key benefits: 'Helps Control the Infection*' and 'Plus General Pain Reliever'. A note states: '*Helps inhibit the progression of infection until you see a healthcare professional. This product is not intended to replace medical care.' The quantity '18 Tablets' is also shown.

The side panel includes the following information:

- Distributed by:** Drug Ocean LLC, 1 Bridge Plaza, North Central Road, 6th Floor, Suite 675, Fort Lee, NJ 07024
- Made in India**
- Mfg License code:** RA/Drug/RAJ.-1750
- ORG 03/2024**
- A barcode with the number 201709850301119
- The text 'DRUG OCEAN' and the company logo are repeated vertically.

The **Drug Facts** section on the side panel provides the following details:

- Active ingredient (in each tablet):** Methenamine 162 mg, Sodium Salicylate 162.5 mg (NSAID Nonsteroidal Anti-Inflammatory Drug)...
- Purpose:** Antibacterial (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 behaviour 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 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 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.
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The bottom of the side panel shows the text 'xxxxxx'.



NDC 70985-030-11

Methenamine and Sodium Salicylate (NSAID) Tablets

Antibacterial Urinary Pain Relief

18 Tablets

Each tablet contains:

162 mg Methenamine (Antibacterial) and
162.5 mg Sodium Salicylate (Analgesic/NSAID)

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 a non-steroidal anti-inflammatory drug (NSAID), which may cause stomach bleeding.

The chance is higher if you:

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

Helps inhibit the progression of infection until you see a healthcare professional.

This product is not intended to replace medical care.

To Remove: gently press tablet from the other side through foil, or slit foil open before pushing tablets out.

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

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Mfg License code: RA/Drug/RAJ.-1750

Methenamine and Sodium Salicylate (NSAID) Tablets
18 Tablets
 Antibacterial Urinary Pain Relief

NDC 70985-030-11

DRUG OCEAN



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 Made in India
 Mfg License code: RA/Drug/RAJ.-1750

Carton Label

DRUG OCEAN NDC 70985- 030-13

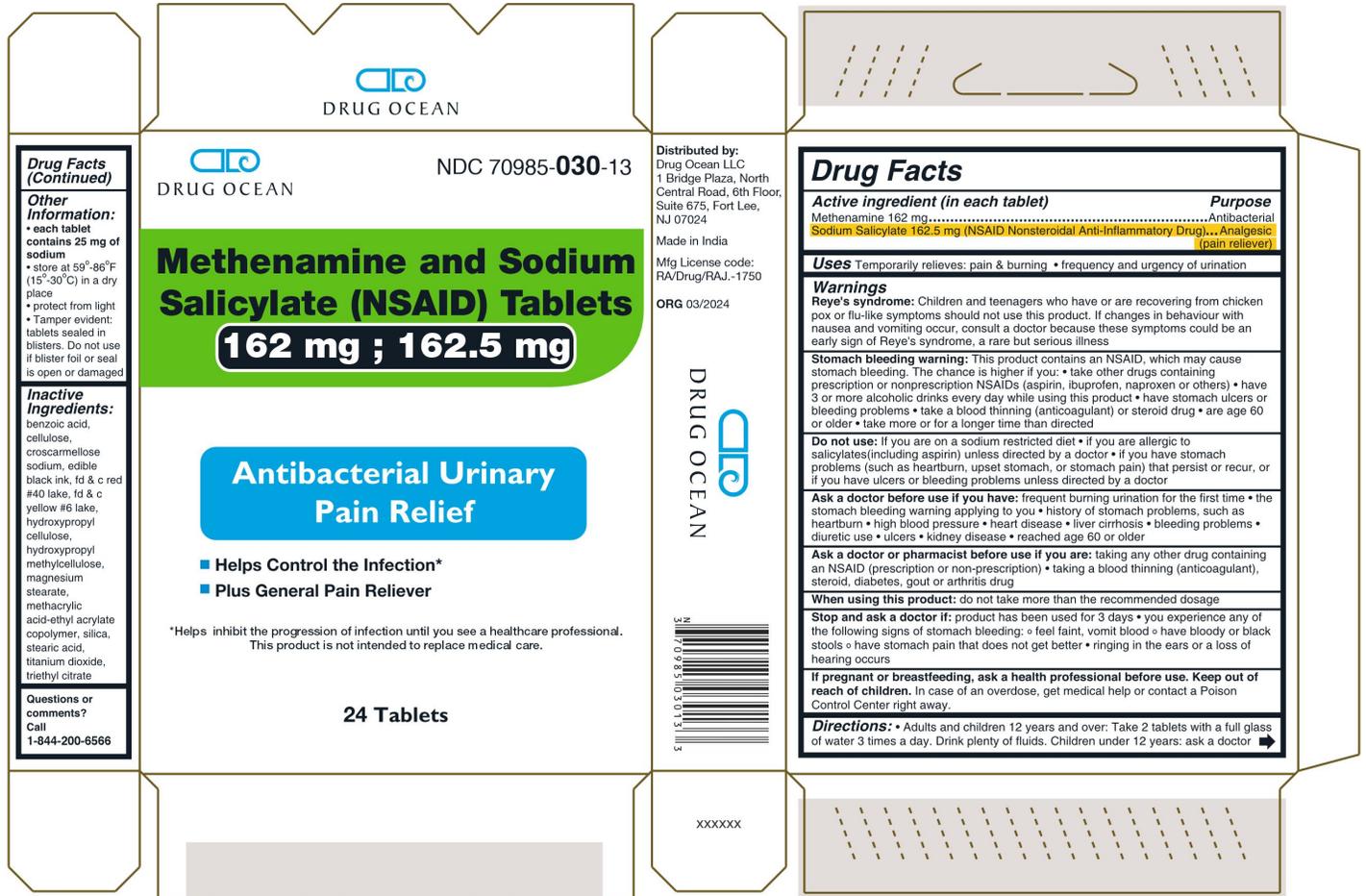
Methenamine and Sodium Salicylate (NSAID) Tablets 162 mg; 162.5 mg

Antibacterial Urinary Pain Relief

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24 Tablets



Blister Label



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(aspirin, ibuprofen, naproxen, or others)

Methenamine and Sodium Salicylate (NSAID) Tablets
 Antibacterial Urinary Pain Relief
24 Tablets
 Each tablet contains:
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- take a blood thinning (anticoagulant) or steroid drug
- take other prescription or nonprescription drugs containing NSAID

DRUG OCEAN


NDC 70985-030-13

METHENAMINE AND SODIUM SALICYLATE (NSAID)
 methenamine, sodium salicylate tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70985-030
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		Strength
Ingredient Name		
BENZOIC ACID (UNII: 8SKN0B0MIM)		
POWDERED CELLULOSE (UNII: SMD1X3XO9M)		
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)		
FERROSFERRIC 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:70985-030-11	1 in 1 BOX	03/12/2024	
1		18 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:70985-030-13	1 in 1 BOX	03/12/2024	
2		24 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		03/12/2024	

Labeler - Drug Ocean LLC (080381835)