

# **METHENAMINE HIPPURATE- methenamine hippurate tablet** **Bionpharma Inc.**

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## **Methenamine Hippurate Tablets USP** **Rx only**

To reduce the development of drug-resistant bacteria and maintain the effectiveness of methenamine hippurate tablets and other antibacterial drugs, methenamine hippurate tablets should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.

### **DESCRIPTION**

Each yellow capsule-shaped tablet contains 1 g Methenamine Hippurate which is the hippuric acid salt of methenamine (hexamethylene tetramine). The tablet also contains inactive ingredients FD&C Yellow No. 5 (tartrazine, see **PRECAUTIONS**), magnesium stearate, povidone, and saccharin sodium.

### **ACTIONS**

**Microbiology:** Methenamine hippurate tablets has antibacterial activity because the methenamine component is hydrolyzed to formaldehyde in acid urine. Hippuric acid, the other component, has some antibacterial activity and also acts to keep the urine acid. The drug is generally active against *E. coli*, enterococci and staphylococci. *Enterobacter aerogenes* generally resistant. The urine must be kept sufficiently acid for urea-splitting organisms such as *Proteus* and *Pseudomonas* to be inhibited.

**Human Pharmacology:** Within 1/2 hour after ingestion of a single 1-gram dose of methenamine hippurate tablets, antibacterial activity is demonstrable in the urine. Urine has continuous antibacterial activity when methenamine hippurate tablets is administered at the recommended dosage schedule of 1-gram twice daily. Over 90% of methenamine moiety is excreted in the urine within 24 hours after administration of a single 1-gram dose. Similarly, the hippurate moiety is rapidly absorbed and excreted, and it reaches the urine by both tubular secretion and glomerular filtration. This action may be important in older patients or in those with some degree of renal impairment.

### **INDICATIONS**

Methenamine hippurate tablets is indicated for prophylactic or suppressive treatment of frequently recurring urinary tract infections when long-term therapy is considered necessary. This drug should only be used after eradication of the infection by other appropriate antimicrobial agents.

To reduce the development of drug-resistant bacteria and maintain the effectiveness of methenamine hippurate tablets and other antibacterial drugs, methenamine hippurate tablets should be used only to treat or prevent infections that are proven or

strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

## **CONTRAINDICATIONS**

Methenamine hippurate tablets is contraindicated in patients with renal insufficiency, severe hepatic insufficiency, or severe dehydration. Methenamine preparations should not be given to patients taking sulfonamides because some sulfonamides may form an insoluble precipitate with formaldehyde in the urine.

## **WARNING**

Large doses of methenamine (8 grams daily for 3 to 4 weeks) have caused bladder irritation, painful and frequent micturition, albuminuria, and gross hematuria.

## **PRECAUTIONS**

Prescribing methenamine hippurate tablets in the absence of a proven or strongly suspected bacterial infection or a prophylactic indication is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

1. Care should be taken to maintain an acid pH of the urine, especially when treating infections due to urea-splitting organisms such as *Proteus* and strains of *Pseudomonas*.
2. In a few instances in one study, the serum transaminase levels were slightly elevated during treatment but returned to normal while the patients were still taking methenamine hippurate tablets. Because of this report, it is recommended that liver function studies be performed periodically on patients taking the drug, especially those with liver dysfunction.

3. Use in Pregnancy: In early pregnancy the safe use of methenamine hippurate tablets is not established. In the last trimester, safety is suggested, but not definitely proved. No adverse effects on the fetus were seen in studies in pregnant rats and rabbits.

Methenamine hippurate tablets taken during pregnancy can interfere with laboratory tests of urine estriol (resulting in unmeasurably low values) when acid hydrolysis is used in the laboratory procedure. This interference is due to the presence in the urine of methenamine and/or formaldehyde. Enzymatic hydrolysis, in place of acid hydrolysis, will circumvent this problem.

4. This product contains FD&C Yellow No. 5 (tartrazine), which may cause allergic-type reactions (including bronchial asthma) in certain susceptible individuals. Although the overall incidence of FD&C Yellow No. 5 (tartrazine) sensitivity in the general population is low, it is frequently seen in patients who also have aspirin hypersensitivity.

## **Geriatric Use**

Clinical studies of methenamine hippurate tablets did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in

responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal or cardiac function, and of concomitant disease or other drug therapy.

Methenamine hippurate tablets is contraindicated in patients with renal insufficiency and severe hepatic insufficiency ( see **CONTRAINDICATIONS**).

### **Information for Patients**

Patients should be counseled that antibacterial drugs including methenamine hippurate tablets should only be used to treat bacterial infections. They do not treat viral infections (e.g., the common cold). When methenamine hippurate tablets is prescribed to treat a bacterial infection, patients should be told that although it is common to feel better early in the course of therapy, the medication should be taken exactly as directed. Skipping doses or not completing the full course of therapy may (1) decrease the effectiveness of the immediate treatment and (2) increase the likelihood that bacteria will develop resistance and will not be treatable by methenamine hippurate tablets or other antibacterial drugs in the future.

### **ADVERSE REACTIONS**

Minor adverse reactions have been reported in less than 3.5% of patients treated. These reactions have included nausea, upset stomach, dysuria, and rash.

To report SUSPECTED ADVERSE REACTIONS, contact Bionpharma Inc. at 1-888-235-2466 or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

### **DOSAGE AND ADMINISTRATION**

1 Tablet (1.0 g) twice daily (morning and night) for adults and pediatric patients over 12 years of age. 1/2 to 1 tablet (0.5 to 1.0 g) twice daily (morning and night) for pediatric patients 6 to 12 years of age. Since the antibacterial activity of methenamine hippurate tablets is greater in acid urine, restriction of alkalinizing foods and medications is desirable. If necessary, as indicated by urinary pH and clinical response, supplemental acidification of the urine should be instituted. The efficacy of therapy should be monitored by repeated urine cultures.

### **HOW SUPPLIED**

Yellow, capsule shaped tablet debossed with E50 on one side and scored on other side, available in bottle of 100's (NDC 69452-470-20).

Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) (See USP Controlled Room Temperature)

Dispense in well-closed, light-resistant container with child-resistant closure.

Manufactured by:  
**Esjay Pharma Private Limited,**  
India


Distributed by:  
**Bionpharma Inc.**  
Princeton, NJ 08540, USA

P3218/00/24

Rev. 12/2024

## PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

### Container Label (100s)

<b>NDC 69452-470-20</b> <b>Methenamine Hippurate Tablets, USP</b> <b>1 g</b> 100 Tablets Rx only <b>BIONPHARMA</b>	Each tablet contains: Methenamine Hippurate, USP 1 g. FD&C Yellow No.5 (Tartrazine) as a color additive <b>Dosage and Administration:</b> See package insert for dosage information. <b>WARNING:</b> Keep out of reach of children. <b>Pharmacist:</b> Dispense in well-closed, light-resistant container with child-resistant closure. <b>Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) [See USP Controlled Room Temperature].</b> Distributed by: <b>Bionpharma Inc.</b> Princeton, NJ 08540, USA Manufactured by: <b>Esjay Pharma Private Limited</b> India	 6 Mfg. Lic. No. TN/25/00074 P3219/00/24 Rev. 11/24 3 69452 47020 6
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## METHENAMINE HIPPURATE

methenamine hippurate tablet

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:69452-470
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>METHENAMINE HIPPURATE</b> (UNII: M329791L57) (METHENAMINE - UNII:J500IX95QV)	METHENAMINE HIPPURATE	1 g

### Inactive Ingredients

Ingredient Name	Strength
<b>FD&amp;C YELLOW NO. 5</b> (UNII: I753WB2F1M)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	

SACCHARIN SODIUM (UNII: SB8ZUX40TY)

### Product Characteristics

<b>Color</b>	yellow	<b>Score</b>	2 pieces
<b>Shape</b>	CAPSULE	<b>Size</b>	19mm
<b>Flavor</b>		<b>Imprint Code</b>	E50
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69452-470-20	100 in 1 BOTTLE; Type 0: Not a Combination Product	01/16/2025	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA017681	01/16/2025	

**Labeler** - Bionpharma Inc. (079637826)

Revised: 1/2025

Bionpharma Inc.