METHENAMINE HIPPURATE- methenamine hippurate tablet
American Health Packaging

Methenamine Hippurate Tablets, USP
Rx Only
8469421/0622F

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

DESCRIPTION

Each white to off-white capsule-shaped tablet contains 1 g Methenamine Hippurate USP which is the Hippuric Acid Salt of Methenamine (hexamethylene tetramine). The tablet also contains inactive ingredients Colloidal silicon dioxide, magnesium stearate and povidone K90.

ACTIONS

Microbiology: Methenamine hippurate 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* is generally resistant. The urine must be kept sufficiently acid for urea-splitting organisms such as *Proteus* and *Pseudomonas* to be inhibited.

Susceptibility Testing
For specific information regarding susceptibility test interpretive criteria and associated test methods and quality control standards recognized by FDA for this drug, please see: https://www.fda.gov/STIC.

Human Pharmacology: Within 1/2 hour after ingestion of a single 1-gram dose of methenamine hippurate, antibacterial activity is demonstrable in the urine. Urine has continuous antibacterial activity when methenamine hippurate 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 USP are 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 and other antibacterial drugs, methenamine hippurate 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 USP are 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.

WARNINGS

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 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. 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 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 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.

Geriatric Use

Clinical studies of methenamine hippurate 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 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 should only be used to treat bacterial infections. They do not treat viral infections (e.g., the common cold). When methenamine hippurate 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 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 Micro Labs USA Inc. at 1-855-839-8195 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DOSAGE AND ADMINISTRATION

1 tablet (1 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 g) twice daily (morning and night) for pediatric patients 6 to 12 years of age. Since the antibacterial activity of methenamine hippurate 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

White to off white colored, capsule shaped, biconvex tablets, debossed with "H" and "1" on either side of breakline on one side and other side plain with approximate length 20.00 mm, width 8.00 mm and thickness 7.40 mm.
Unit dose packages of 30 (3 x 10) NDC 60687-694-21

Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C and 30°C (59°F and 86°F) [see USP Controlled Room Temperature].

FOR YOUR PROTECTION: Do not use if blister torn or broken.

PACKAGING INFORMATION

American Health Packaging unit dose blisters (see How Supplied section) contain drug product from Micro Labs USA, Inc. as follows:

(1 g / 30 UD) NDC 60687-694-21 packaged from NDC 42571-332

Distributed by:
American Health Packaging
Columbus, OH 43217

8469421/0622F

Package/Label Display Panel – Carton – 1 g

NDC 60687- **694**-21

Methenamine Hippurate
Tablets, USP

1 g

30 Tablets (3 x 10) **Rx Only**

Each Tablet Contains:
Methenamine Hippurate, USP..... 1 g

Usual Dosage: See full prescribing information.

Store at 20° to 25°C (68° to 77°F); excursions permitted between 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].

FOR YOUR PROTECTION: Do not use if blister is torn or broken.

The drug product contained in this package is from NDC # 42571-332, Micro Labs USA, Inc.

Distributed by: American Health Packaging, Columbus, Ohio 43217

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0469421/0824

Package/Label Display Panel – Blister – 1 g

Methenamine Hippurate
Tablet, USP

1 g

METHENAMINE HIPPURATE
methenamine hippurate tablet
Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:60687-694(NDC:42571-332)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
METHENAMINE HIPPURATE (UNII: M329791L57) (METHENAMINE - UNII:J50OIX95QV)	METHENAMINE HIPPURATE	1000 mg

Inactive Ingredients

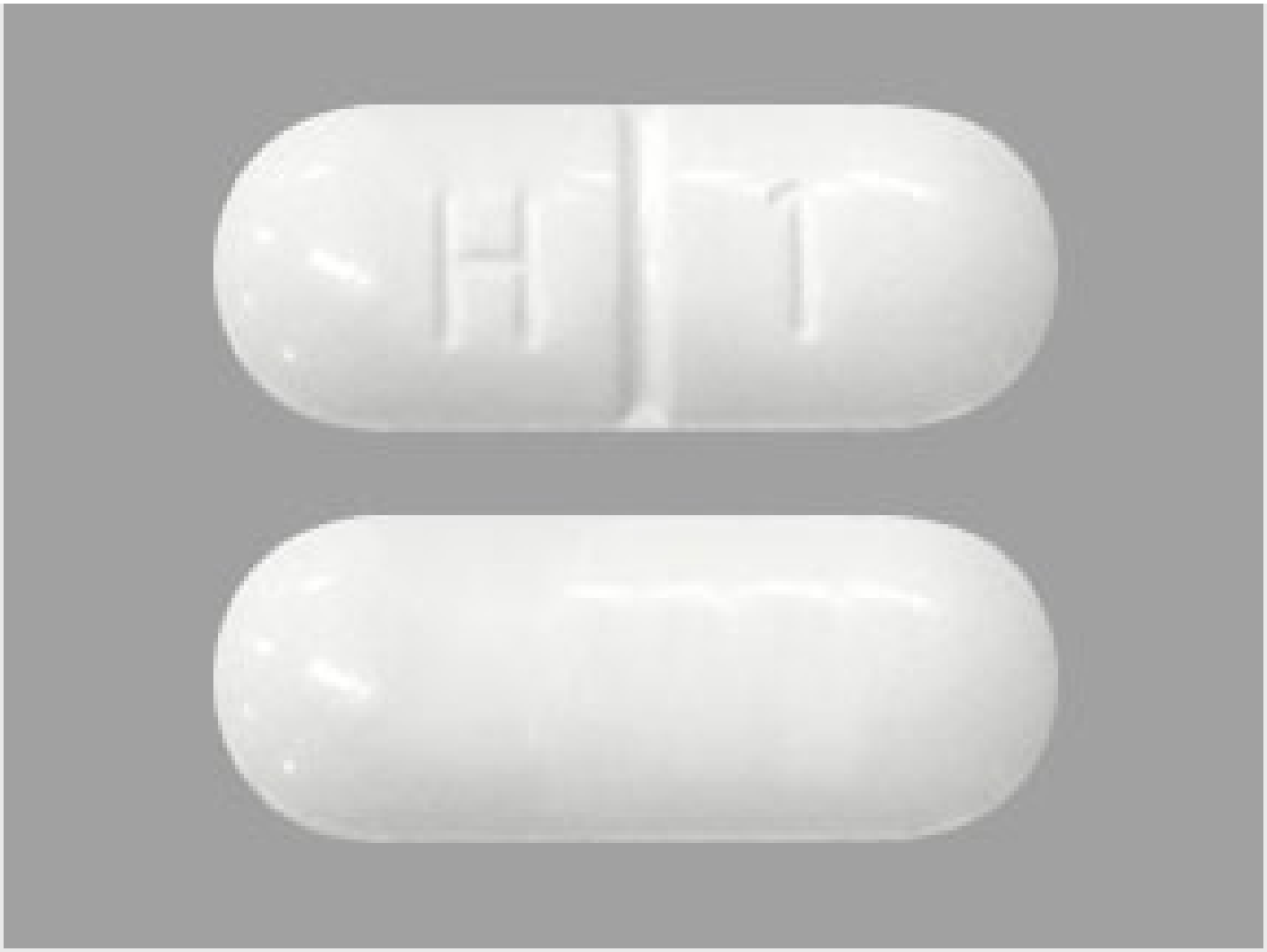
Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POVIDONE K90 (UNII: RDH86HJV5Z)	

Product Characteristics

Color	white (White to Off-white)	**Score**	2 pieces
Shape	CAPSULE	**Size**	20mm
Flavor		**Imprint Code**	H;1
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60687-694-21	30 in 1 CARTON	08/12/2022	
1	NDC:60687-694-11	1 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
ANDA	ANDA212172	08/12/2022	

Labeler - American Health Packaging (929561009)

Establishment

Name	Address	ID/FEI	Business Operations
American Health Packaging		929561009	repack(60687-694)

Revised: 9/2024 American Health Packaging