

METHENAMINE HIPPURATE- methenamine hippurate tablet
Jubilant Cadista Pharmaceuticals Inc.

Methenamine Hippurate Tablets, USP

To reduce the development of drug-resistant bacteria and maintain the effectiveness of methenamine hippurate tablets 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 bacteria.

DESCRIPTION

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

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* 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 1gram 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 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, USP 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 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 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.

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, USP. 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.

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, USP are 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 Jubilant Cadista Pharmaceuticals Inc. at 1-800-313-4623 or FDA at 1-800-FDA-1088 or 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 g) twice daily (morning and night) for pediatric patients 6 to 12 years of age. Since the antibacterial activity of methenamine hippurate tablets, USP 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

Methenamine Hippurate Tablets USP, 1 g are white to off-white capsule shaped tablet, debossed with "L" and "59" on one side and break line (functional) on other side.

Bottle pack of 20 tablets with Child Resistant Closure, NDC 59746-797-65
Bottle pack of 100 tablets with Child Resistant Closure, NDC 59746-797-01

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

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

Rx Only

Distributed by:

Jubilant Cadista Pharmaceuticals Inc.
Salisbury, MD 21801, USA.

Manufactured by:

Unichem Laboratories Limited,
Plot No. 10 to 18, Pilerne Industrial Estate,
Pilerne, Bardez, Goa - 403511, India (IND)

Revision 01/2024

PRINCIPAL DISPLAY PANEL**NDC 59746-797-65****Methenamine
Hippurate Tablets, USP****1 gram****CADISTA****20 Tablets****Rx Only****Each Tablet contains:**

Methenamine Hippurate USP 1g.

Usual Dosage: see package
insert for dosage information.

Warning: Keep out of the reach of
children.

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

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

Code: G0/DRUGS/321


Distributed by:

Jubilant Cadista Pharmaceuticals Inc.
Salisbury, MD 21801, USA

Made in India

13015249

Rev. # 01/24



3 59746 79765 2

Each Tablet contains:
Methenamine Hippurate USP 1g.

Usual Dosage: see package insert for dosage information.

Warning: Keep out of the reach of children.

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

Code: GO/DRUGS/321

NDC 59746-797-65

Methenamine Hippurate Tablets, USP

1 gram



20 Tablets **R Only**

Distributed by:
Jubilant Cadista Pharmaceuticals Inc.
Salisbury, MD 21801, USA
Made in India

13015249


UNVARNISHED AREA

NDC 59746-797-01

100 Tablets

13015250

Rev. # 01/24



3 59746 79701 0

Each Tablet contains:
Methenamine Hippurate USP 1 g.

Usual Dosage: see package insert for dosage information.

Warning: Keep out of the reach of children.

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


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

Code: GO/DRUGS/321

NDC 59746-797-01

Methenamine Hippurate Tablets, USP

1 gram



100 Tablets **R Only**

Distributed by:
Jubilant Cadista Pharmaceuticals Inc.
Salisbury, MD 21801, USA
Made in India

13015250

UNVARNISHED AREA

METHENAMINE HIPPURATE

methenamine hippurate tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:59746-797
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
METHENAMINE HIPPURATE (UNII: M329791L57) (METHENAMINE - UNII:J50OIX95QV)	METHENAMINE HIPPURATE	1 g

Inactive Ingredients

Ingredient Name	Strength
Silicon Dioxide (UNII: ETJ7Z6XBU4)	
Microcrystalline Cellulose (UNII: OP1R32D61U)	
Magnesium Stearate (UNII: 70097M6I30)	
Povidone, Unspecified (UNII: FZ989GH94E)	
Sodium Starch Glycolate Type A (UNII: H8AV0SQX4D)	

Product Characteristics

Color	WHITE (White to off white)	Score	2 pieces
Shape	CAPSULE	Size	19mm
Flavor		Imprint Code	L;59
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59746-797-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	01/24/2023	
2	NDC:59746-797-65	20 in 1 BOTTLE; Type 0: Not a Combination Product	01/24/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA217675	01/24/2023	

Labeler - Jubilant Cadista Pharmaceuticals Inc. (022490515)

Establishment

Name	Address	ID/FEI	Business Operations
Unichem Laboratories Limited		915389741	analysis(59746-797) , label(59746-797) , manufacture(59746-797) , pack(59746-797)

