

METHENAMINE HIPPURATE- methenamine hippurate tablet

Ingenus Pharmaceuticals, LLC

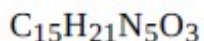
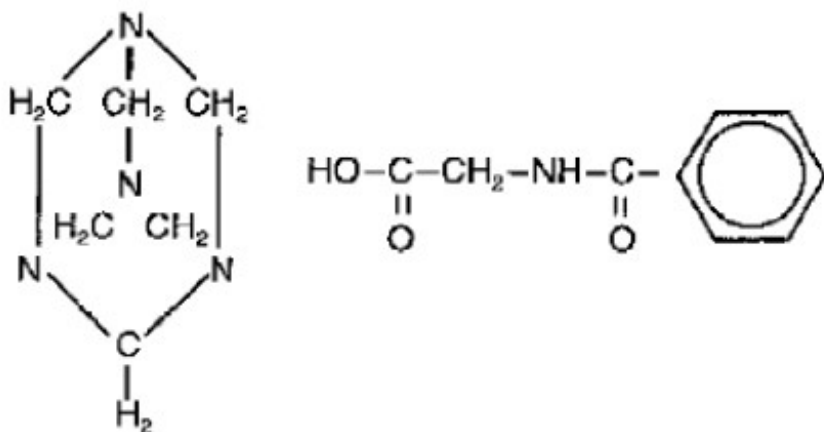
Methenamine Hippurate Tablets, USP

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

DESCRIPTION

Methenamine Hippurate Tablets, USP is a urinary tract antiseptic drug. Each peach color, capsule-shaped bi-convex 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. 6, Magnesium Stearate, Colloidal Silicon Dioxide, Povidone, and Saccharin Sodium.

Structural Formula:



Molecular Weight 319.37

ACTIONS

Microbiology

Methenamine hippurate tablets have 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 tablets antibacterial activity is demonstrable in the urine. Urine has continuous antibacterial activity when methenamine hippurate tablets are 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 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 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 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 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.

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 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 are 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 Ingenus Pharmaceuticals, LLC at 1-877-748-1970 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 1.0 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

Peach colored, capsule shaped, biconvex tablets debossed with "I" and "7" on one side and scoreline on two sides, free from mottled surface in bottles of 100 (NDC 50742-142-01).

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

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

Manufactured for:

Ingenus Pharmaceuticals, LLC


Orlando, FL 32839-6408

553501

Revised: 12/2020

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

6" Width



NDC 50742-142-01

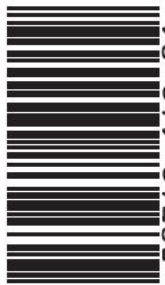
**Methenamine Hippurate
Tablets, USP**

1 gram

Rx Only
100 Tablets

Each Tablet contains:
Methenamine hippurate USP 1g.
Usual Dosage: See package insert for dosage information.
Warning: Keep out of reach of children.
Pharmacist: Dispense in well-closed, light-resistant container with child-resistant closure.
Store at 25°C (77°F); excursions permitted to 15-30°C (59-86°F) [see USP Controlled Room Temperature].

510201


N 50742-142-01 9

**NO VARNISH
2.5" x 1"**

2.5" Height

Manufactured for:
Ingenus Pharmaceuticals, LLC
Orlando, FL 32839-6408

142-01 v2/12-2020

Container Label - 100s Count

METHENAMINE HIPPURATE

methenamine hippurate tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:50742-142
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
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
POVIDONE (UNII: FZ989GH94E)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

Product Characteristics

Color	ORANGE (Peach)	Score	2 pieces
Shape	CAPSULE	Size	19mm
Flavor		Imprint Code	I;7
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50742-142-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	12/18/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA210068	12/18/2020	

Labeler - Ingenus Pharmaceuticals, LLC (833250017)

Registrant - Novast Laboratories Ltd. (527695995)

Establishment

Name	Address	ID/FEI	Business Operations
Ingenus Pharmaceuticals NJ, LLC		964680206	ANALYSIS(50742-142) , LABEL(50742-142) , MANUFACTURE(50742-142) , PACK(50742-142)

Revised: 9/2021

Ingenus Pharmaceuticals, LLC