METHENAMINE MANDELATE- methenamine mandelate tablet, film coated
Seton Pharmaceuticals

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.

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Methenamine Mandelate Tablets (USP)

DESCRIPTION:

Methenamine mandelate, a urinary antibacterial agent, is the chemical combination of
mandelic acid with methenamine. Methenamine mandelate is available for oral use as film-
coated tablets.

Methenamine mandelate tablets contain 1000 mg (1 g) methenamine mandelate and the
following inactive ingredients: croscarmellose sodium, FD&C blue #2 aluminum lake,
magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol,
silicon dioxide, talc and titanium dioxide.

CLINICAL PHARMACOLOGY

Methenamine mandelate is readily absorbed but remains essentially inactive until it is
excreted by the kidneys and concentrated in the urine. An acid urine is essential for
antibacterial action, with maximum efficacy occurring at pH 5.5 or less. In an acid urine,
mandelic acid exerts its antibacterial action and also contributes to the acidification of
the urine. Mandelic acid is excreted both by glomerular filtration and tubular excretion.
The methenamine component is hydrolyzed in acid urine to ammonia and to the
bactericidal agent formaldehyde. Proportionally less formaldehyde is released as urinary
pH approaches 6.0 and insufficient quantities are released above this level for
therapeutic response. There is equally effective antibacterial activity against both gram-
positive and gram-negative organisms, since the antibacterial action of mandelic acid and
formaldehyde is nonspecific. There are reports that methenamine mandelate is
ineffective in some infections with Proteus vulgaris and urea-splitting strains of
Pseudomonas aeruginosa and A aerogenes. Since urea-splitting strains may raise the pH
of the urine, particular attention to supplementary acidification with agents such as
ascorbic acid, and urinary pH monitoring is required. However, results in any single case
will depend to a large extent on the underlying pathology and the overall management.

INDICATIONS AND USAGE

Methenamine mandelate is indicated for the suppression or elimination of bacteriuria
associated with pyelonephritis, cystitis, and other chronic urinary tract infections; also
those neurologic diseases leading to an infected residual urine. When used as
recommended, methenamine mandelate is particularly suitable for long-term therapy
because of its safety and because resistance to the nonspecific bactericidal action of
formaldehyde does not develop. Pathogens resistant to other antibacterial agents may
respond to methenamine mandelate because of the nonspecific effect of formaldehyde.
formed in an acid urine.

**Prophylactic Use Rationale:** Urine is a good culture medium for many urinary pathogens. Inoculation by a few organisms (relapse or reinfection) may lead to bacteriuria in susceptible individuals. Thus, the rationale of management in recurring urinary tract infection (bacteriuria) is to change the urine from a growth-supporting to a growth-inhibiting medium. There is a growing body of evidence that long-term administration of methenamine mandelate can prevent the recurrence of bacteriuria in patients with chronic pyelonephritis.

**Therapeutic Use Rationale:** Methenamine mandelate helps to sterilize the urine, and in some situations in which underlying pathologic conditions prevent sterilization by any means, it can help to suppress the bacteriuria. Methenamine mandelate should not be used alone for acute infections with parenchymal involvement causing systemic symptoms such as chills and fever. A thorough diagnostic investigation as a part of the overall management of the urinary tract infection should accompany the use of methenamine mandelate.

**CONTRAINDICATIONS**

Methenamine mandelate tablets are contraindicated in patients with renal insufficiency, severe hepatic disease severe dehydration, and in patients who have exhibited hypersensitivity to any components of this product.

**WARNINGS**

Methenamine mandelate should be avoided in patients with gout because it may precipitate urate crystals in their urine. A similar situation may arise in patients with a predisposition to the formation of uric acid stones.

Methenamine preparations should not be given to patients taking sulfonamides because some sulfonamides may form an insoluble precipitate with formaldehyde in the urine.

**PRECAUTIONS**

**General**

Dysuria may occur (usually at higher than recommended dosage). This can be controlled by reducing the dosage and the acidification. When urine acidification is contraindicated or unattainable (as with some urea-splitting bacteria), the drug is not recommended.

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

**Information for Patients**

To assure an acidic pH, patients should be instructed to restrict or avoid milk products and antacids containing sodium carbonate or bicarbonate.

**Laboratory Tests**

As with all urinary tract infections, the efficacy of therapy should be monitored by repeated urine cultures.
Urinary pH monitoring is required to assure an acidic urinary pH (below 5.5).

**Drug Interactions**

Formaldehyde and sulfamethizole form an insoluble precipitate in acid urine; therefore, methenamine mandelate should not be administered concurrently with sulfamethizole or other sulfonamides. Concurrent use of salicylates may lead to increased serum salicylate levels since excretion of salicylates is reduced in acidified urine.

**Drug/Laboratory Test Interactions**

Formaldehyde interferes with fluorometric procedures for determination of urinary catecholamines and vanillylmandelic acid (VMA), causing erroneously high results. Formaldehyde also causes falsely decreased urine estriol levels by reacting with estriol when acid hydrolysis techniques are used; estriol determinations which use enzymatic hydrolysis are unaffected by formaldehyde. Formaldehyde causes falsely elevated 17-hydroxycorticosteroid levels when the Porter-Silber method is used and falsely decreased 5-hydroxyindoleacetic acid (5HIAA) levels by inhibiting color development when nitrosonaphthol methods are used.

**CARCINOGENESIS and MUTAGENESIS**

Methenamine mandelate has not been evaluated for carcinogenicity or mutagenicity. Methenamine was evaluated for mutagenicity in the Ames Salmonella/mammalian microsome test. Five strains of Salmonella typhimurium (TA98, TA100, TA1535, TA1537 and TA1538) and a strain of Escherichia coli (WP2uvrA) were used. At a dose of 10,000 µg/plate methenamine showed mutagenic activity in Salmonella typhimurium TA98 and TA100 by metabolic activation and also showed mutagenic activity in TA98 without microsomal activation.

In one large study, no evidence of carcinogenicity was found following long-term oral administration of methenamine 1.25 g/kg/day to rats (104 weeks) and mice (60 weeks).

**Pregnancy**

**Teratogenic Effects.**

**Pregnancy Category C.**

Animal reproduction studies have not been conducted with methenamine mandelate. It is also not known whether methenamine mandelate can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Since methenamine is known to cross the placental barrier, methenamine mandelate should be given to a pregnant woman only if the potential benefit outweighs the risk.

**Nursing Mothers**

Methenamine is excreted in breast milk. Because of the potential for serious adverse reactions in nursing infants, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the
ADVERSE REACTIONS
Gastrointestinal disturbances (nausea, stomach upset), generalized skin rash, dysuria, painful or difficult urination may occur occasionally with the use of methenamine preparations. Microscopic and rarely, gross hematuria have been described.

OVERDOSAGE
Minimize absorption by inducing vomiting or by gastric lavage followed by administration of activated charcoal. Administer orally fluids and alkalinize with sodium bicarbonate.

DOSAGE AND ADMINISTRATION
The average adult dose is 4 g a day given as 1 g tablet after each meal and at bedtime. Children 6 to 12 years of age should receive half the adult dose; one-half tablet 4 times a day.

HOW SUPPLIED
Methenamine Mandelate Tablets 1000 mg (1 g) are blue, scored, oblong, film-coated, debossed with "ERTH" on one side and "1000" on the other side. Supplied in bottles of 100 (NDC 13925-107-01)

Preserve in well-closed containers
Store at 25°C (77°F) excursions permitted to 15°-30°C (59°-86°F). [See USP Controlled Room Temperature.]

Rx only
Marketed by:
Seton Pharmaceuticals Inc.
Manasquan, NJ 08736 USA
1-800-510-3401

Iss. 06/11
Part No. 70023501

Methenamine Mandelate Tablets 1000 mg
NDC 13925-107-01

Methenamine
Mandelate
Tablets USP

URINARY ANTIBACTERIAL
1000 mg
Rx Only
100 Tablets
SETON PHARMACEUTICALS

METHENAMINE MANDELATE
methenamine mandelate tablet, film coated

Product Information

Product Type: HUMAN PRESCRIPTION DRUG
Route of Administration: ORAL

Active Ingredient/Active Moiety

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<td>METHENAMINE MANDELATE</td>
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Inactive Ingredients

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Product Characteristics
Seton Pharmaceuticals

Color: BLUE  Score: 2 pieces  
Shape: OVAL  Size: 19mm  
Flavor:  
Imprint Code: ERTH;1000

Packaging

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Marketing Information

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Labeler - Seton Pharmaceuticals (828898002)

Revised: 5/2022