ME NAPHOS MB HYO 1- urinary antiseptic antispasmodic tablet
Method 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.

Me-NaPhos-MB-Hyo 1 Tablets

Description

Each tablet contains:

Methenamine, USP ..... 81.6 mg
Monobasic Sodium Phosphate, USP ..... 40.8 mg
Methylene Blue ..... 10.8 mg
Hyoscyamine Sulfate ..... 0.12 mg

Inactive Ingredients include:

Microcrystalline
Cellulose, Mannitol, Croscarmellose Sodium, Magnesium Stearate, FD&C Blue #1

HYOSCYAMINE SULFATE is an alkaloid of belladonna. Exists as a white crystalline powder. Affected by light It is very soluble in water; freely soluble in alcohol; practically insoluble in ether.
METHENAMINE exists as colorless, lustrous crystals or white crystalline powder. Its solutions are alkaline to litmus. Freely soluble in water; soluble in alcohol and in chloroform.

METHYLENE BLUE exists as dark green crystals. It is soluble in water and in chloroform; sparingly soluble in alcohol.

MONOBASIC SODIUM PHOSPHATE exists as a white crystalline powder. Its solutions are acidic to litmus. It is freely soluble in water and practically insoluble in alcohol.

This product is not an Orange Book (OB) rated product, therefore all prescriptions using this product shall be pursuant to state statutes as applicable. There are no claims of bioequivalence

or therapeutic equivalence.

CLINICAL PHARMACOLOGY

HYOSCYAMINE is a parasympatholytic which relaxes smooth muscles and thus produces an antispasmodic effect. It is well absorbed from the gastrointestinal tract and is rapidly distributed throughout body tissues. Most is excreted in the urine within 12 hours, 13% to 50% being unchanged.

Its biotransformation is hepatic. Its protein binding is moderate.

METHENAMINE degrades in an acidic urine environment releasing formaldehyde which provides bactericidal or bacteriostatic action. It is well absorbed from the gastrointestinal tract. 70% to 90% reaches the urine unchanged at which point it is hydrolyzed if the urine is acidic. Within 24 hours it is almost completely (90%) excreted; of this amount at pH 5, approximately 20% is formaldehyde. Protein binding: some formaldehyde is bound to substances in the urine and surrounding tissues. Methenamine is freely distributed to body tissue and fluids but is not clinically significant as it does not hydrolyze at pH greater than 6.8.

METHYLENE BLUE possesses weak antiseptic properties. It is well absorbed in the gastrointestinal tract and is rapidly reduced to leukomethylene blue which is stabilized in some combination form in the urine. 75% is excreted unchanged.

MONOBASIC SODIUM PHOSPHATE helps to maintain an acid pH in the urine necessary for the degradation of methenamine.

INDICATION AND USAGE

ME/NaPhos/MB/Hyo 1 Tablets is indicated for the treatment of symptoms of irritative voiding. Indicated for the relief of local symptoms, such as hypermotility which accompany lower urinary tract infections and as antispasmodic. Indicated for the relief of urinary tract symptoms caused by diagnostic procedures.

WARNINGS

Do not exceed recommended dosage. If rapid pulse, dizziness, or blurring of vision occurs **discontinue use immediately.**

PRECAUTIONS

(Pregnancy Category C)
hyoscyamine and methenamine cross the placenta. Studies have not been done in animals or humans. It is not known whether **ME/NaPhos/MB/Hyo 1 Tablets** cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. **ME/NaPhos/MB/Hyo 1 Tablets** should be given to a pregnant woman only if clearly needed.

Breast-feeding

problems in humans have not been documented; however, methenamine and traces of hyoscyamine are excreted in breast milk.

Prolonged use

there have been no studies to establish the safety of prolonged use in humans. No known long-term animal studies have been performed to evaluate carcinogenic potential.

Pediatric

infants and young children are especially susceptible to the toxic effect of the belladonna alkaloids.

Geriatric

use with caution in elderly patients as they may respond to usual doses of hyoscyamine with excitement, agitation, drowsiness, or confusion.

Drug Interactions

because of this product's effect on gastrointestinal

motility and gastric emptying, it may decrease the absorption of other oral medications during concurrent use such as: urinary alkalizers; thiazide diuretics (may

cause the urine to become alkaline reducing the effectiveness of methenamine by inhibiting its conversion to formaldehyde); antimuscarinics (concurrent use may intensify antimuscarinic effects of hyoscyamine because of secondary antimuscarinic activities of these medications); antacids/antidiarrheals (may reduce absorption of hyoscyamine, concurrent use with antacids may cause urine to become alkaline reducing effectiveness of methenamine by inhibiting its conversion to formaldehyde) doses of these medications should be spaced 1 hour apart from doses of hyoscyamine; antimyasthenics (concurrent use with hyoscyamine may further reduce intestinal motility); ketoconazole (patients should be advised to take this combination at least 2 hours after ketoconazole); monoamine oxidase (MAO) Inhibitors (concurrent use may intensify antimuscarinic side effects, opioid (narcotic) analgesics may result in increased risk of severe constipation); sulfonamides (these drugs may precipitate with formaldehyde in the urine, increasing the danger of crystalluria).
Patients should be advised that the urine may become blue to blue green and the feces may be discolored as a result of the excretion of methylene blue.

ADVERSE REACTIONS

Cardiovascular – rapid pulse, flushing

Central Nervous System – blurred vision, dizziness

Respiratory – shortness of breath or troubled breathing

Genitourinary – difficulty micturition, acute urinary retention

Gastrointestinal – dry mouth, nausea/vomiting

DRUG ABUSE AND DEPENDENCE

A dependence on the use of **ME/NaPhos/MB/Hyo 1 Tablets** has not been reported and due to the nature of its ingredients, abuse of **ME/NaPhos/MB/Hyo 1 Tablets** is not expected.

OVERDOSAGE

Emesis or gastric lavage. Slow intravenous administration of physostigmine in doses of 1 mg to 4 mg (0.5 mg to 1 mg in children), repeated as needed in one to two hours to reverse severe antimuscarinic symptoms. Administration of small doses of diazepam to control excitement and seizures. Artificial respiration with oxygen if needed for respiratory depression. Adequate hydration. Symptomatic treatment as necessary.

DOSAGE AND ADMINISTRATION

Adults

One tablet orally 4 times per day followed by liberal fluid intake.

Older Children

Dosage must be individualized by physician. Not recommended for use in children up to 6 years of age.

HOW SUPPLIED

ME/NaPhos/MB/Hyo 1 Tablets are light blue to blue, oval, biconvex tablets debossed with "M455" with scoreline on one side and plain on the other side. Supplied in bottles of 100 tablets (NDC 58657-454-01).

CAUTION

RX ONLY

STORAGE

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

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Arlington, TX 76006

Rev. Date: 01/2016

DIRECTIONS: 1 Tablet 4 times daily followed by liberal fluid intake, or as directed by a physician.

FOR FULL PRODUCT INFORMATION SEE ATTACHED BOOKLET.
Store at 25° C (77° F); excursions permitted to 15° C to 30° C (59° F to 86° F) [See USP Controlled Room Temperature]. Protect from moisture or direct sunlight.

NOTE: Patient should be advised that urine will be colored blue while taking this medication.

PHARMACIST: Preserve and dispense in tight-light resistant container as defined in the USP.

KEEP THIS AND ALL MEDICINES OUT OF THE REACH OF

CHILDREN.

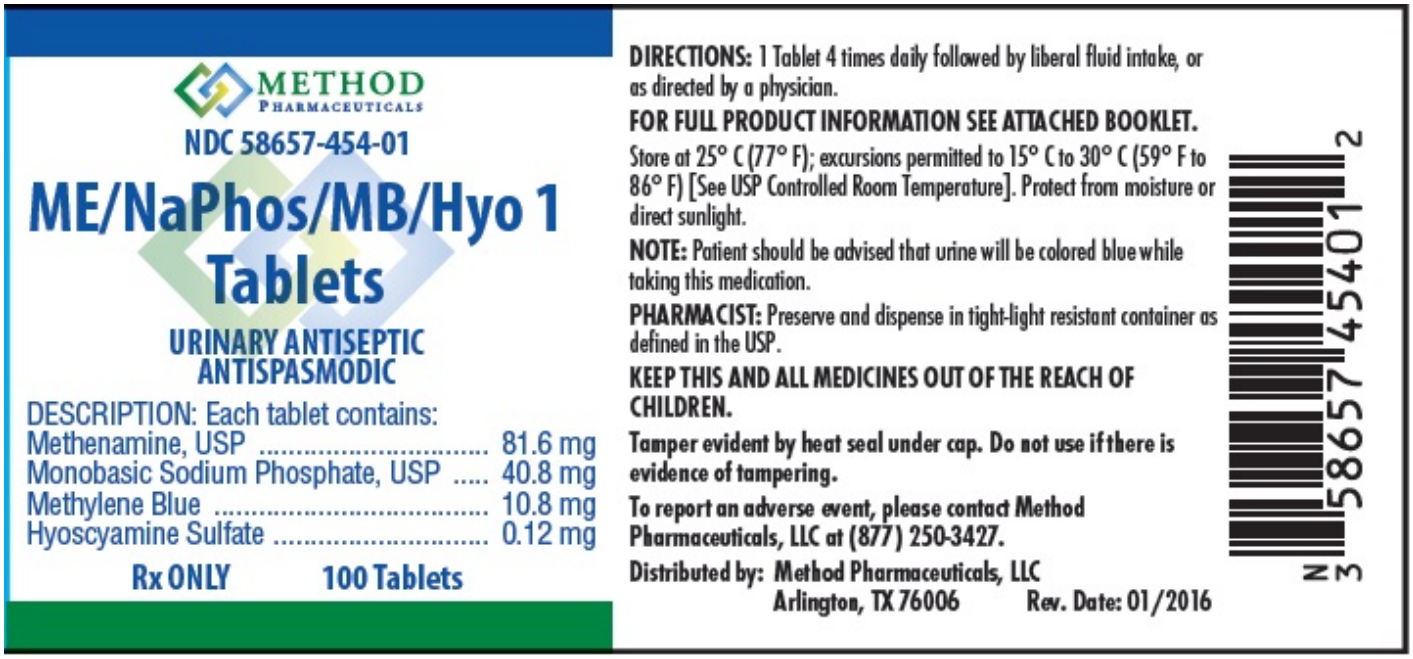
Tamper evident by heat seal under cap. Do not use if there is evidence of tampering.

To report an adverse event, please contact Method Pharmaceuticals, LLC at (877) 250-3427.

Distributed by: Method Pharmaceuticals, LLC

Arlington, TX 76006 Rev. Date: 01/2016

Pinciple Display Panel



Booklet

motility and gastric emptying. It may decrease the absorption of other oral medications during concurrent use such as: urinary alkalizers: bicarbonate salts (may cause the urine to become alkaline reducing the effectiveness of methenamine by inhibiting its conversion to formaldehyde); cardiovascular: [concurrent use may intensify anticholinergic effects of hyoscyamine because of secondary anticholinergic activities of these medications]; antacids/ adsorbents [may reduce absorption of hyoscyamine]; concurrent use with cholestyramine may cause urine to become alkaline reducing effectiveness of methenamine by inhibiting its conversion to formaldehyde] doses of these medications should be spaced 1 hour apart from doses of hyoscyamine; antipsychotics [concurrent use with hyoscyamine may further reduce intestinal motility]; ketoconazole [patients should be advised to take this combination at least 2 hours after ketoconazole]; monoamine oxidase (MAO) inhibitors [concurrent use may intensify anticholinergic side effects]; opioid [narcotic] analgesics may result in increased risk of severe constipation]; sulfonamides [these drugs may precipitate with formaldehyde in the urine, increasing the danger of crystalluria].

Patients should be advised that the urine may become blue to blue green and the feces may be discolored as a result of the association of methylene blue.

ADVERSE REACTIONS

Cardiovascular – rapid pulse, Flushing

Central Nervous System – blurred vision, dizziness

Respiratory – shortness of breath or troubled breathing

Genitourinary – difficulty micturition, acute urinary retention

Gastrointestinal – dry mouth, nausea/vomiting

DRUG ABUSE AND DEPENDENCE

A degree less on the use of ME/NaPhos/MB/Hyo 1 Tablets has not been reported and due to the nature of its ingredients, abuse of ME/NaPhos/MB/Hyo 1 Tablets is not reported.

OVERDOSAGE

Emesis or gastric lavage. Slow intravenous administration of physostigmine in doses of 1 mg to 4 mg (0.5 mg to 1 mg in children) repeated as needed to relieve severe anticholinergic symptoms. Administration of small doses of diazepam to control excitement and seizures. Artificial respiration with oxygen if needed for respiratory depression. Adequate hydration. Symptomatic treatment as necessary.

DOSAGE AND ADMINISTRATION

Adults

One tablet orally 4 times per day followed by a bland diet if nausea.

Older Children

Dosage must be individualized by physician. Not recommended for use in children up to 6 years of age.

HOW SUPPLIED

ME/NaPhos/MB/Hyo 1 Tablets are light blue to blue, oval, biconvex tablets debossed with "M455" with scored line on one side and plain on the other side. Supplied in bottles of 100 tablets (NDC 58657-4540 1).

CAUTION

Rx ONLY

STORAGE

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Methylene Blue ..... 10.8 mg
Hyoscyamine Sulfate ..... 0.12 mg

Inactive Ingredients Include: Microcrystalline Cellulose, Hydrated Croscarmellose Sodium, Magnesium Stearate, FD&C Blue #1

HYOSCYAMINE SULFATE is an alkaloid of belladonna. Exists as colorless crystalline powder. Affected by light it is very soluble in water; freely soluble in alcohol; practically insoluble in ether.

METHENAMINE exists as colorless, lustrous crystals or white crystalline powder. Its solutions are alkaline to litmus. Freely soluble in water; soluble in alcohol and in chloroform.

METHYLENE BLUE exists as dark green crystals. It is soluble in water and in chloroform; sparingly soluble in alcohol.

MONOBASIC SODIUM PHOSPHATE exists as a white crystalline powder. Its solutions are acid to litmus. It is freely soluble in water and practically insoluble in alcohol.

This product is not an Orange Book (OB) rated product, therefore all prescriptions using this product should be processed to state statutes as applicable. There are no studies of bioequivalence or therapeutic equivalence.

CLINICAL PHARMACOLOGY

HYOSCYAMINE is a parasympatholytic which relaxes smooth muscle and has profound effects on antisecretory effect. It is well absorbed from the gastrointestinal tract and is rapidly distributed throughout body tissues. About 1/3 is excreted in the urine within 12 hours, 13% to 50% being unchanged.

Its biotransformation is hepatic. Its protein binding is moderate.

METHENAMINE degrades in an acidic urine environment releasing formaldehyde which provides bactericidal or bacteriostatic action. It is well absorbed from the gastrointestinal tract, 70% to 90% reaches the urine unchanged at which point it is hydrolyzed if the urine is acidic. Within 24 hours it is almost completely (99%) excreted. At the onset of pH 5, approximately 23% is formaldehyde. Protein binding: some formed aldehyde is bound to substances in the urine and surrounding tissues. Methenamine is largely distributed to body tissues and fluids but is not clinically significant as it does not hydrolyze at pH greater than 6.8.

METHYLENE BLUE possesses weak antiseptic properties. It is well absorbed in the gastrointestinal tract and is rapidly reduced to leukomethylene blue in which it is still active. Some conversion form in the urine. 75% is excreted unchanged.

MONOBASIC SODIUM PHOSPHATE helps to maintain an acid pH in the urine necessary for the degradation of methenamine.

INDICATIONS AND USAGE

ME/NaPhos/MB/Hyo 1 Tablets is indicated for the treatment of symptoms of irritative voiding, indicated for the relief of bowel symptoms, such as hyperactivity which accompany lower urinary tract infections and as antispasmodic. Indicated for the relief of urinary tract symptoms caused by diagnostic procedures.

CONTRAINDICATIONS

ME/NaPhos/MB/Hyo 1 Tablets is contraindicated in patients with a hypersensitivity to any of the ingredients. Belladonna should be considered when the following medical problems exist: Cardiac disease, tachycardia cardiac arrhythmias, congestive heart failure, coronary heart disease, mitral stenosis]; gastrointestinal tract obstructive disease; glaucoma; myasthenia gravis; acute urinary retention may be precipitated in old patients by anticholinergics [such as bladder neck obstruction due to prostatic hypertrophy].

WARNINGS

Do not exceed recommended dosage. If rapid pulse, dizziness, or blurring of vision occurs discontinue use immediately.

PRECAUTIONS

Cross sensitivity and/or related problems

patients intolerant of belladonna alkaloids may be intolerant of this medication also.

Pregnancy/ Reproduction

[Pregnancy Category C]

Hyoscyamine and methenamine cross the placenta. Studies have not been done in animals or humans. It is not known whether ME/NaPhos/MB/Hyo 1 Tablets can cause fetal harm or low stimulation to a pregnant woman or can affect reproduction capacity. ME/NaPhos/MB/Hyo 1 Tablets should be given to a pregnant woman only if clearly needed.

Breast-feeding

problems in humans have not been documented; however, methenamine and traces of hyoscyamine are excreted in breast milk.

Prolonged use

there have been no studies to establish the safety of prolonged use in humans. Its known long-term animal studies have been performed to evaluate carcinogenic potential.

Pediatric

infants and young children are especially susceptible to the toxic effect of the belladonna alkaloids.

Geriatric

use with caution in elderly patients as they may respond to usual doses of hyoscyamine with confusion, agitation, drowsiness, or confusion.

Drug Interactions

because of this product's effect on gastrointestinal

ME NAPHOS MB HYO 1

urinary antiseptic antispasmodic tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:58657-454
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
METHENAMINE (UNII: J50OIX95QV) (METHENAMINE - UNII:J50OIX95QV)	METHENAMINE	81.6 mg
SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE (UNII: 593YOG76RN) (PHOSPHATE ION - UNII:NK08V8K8HR)	SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE	40.8 mg
METHYLENE BLUE ANHYDROUS (UNII: 8NAP7826UB) (METHYLENE BLUE CATION - UNII:ZMZ79891ZH)	METHYLENE BLUE CATION	10.8 mg
HYOSCYAMINE SULFATE ANHYDROUS (UNII: OB570Z127K) (HYOSCYAMINE - UNII:PX44XO846X)	HYOSCYAMINE SULFATE ANHYDROUS	0.12 mg

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Product Characteristics

Color	blue (light blue to blue)	**Score**	no score
Shape	OVAL	**Size**	10mm
Flavor		**Imprint Code**	M455
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58657-454-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	12/01/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		12/01/2015	

Labeler - Method Pharmaceuticals (060216698)

Revised: 12/2023 Method Pharmaceuticals