

**VILAMIT MB- methenamine, phenyl salicylate, sodium phosphate, monobasic, anhydrous, methylene blue anhydrous, and hyoscyamine sulfate capsule**  
**Vilvet Pharmaceuticals Inc**

*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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**VILAMIT MB Capsules**

Rx Only

Each Capsule Contains:

<b>Methenamine</b>	118 mg
<b>Sodium Phosphate Monobasic</b>	40.8 mg
<b>Phenyl Salicylate</b>	36 mg
<b>Methylene Blue</b>	10 mg
<b>Hyoscyamine Sulfate</b>	0.12 mg

Inactive Ingredients: Dicalcium Phosphate, Microcrystalline Cellulose, Sodium Starch Gylcolate, Magnesium Stearate, Carbopol, FD&C Blue #1, Titanium Dioxide, FD&C Yellow 5. FD&C Red 3, Amaranth, and Purified Water.

**METHENAMINE.** [100-97-0] 1, 3, 5, 7 – Tetraazatricyclo [3.3.1.-1<sub>3,7</sub>] decane; hexamethylenetetramine; HMT; HMTA; hexamine; 1, 3, 5, 7- tetraazaadamantane hexamethylenimine; Uritone; Urotropin. C<sub>6</sub>H<sub>12</sub>N<sub>4</sub>; mol wt 140.19; C 51.40%, H 8.63%, N 39.96%. Methenamine (hexamethylenetetramine) 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.

**SODIUM PHOSPHATE MONOBASIC.** [7558-80-7] Phosphoric acid sodium salt (1:1); Sodium biphosphate; sodium dihydrogen phosphate; acid sodium phosphate; monosodium orthophosphate; primary sodium phosphate; H<sub>2</sub>NaO<sub>4</sub>P; mol wt 119.98, H 1.68%, Na 19.16%, O 53.34%, P 25.82 %. Monohydrate, white, odorless slightly deliquesce crystals or granules. At 100 °C loses all its water; when ignited it converts to metaphosphate. It is freely soluble in water and practically insoluble in alcohol. The aqueous solution is acid. pH of 0.1 molar aqueous solution at 25 °C: 4.5.

**PHENYL SALICYLATE.** [118-55-8] 2-Hydroxybenzoic acid phenyl ester; Salol. C<sub>13</sub>H<sub>10</sub>O<sub>3</sub>; mol wt 214.22, C 72.89%, H 4.71%, O 22.41%. Made by the action of phosphorous oxy-chloride on a mixture of phenol and salicylic acid. Phenyl Salicylate exists as white crystals with a melting point of 41° - 43°C. It is very slightly soluble in water and freely soluble in alcohol.

**METHYLENE BLUE.** [61-73-4] 3,7-BIS(dimethylamino) phenothiazine-5-ium chloride; C.I. Basic Blue 9; methylthioninium chloride tetramethylthionine chloride; 3,7-bis(dimethylamino) phenazathionium chloride. C<sub>16</sub>H<sub>18</sub>ClN<sub>3</sub>S; mol wt 319.85, C 60.08%, H 5.67%, Cl 11.08%, N 13.14%, S 10.03%. Methylene Blue (Methylthionine chloride) exists as dark green crystals. It is soluble in water and in chloroform; sparingly soluble in alcohol.

**HYOSCYAMINE SULFATE.** [620-31-1] [3(S)-endo]-α-(Hydroxymethyl)-benzeneacetic acid 8-mehtyl-8-azabicyclo [3.2.1] oct-3-yl ester sulfate (2:1) (salt); 1αH, 5αH-tropan-3α-ol(-)-tropate (ester) sulfate (2:1) (salt); 3α-tropanyl S-(-)-tropate; I-tropic acid ester with tropine; I-tropine tropate. C<sub>34</sub>H<sub>48</sub>N<sub>2</sub>O<sub>10</sub>S. Hyoscyamine Sulfate is an alkaloid of belladonna. Exists as a white crystalline powder. Its solutions are alkaline to litmus. Affected by light, it is slightly soluble in water freely soluble in alcohol; sparingly soluble in ether.

## **VILAMIT MB - CLINICAL PHARMACOLOGY**

METHENAMINE degrades in an acidic urine environment releasing formaldehyde which provide 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.

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

PHENYL SALICYLATE releases salicylate, a mild analgesic for pain.

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

HYOSCYAMINE SULFATE is a parasympatholytic drug which relaxes smooth muscles and this produces an antispasmodic effect. It is well absorbed from the gastrointestinal tract and is rapidly distributed throughout the body tissues. Most is excreted in the urine within 12 hours, 13% to 50% being unchanged. Protein binding for hyoscyamine sulfate is moderate and biotransformation is hepatic.

## **INDICATIONS AND USAGE FOR VILAMIT MB:**

VILAMIT MB is indicated for the treatment of symptoms of irritative voiding. Indicated for the relief of local symptoms, such as inflammation, hypermotility, and pain which accompany lower urinary tract infections. Indicated for the relief of urinary tract symptoms caused by diagnostic procedures.

## **CONTRAINDICATIONS**

VILAMIT MB is contraindicated in patients with a hypersensitivity to any of the ingredients. Risk-benefit should be considered when the following medical problems exist: Cardiac disease (especially cardiac arrhythmias, congestive heart failure, coronary heart disease, and mitral stenosis); gastrointestinal tract obstructive disease; glaucoma; myasthenia gravis; acute urinary retention may be precipitated in obstructive uropathy (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.

Patients should be advised that urine will be colored blue to blue-green while taking this medication. Do not exceed recommended dosage.

## **PRECAUTIONS**

Contains Methylene Blue and should NOT be taken with serotonergic psychiatric medications.

### **Cross sensitivity and/or related problems**

Patients intolerant of other belladonna alkaloids may be intolerant of this medication also. Delay in gastric emptying could complicate the management of gastric ulcers.

### **Pregnancy/Reproduction (FDA Pregnancy Category C)**

Hyoscyamine and methenamine cross the placenta. Studies have not been done in either animals or

humans. It is not known whether VILAMIT MB can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. VILAMIT MB should be given to a pregnant woman only if clearly needed.

### **Nursing Mothers**

Methenamine and traces of Hyoscyamine are excreted in breast milk. Caution should be exercised when VILAMIT MB is administered to a nursing mother.

### **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 the usual doses of the belladonna alkaloids with excitement, agitation, drowsiness, or confusion.

### **Drug Interactions**

Although the exact mechanism of this drug interaction is unknown, methylene blue inhibits the action of monoamine oxidase A – an enzyme responsible for breaking down serotonin in the brain. It is believed that when methylene blue is given to patients taking serotonergic psychiatric medications, high levels of serotonin can build up in the brain, causing toxicity. This is referred to as Serotonin Syndrome. Signs and symptoms of Serotonin Syndrome include mental changes (confusion, hyperactivity, memory problems), muscle twitching, excessive sweating, shivering or shaking, diarrhea, and trouble with coordination and/or fever.

#### **Additional Information for Healthcare Professionals**

Methylene blue can interact with serotonergic psychiatric medications and cause serious CNS toxicity.

In emergency situations requiring life-threatening or urgent treatment with methylene blue (as described above), the availability of alternative interventions should be considered and the benefit of methylene blue treatment should be weighed against the risk of serotonin toxicity. If methylene blue must be administered to a patient receiving a serotonergic drug, the serotonergic drug must be immediately stopped, and the patient should be closely monitored for emergent symptoms of CNS toxicity for two weeks (five weeks if fluoxetine [Prozac] was taken), or until 24 hours after the last dose of methylene blue, whichever comes first.

In non-emergency situations when non-urgent treatment with methylene blue is contemplated and planned, the serotonergic psychiatric medication should be stopped to allow its activity in the brain to dissipate. Most serotonergic psychiatric drugs should be stopped at least 2 weeks in advance of methylene blue treatment. Fluoxetine (Prozac), which has a longer half-life compared to similar drugs, should be stopped at least 5 weeks in advance.

Treatment with the serotonergic psychiatric medication may be resumed 24 hours after the last dose of methylene blue.

Serotonergic psychiatric medications should not be started in a patient receiving methylene blue. Wait until 24 hours after the last dose of methylene blue before starting the antidepressant.

Educate your patients to recognize the symptoms of serotonin toxicity or CNS toxicity and advise them to contact a healthcare professional immediately if they experience any symptoms while taking serotonergic psychiatric medications or methylene blue.

As a result of hyoscyamine's effect on gastrointestinal motility and gastric emptying, absorption of other oral medications may be decreased during concurrent use with this combination medications.

#### *Urinary alkalizers and 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*

Concurrent use may reduce absorption of Hyoscyamine resulting in decreased therapeutic effectiveness. Concurrent use with antacids may cause urine to become alkaline reducing the effectiveness of methenamine by inhibiting its conversion to formaldehyde. Doses of these medications should be spaced for 1 hour apart from doses of Hyoscyamine.

#### *Antimyasthenics*

Concurrent use with Hyoscyamine may further reduce intestinal motility, therefore, caution is recommended.

Ketoconazole and Hyoscyamine may cause increased gastrointestinal pH. Concurrent administration with Hyoscyamine may result in marked reduction in the absorption of ketoconazole. Patients should be advised to take this combination at least 2 hours after ketoconazole.

#### *Monoamine oxidase (MAO) inhibitors*

Concurrent use with Hyoscyamine 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 and/or stools may become blue to blue-green as a result of the excretion of methylene blue.

## **ADVERSE REACTIONS**

**Cardiovascular** – rapid pulse, flushing

**Central Nervous System** – blurred vision, dizziness, drowsiness

**Respiratory** – shortness of breath or troubled breathing

**Genitourinary** – difficult micturition, acute urinary retention

**Gastrointestinal** – dry mouth, nausea and vomiting

Serious allergic reactions to this drug are rare. Seek immediate medical attention if you notice symptoms of a serious allergic reaction, including itching, rash, severe dizziness, swelling or trouble breathing.

This medication can cause urine and sometimes stools to turn blue to blue-green. This effect is harmless and will subside after medication is stopped.

**Call your doctor or physician for medical advice about side effects. To report SUSPECTED ADVERSE REACTIONS, contact Vilvet Pharmaceuticals Inc., at 1-888-705-4369 or FDA at 1-**

**800-FDA-1088, [www.fda.gov/medwatch](http://www.fda.gov/medwatch).**

### **Drug Abuse and Dependence**

A dependence on the use of VILAMIT MB has not been reported and due to the nature of its ingredients, abuse of VILAMIT MB is not expected.

### **OVERDOSAGE**

Emesis or gastric lavage. Slow intravenous administration of physostigmine in doses of 1 to 4 mg (0.5 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.

If overdose is suspected, contact the poison control center at 1-800-222-1222, or your local emergency room immediately.

### **VILAMIT MB DOSAGE AND ADMINISTRATION**

#### **Adults**

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

#### **Older Children**

Dosage must be individualized by physician. Not recommended for use in children six years of age or younger.

### **STORAGE**

Store in a cool, dry place at controlled room temperature 15° to 30°C (59° to 86°F). Keep container tightly closed. Protect from moisture and direct sunlight.

**KEEP OUT OF REACH OF CHILDREN.**

**IN CASE OF ACCIDENTAL OVERDOSE, SEEK PROFESSIONAL ASSISTANCE OR CONTACT A POISON CONTROL CENTER IMMEDIATELY.**

Note: Patients should be advised that urine will be colored blue when taking this medication.

### **HOW IS VILAMIT MB SUPPLIED**

VILAMIT MB capsules are purple opaque, oblong, imprinted with "VIP101" and plain on the other side, available in bottles of 100 capsules, NDC 71186-002-35.

Dispense in a tight, light-resistant container as defined in the USP/NF with a child resistant closure.

Rx Only

Manufactured for:  
Vilvet Pharmaceuticals Inc  
Chester Springs, PA 19425  
Rev /2011

**PRINCIPAL DISPLAY PANEL - 100 Capsule Bottle Label**

NDC 71186-002-35

## VILAMIT MB

### EACH CAPSULE CONTAINS:

**Methenamine**

**118 mg**

**Sodium Phosphate Monobasic**

**40.8 mg**

**Phenyl Salicylate**

**36 mg**

**Methylene Blue**

**10 mg**

**Hyoscyamine Sulfate**

**0.12 mg**

**RX ONLY**

**Vilvet**

**Pharmaceuticals**

**100 Capsules**

<p><b>Pharmacist:</b> Dispense in a tight, light resistant container as defined in the USP/NF with a child resistant closure.</p> <p><b>Patient Note:</b> Patients should be advised that urine may be colored blue to blue-green when taking this medication.</p> <p><b>PRECAUTIONS:</b> Contains Methylene Blue and should NOT be taken with serotonergic psychiatric medications. FOR FULL PRODUCT INFORMATION SEE PACKAGE OUTSERT.</p> <p><b>KEEP OUT OF THE REACH OF CHILDREN. IN CASE OF ACCIDENTAL OVERDOSE, CALL A DOCTOR OR CONTACT A POISON CONTROL CENTER IMMEDIATELY.</b></p> <p>Store at controlled room temperature 15°-30°C (59°- 86°F). Keep in a cool, dry place.</p> <p>Rev./2011 Lot# Exp Date:</p>	<p>NDC 71186-002-35</p> <h2>VILAMIT MB</h2> <p><b>EACH CAPSULE CONTAINS:</b></p> <p>Methenamine.....118 mg Sodium Phosphate Monobasic.....40.8 mg Phenyl Salicylate.....36 mg Methylene Blue.....10 mg Hyoscyamine Sulfate.....0.12 mg</p> <p><b>RX ONLY</b></p>  <p><b>100 Capsules</b></p>	<p><b>INDICATIONS AND USAGE</b> For the treatment of symptoms of irritative voiding. Indicated for the relief of local symptoms, such as inflammation, hypermotility, and pain, which accompany lower urinary tract infections. Indicated for the relief of urinary tract symptoms caused by diagnostic procedures.</p> <p><b>DOSAGE AND ADMINISTRATION</b> <b>Adults:</b> One capsule orally 4 times per day followed by liberal fluid intake. <b>Older Children:</b> Dosage must be individualized by physician. Not recommended for use in children six years of age or younger.</p> <p>To report a serious adverse event or obtain product information, call 888-705-4369 or FDA at 1-800-FDA-1088, <a href="http://www.fda.gov/medwatch">www.fda.gov/medwatch</a>.</p> <p>Manufactured For: Vilvet Pharmaceuticals Inc. Chester Springs, PA 19425</p>  <p>N 3 71186 00235 6</p>
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## VILAMIT MB

methenamine, phenyl salicylate, sodium phosphate, monobasic, anhydrous, methylene blue anhydrous, and hyoscyamine sulfate capsule

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:71186-002
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
METHENAMINE (UNII: J50OIX95QV) (METHENAMINE - UNII:J50OIX95QV)	METHENAMINE	118 mg
PHENYL SALICYLATE (UNII: 28A37T47QO) (PHENYL SALICYLATE - UNII:28A37T47QO)	PHENYL SALICYLATE	36 mg

<b>SODIUM PHOSPHATE, MONOBASIC, ANHYDROUS</b> (UNII: KH7I04HPUU) (PHOSPHATE ION - UNII:NK08V8K8HR)	SODIUM PHOSPHATE, MONOBASIC, ANHYDROUS	40.8 mg
<b>METHYLENE BLUE ANHYDROUS</b> (UNII: 8NAP7826UB) (METHYLENE BLUE CATION - UNII:ZMZ79891ZH)	METHYLENE BLUE	10 mg
<b>HYOSCYAMINE SULFATE</b> (UNII: F2R8V82B84) (HYOSCYAMINE - UNII:PX44XO846X)	HYOSCYAMINE SULFATE	0.12 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>FD&amp;C YELLOW NO. 5</b> (UNII: I753WB2F1M)	
<b>FD&amp;C RED NO. 3</b> (UNII: PN2ZH5LOQY)	
<b>Amaranth</b> (UNII: 37RBV3X49K)	
<b>WATER</b> (UNII: 059QF0KO0R)	

### Product Characteristics

<b>Color</b>	PURPLE	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	19mm
<b>Flavor</b>		<b>Imprint Code</b>	VIP101
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71186-002-35	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2011	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		05/01/2011	

**Labeler** - Vilvet Pharmaceuticals Inc (080444356)

Revised: 2/2019

Vilvet Pharmaceuticals Inc