METHYLENE BLUE INJ- methylene blue anhydrous injection, solution
Cameron 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.

Methylene Blue Injection 1%, USP

(FOR SLOW INTRAVENOUS ADMINISTRATION)

Rx only

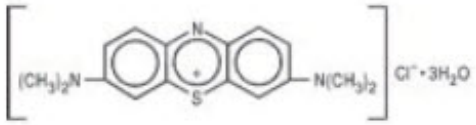
WARNING: SEROTONIN SYNDROME WITH CONCOMITANT USE OF SEROTONERGIC DRUGS

Methylene Blue Injection may cause serious or fatal serotonergic syndrome when used in combination with serotonergic drugs. Avoid concomitant use of Methylene Blue Injection with selective serotonin reuptake inhibitors (SSRIs), serotonin and norepinephrine reuptake inhibitors (SNRIs), and monoamine oxidase inhibitors (see WARNINGS and PRECAUTIONS, Drug Interactions).

DESCRIPTION

Methylene Blue Injection is a sterile solution of Phenothiazin-5-ium, 3, 7-bis (dimethylamino)-, chloride, trihydrate. Each mL contains methylene blue, 10 mg in water for injection q.s. pH adjusted with hydrochloric acid and/or sodium hydroxide when necessary.

The structural formula is:



The molecular formula is:

$C_{16}H_{18}ClN_3S \bullet 3H_2O$ MW = 373.90

CLINICAL PHARMACOLOGY

Methylene blue will produce two opposite actions on hemoglobin. Low concentrations will convert methemoglobin to hemoglobin. High concentrations convert the ferrous iron of reduced hemoglobin to ferric iron which results in the formation of methemoglobin.

Methylene blue is metabolized in the body to leukomethylene blue which is excreted primarily in the urine. Some unchanged drug is also excreted in the urine. (1)

INDICATIONS AND USAGE

Drug-induced methemoglobinemia.

CONTRAINDICATIONS

Methylene blue can cause fetal harm when administered to a pregnant woman. An association exists between the use of methylene blue in amniocentesis and atresia of the ileum and jejunum, ileal occlusions, and other adverse effects in the neonate. (2, 3) Methylene blue is contraindicated in women who are or may become pregnant. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to the fetus.

Intraspinal and subcutaneous injections are contraindicated.

Methylene blue is contraindicated in patients with a known hypersensitivity to the drug.

WARNINGS

Methylene blue should not be given by subcutaneous or intrathecal injection.

Methylene blue is a potent monoamine oxidase inhibitor: Methylene blue has been demonstrated to be a potent monoamine oxidase inhibitor (MAOI) and may cause potentially fatal serotonin toxicity (serotonin syndrome) when combined with serotonin reuptake inhibitors (SRIs). (4) (See ***Drug Interactions***.) Serotonin toxicity is characterized by development of neuromuscular hyperactivity (tremor, clonus, myoclonus and hyperreflexia, and, in the advanced stage, pyramidal rigidity); autonomic hyperactivity (diaphoresis, fever, tachycardia, tachypnoea, and mydriasis); and altered mental status (agitation, excitement, and in the advanced stage, confusion). If methylene blue is judged to be indicated, SRIs must be ceased, prior to treatment/procedure/surgery.

PRECAUTIONS

Drug Interactions

Methylene blue may interact with any drug that acts as a serotonin reuptake inhibitor (SRI) including, amongst others, selective serotonin reuptake inhibitors (SSRIs), serotonin and norepinephrine reuptake inhibitors (SNRIs), tricyclic antidepressants (TCAs), norepinephrine-dopamine reuptake inhibitors (NDRIs), triptans and ergot alkaloids; such combinations may have the consequence of potentially fatal serotonin toxicity (serotonin syndrome). Methylene blue should not be co-administered with any drug that acts as an SRI.

Pregnancy

Pregnancy Category X

Epidemiologic evidence exists that methylene blue is a teratogen. An association exists between the use of methylene blue in amniocentesis and atresia of the ileum and jejunum, ileal occlusions, and other adverse effects in the neonate. (2,3) Methylene blue

injection should not be administered to pregnant women during amniocentesis due to the risk of teratogenicity and other newborn adverse effects (see **CONTRAINDICATIONS**).

Glucose-6-Phosphate Dehydrogenase Deficiency (G6PD Deficiency)

Methylene blue should be avoided in patients with G6PD deficiency due to the risk of paradoxical methemoglobinemia and hemolysis. (5,6)

Renal Failure

Methylene blue should be used with caution in patients with severe renal impairment (see **CLINICAL PHARMACOLOGY**).

Methylene blue must be injected intravenously very slowly over a period of several minutes to prevent local high concentration of the compound from producing additional methemoglobin. Do not exceed recommended dosage.

Large intravenous doses of methylene blue produce nausea, abdominal and precordial pain, dizziness, headache, profuse sweating, mental confusion and the formation of methemoglobin.

DOSAGE AND ADMINISTRATION

0.1 to 0.2 mL per kg body weight (0.045 to 0.09 mL per pound body weight). Inject methylene blue intravenously very slowly over a period of several minutes.

Methylene blue must be injected intravenously very slowly over a period of several minutes to prevent local high concentration of the compound from producing additional methemoglobin. Do not exceed recommended dosage.

Parenteral drug products should be inspected visually for particulate matter and discoloration, whenever solution and container permit.

To report SUSPECTED ADVERSE REACTIONS, contact: Cameron Pharmaceuticals, LLC at 1-888-296-9383 (or FDA 1-800-FDA-1088) or through email at www.fda.gov/medwatch.

HOW SUPPLIED

Methylene Blue Injection, 1%, USP is supplied as follows:

NDC 42494-419-05

10 mL vials in packages of 5.

The vials are packaged with a Flip Tear-Off Seal. The seal can either be flipped normally to reveal the rubber stopper or be totally removed so the rubber stopper can be taken out of the vial. The plastic button is attached to the metal seal, which when pulled, tears the seal at the score line allowing the metal portion to be removed.

STORAGE

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

Flip Tear-Off Seal: Directions for Use:

1. With the thumb, flip the plastic button up to reveal the rubber stopper.
2. Pull the button to tear the seal at the score line and twist to remove.

Manufactured for: **Cameron Pharmaceuticals, LLC.**

Rev. 05/23

PRINCIPAL DISPLAY PANEL - 10 mg/mL Vial Carton Label

NDC 42494-419-05

Methylene Blue 1%
Injection, USP

1% (10mg/mL)
For slow Intravenous administration
R_x only

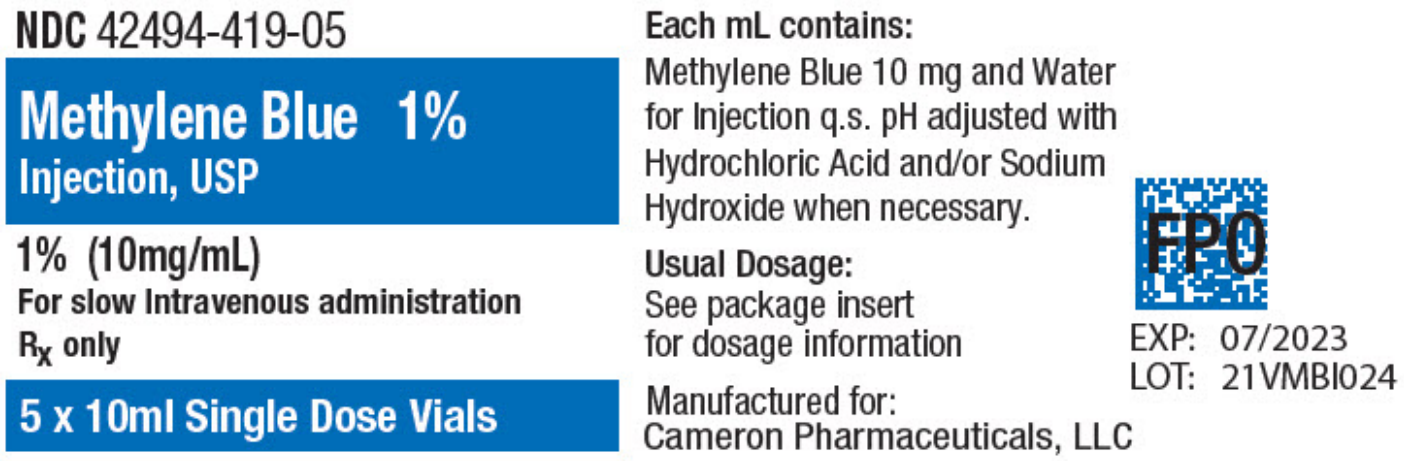
5 x 10ml Single Dose Vials

Each mL contains:
Methylene Blue 10 mg and Water for Injection q.s. pH adjusted with Hydrochloric Acid and/or Sodium Hydroxide when necessary.

Usual Dosage:
See package insert
for dosage information

Manufactured for:
Cameron Pharmaceuticals, LLC

EXP: 07/2023
LOT: 21VMBI024



METHYLENE BLUE INJ

methylene blue anhydrous injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:42494-419
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
METHYLENE BLUE ANHYDROUS (UNII: 8NAP7826UB) (METHYLENE BLUE CATION - UNII:ZMZ79891ZH)	METHYLENE BLUE	10 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
Water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42494-419-05	5 in 1 CARTON	08/07/2023	
1		10 mL in 1 VIAL; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug other		08/07/2023	

Labeler - Cameron Pharmaceuticals (078371442)

Establishment

Name	Address	ID/FEI	Business Operations
Vitae Enim Vitae Scientific, Inc.		080492645	MANUFACTURE(42494-419)

Revised: 8/2023 Cameron Pharmaceuticals