

## DISCLAIMER

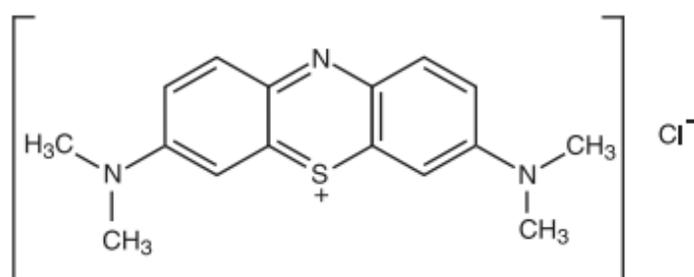
All labeling reflected on this website is for informational and promotional purposes only. It is not intended to be used by healthcare professionals or patients for the purpose of prescribing or administering these products. Questions regarding the current content of product labeling should be directed to Akorn's Customer Service department at 800.932.5676.

# Methylene Blue Injection, USP 1%

(FOR INTRAVENOUS INJECTION)

R<sub>x</sub> only

**DESCRIPTION:** Methylene Blue Injection, USP is a sterile solution of methylene blue in water for injection suitable for parenteral administration.



$\text{C}_{16}\text{H}_{18}\text{ClN}_3\text{S}$

MW = 319.86

Each mL of solution contains 10 mg of methylene blue and water for injection q.s. pH adjusted with hydrochloric acid and/or sodium hydroxide when necessary.

**ACTIONS:** Methylene blue is Phenothiazin-5-ium, 3,7-bis (dimethylamino)-, chloride, trihydrate. It 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.

**INDICATIONS:** Drug induced methemoglobinemia.

**CONTRAINDICATIONS:** Intraspinal injection is contraindicated.

**WARNINGS:** Methylene Blue should not be given by subcutaneous or intrathecal injection.

**PRECAUTIONS:** 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.

**ADVERSE REACTIONS:** Large intravenous doses of Methylene Blue produce nausea, abdominal and precordial pain, dizziness, headache, profuse sweating, mental confusion and the formation of methemoglobin.

**USE IN PREGNANCY:** Safety for use in pregnancy has not been established. Use of Methylene Blue in women of childbearing potential requires that anticipated benefits be weighed against possible hazards.

**DOSAGE AND ADMINISTRATION:** 0.1 to 0.2 mL per kilogram of body weight (0.045 to 0.09 mL per pound of body weight). Inject Methylene Blue intravenously very slowly over a period of several minutes.

**HOW SUPPLIED:**

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

NDC 17478-504-01

1 mL in 2 cc (partially filled) vials in packages of 10.

NDC 17478-504-10

10 mL vials in packages of 10.

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 by: Akorn, Inc.  
Lake Forest, IL 60045