

METHYLENE BLUE- methylene blue injection
Zydus Lifesciences Limited

Methylene Blue Injection, USP

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1768-1

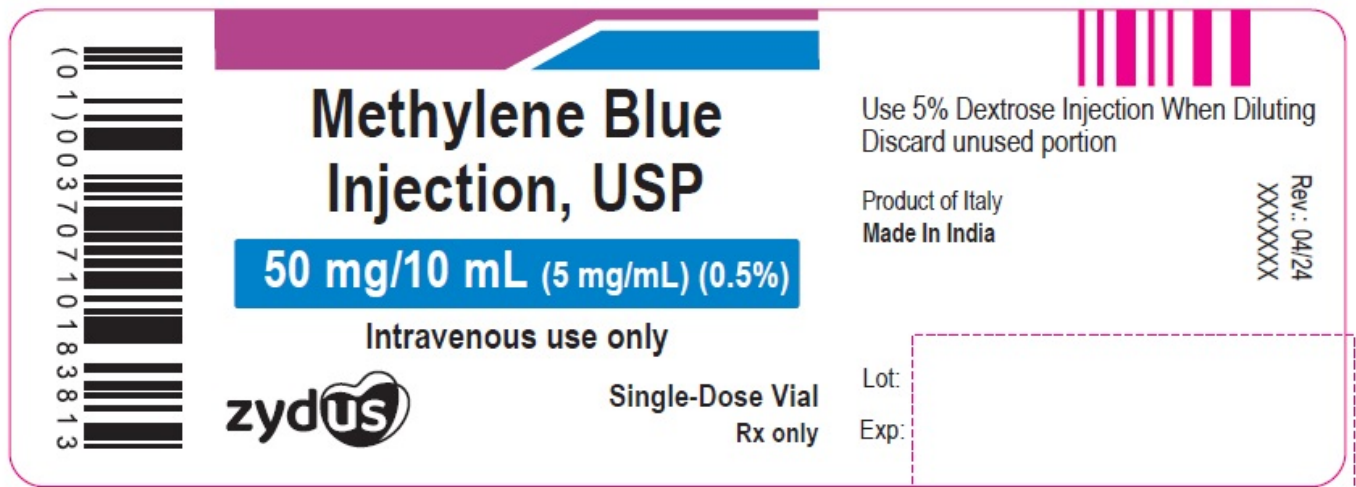
Methylene Blue Injection, USP

50 mg/10 mL (5 mg/mL)

Intravenous use only

Single-Dose vial

Rx only



NDC 70771-1768-5

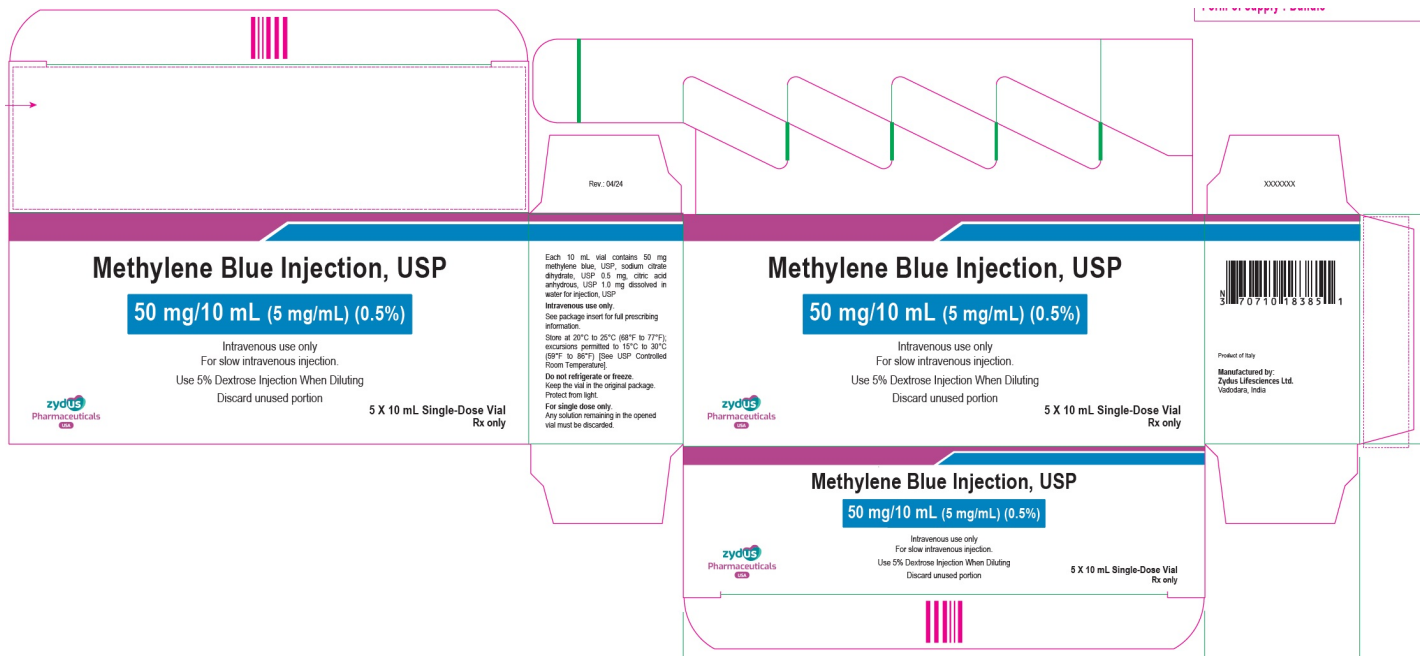
Methylene Blue Injection, USP

50 mg/10 mL (5 mg/mL)

Intravenous use only

5 X 10 mL Single-Dose Vial

Rx only



NDC 70771-1767-1

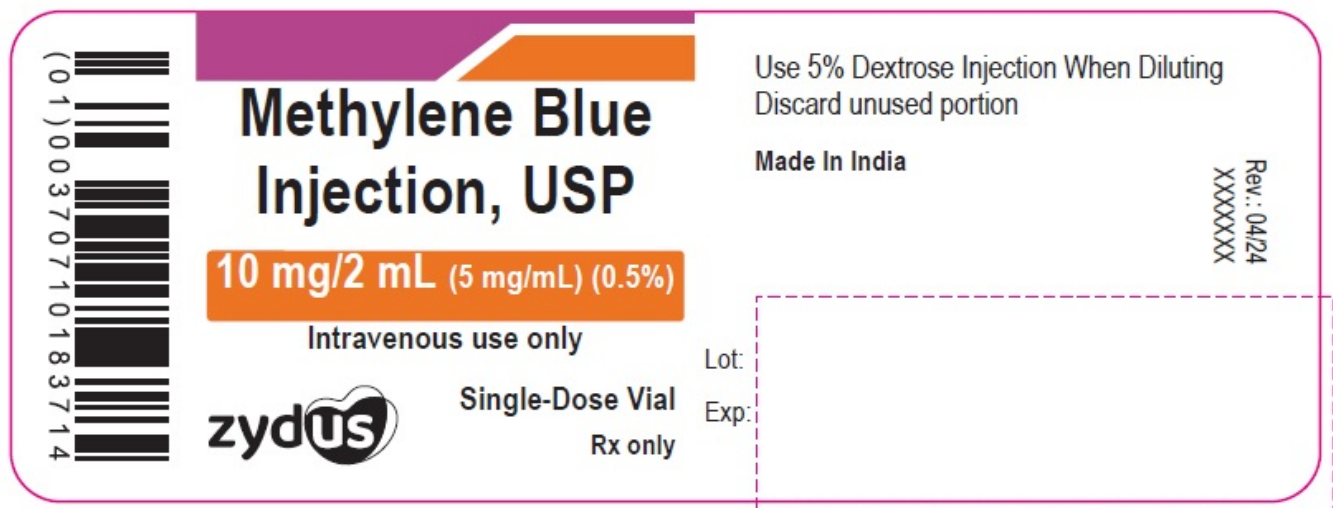
Methylene Blue Injection, USP

10 mg/2 mL (5 mg/mL)

Intravenous use only

Single-Dose vial

Rx only



NDC 70771-1767-5

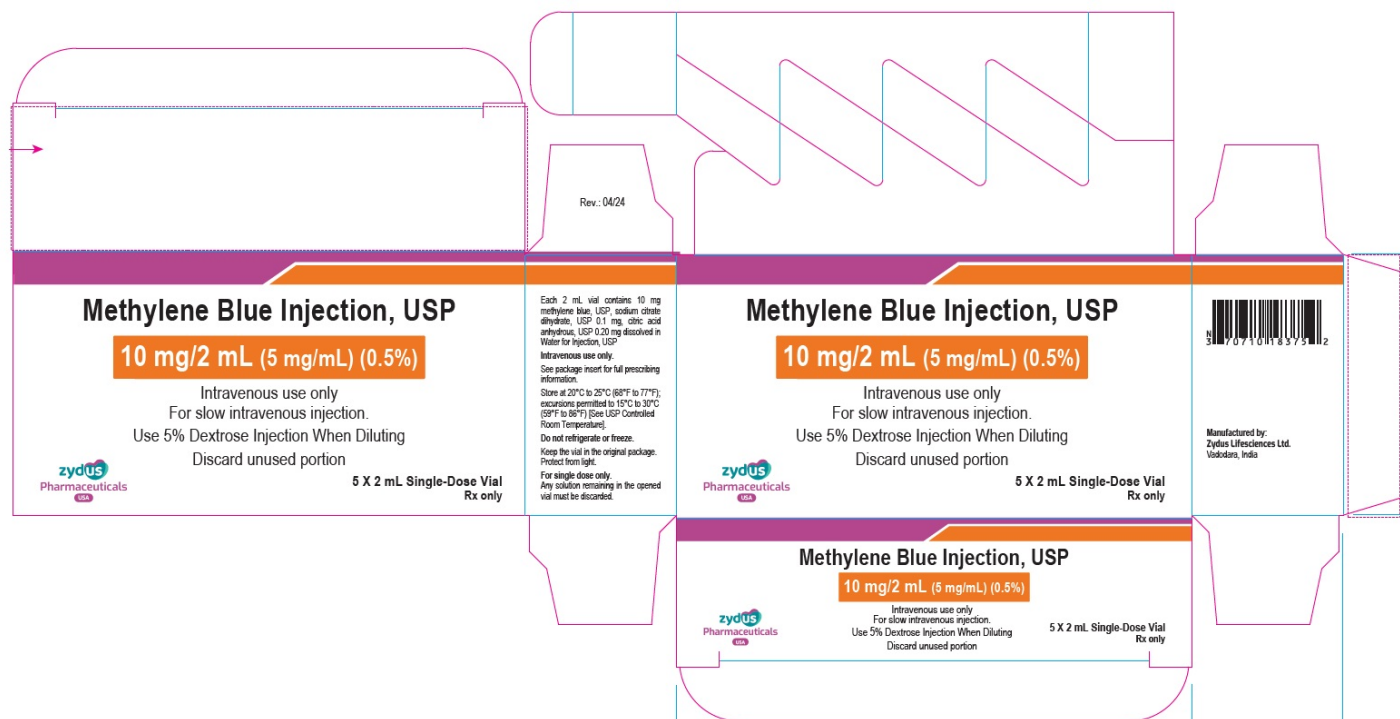
Methylene Blue Injection, USP

10 mg/2 mL (5 mg/mL)

Intravenous use only

5 X 2 mL Single-Dose Vial

Rx only



METHYLENE BLUE

methylene blue injection

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1767
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
METHYLENE BLUE (UNII: T42P99266K) (METHYLENE BLUE CATION - UNII:ZMZ79891ZH)	METHYLENE BLUE	5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1767-5	5 in 1 CARTON	12/05/2023	
1	NDC:70771-1767-1	2 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
ANDA	ANDA215636	12/05/2023	

METHYLENE BLUE

methylene blue injection

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1768
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
METHYLENE BLUE (UNII: T42P99266K) (METHYLENE BLUE CATION - UNII:ZMZ79891ZH)	METHYLENE BLUE	5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1768-5	5 in 1 CARTON	12/05/2023	
1	NDC:70771-1768-1	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
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ANDA	ANDA215636	12/05/2023	
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Labeler - ZyduS Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
ZyduS Lifesciences Limited		873671928	MANUFACTURE(70771-1767, 70771-1768) , ANALYSIS(70771-1767, 70771-1768)

Revised: 4/2024

ZyduS Lifesciences Limited