

MICAFUNGIN - micafungin injection, powder, lyophilized, for solution

Zyudus Lifesciences Limited

Micafungin for Injection, for intravenous use

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1683-6

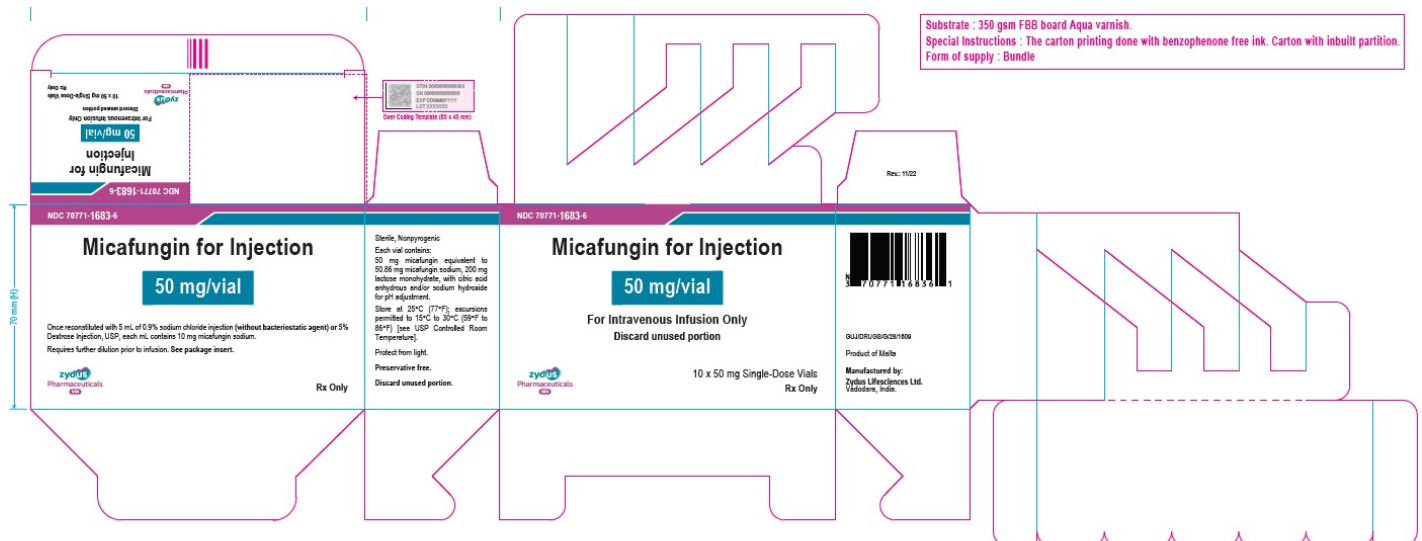
Micafungin for Injection

50 mg/vial

For Intravenous Infusion Only

10 x 50 mg Single-Dose Vials

Rx only



NDC 70771-1684-6

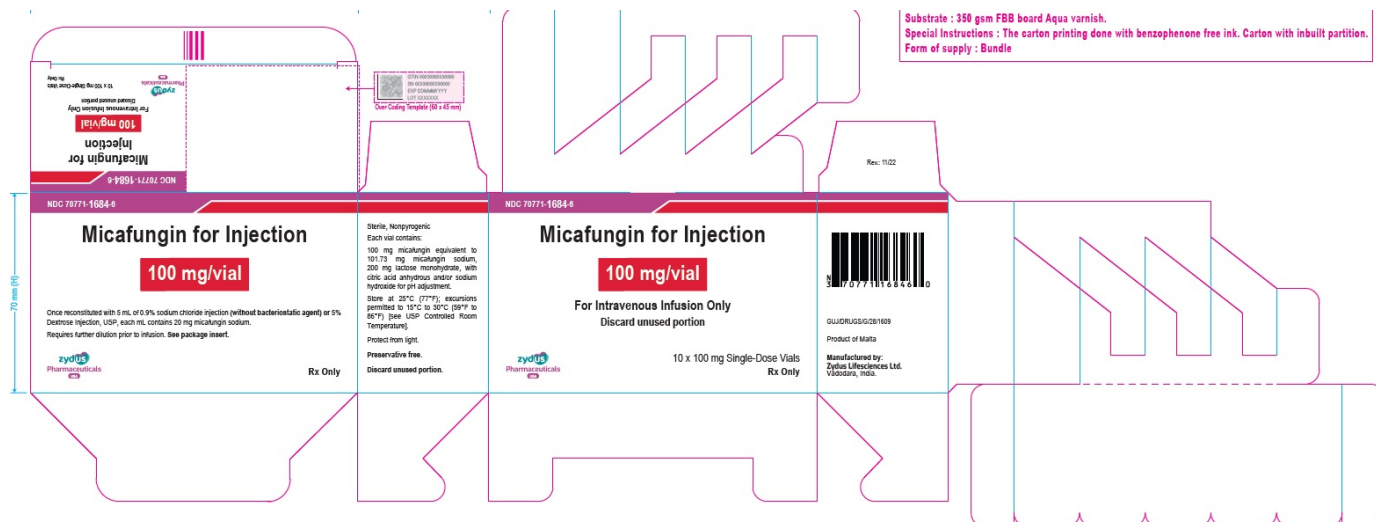
Micafungin for Injection

100 mg/vial

For Intravenous Infusion Only

10 x 100 mg Single-Dose Vials

Rx only



MICAFUNGIN

micafungin injection, powder, lyophilized, for solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1683
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MICAFUNGIN SODIUM (UNII: IS1UP79R56) (MICAFUNGIN - UNII:R10H71BSWG)	MICAFUNGIN SODIUM	10 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1683-6	10 in 1 CARTON	04/10/2023	

1	NDC:70771-1683-1	5 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	ANDA215241		04/10/2023	

MICA FUNGIN				
micafungin injection, powder, lyophilized, for solution				
Product Information				
Product Type		HUMAN PRESCRIPTION DRUG	Item Code (Source)	
Route of Administration		INTRAVENOUS	NDC:70771-1684	
Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
MICA FUNGIN SODIUM (UNII: IS1UP79R56) (MICA FUNGIN - UNII:R10H71BSWG)			MICA FUNGIN SODIUM	20 mg in 1 mL
Inactive Ingredients				
Ingredient Name				Strength
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)				
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)				
SODIUM HYDROXIDE (UNII: 55X04QC32I)				
Product Characteristics				
Color		WHITE	Score	
Shape			Size	
Flavor			Imprint Code	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1684-6	10 in 1 CARTON	04/10/2023	
1	NDC:70771-1684-1	5 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	ANDA215241	04/10/2023	

Labeler - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		873671928	MANUFACTURE(70771-1683, 70771-1684) , ANALYSIS(70771-1683, 70771-1684)

Revised: 11/2022

Zydus Lifesciences Limited