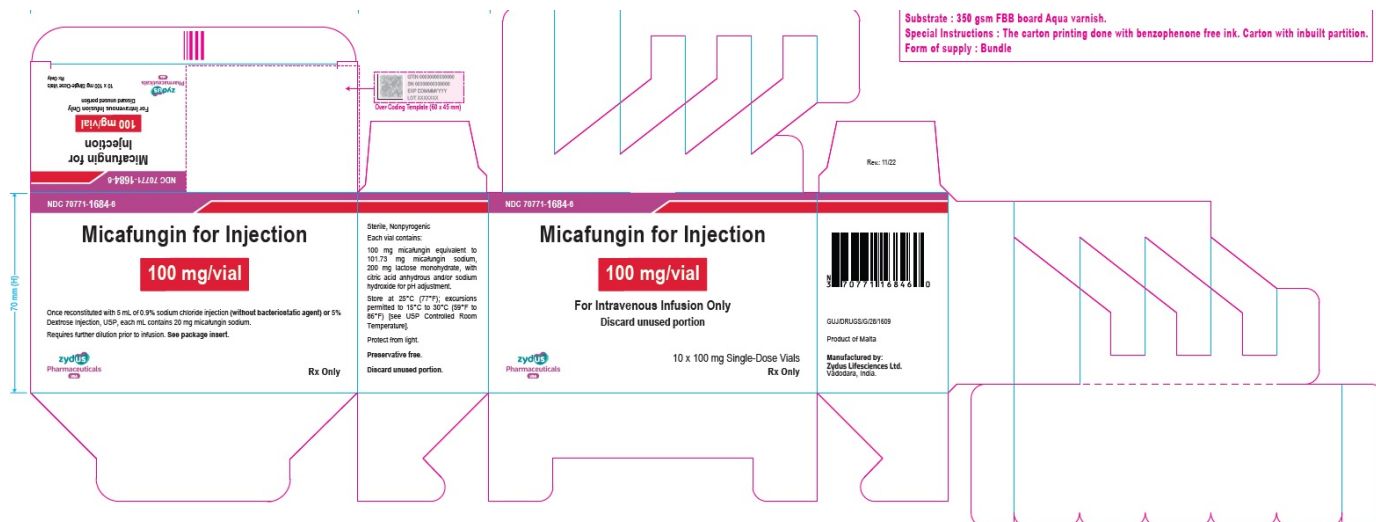


Rx only



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	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		5 mL in 1 VIAL; Type 0: Not a Combination Product		
2	NDC:70771-1683-1	1 in 1 CARTON	08/20/2024	
2		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	

MICAFUNGIN

miconazole injection, powder, lyophilized, for solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1684
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
MICAFUNGIN SODIUM (UNII: IS1UP79R56) (MICONAZOLE - UNII:R10H71BSWG)	MICONAZOLE	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		5 mL in 1 VIAL; Type 0: Not a Combination Product		
	NDC:70771			

2	NDC: 70771-1684-1	1 in 1 CARTON	08/20/2024	
2		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)