

IVERMECTIN- ivermectin cream
Zydus Lifesciences Limited

Ivermectin Cream

SPL UNCLASSIFIED

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Ivermectin Cream, 1%

45 gm

NDC 70771-1728-4

Rx only





IVERMECTIN

ivermectin cream

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1728
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IVERMECTIN (UNII: 8883YP2R6D) (IVERMECTIN - UNII:8883YP2R6D)	IVERMECTIN	10 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
COCO DIETHANOLAMIDE (UNII: 92005F972D)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
DIMETHYL ISOSORBIDE (UNII: SA6A6V432S)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	

SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	WHITE (white to pale yellow)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1728-2	1 in 1 CARTON	06/10/2023	
1		30 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:70771-1728-4	1 in 1 CARTON	06/10/2023	
2		45 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:70771-1728-3	1 in 1 CARTON	06/10/2023	
3		60 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA215210	06/10/2023	

Labeler - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		650650802	ANALYSIS(70771-1728) , MANUFACTURE(70771-1728)

Revised: 6/2023

Zydus Lifesciences Limited