INDOMETHACIN- indomethacin capsule
Cadila Healthcare Limited

INDOMETHACIN CAPSULES

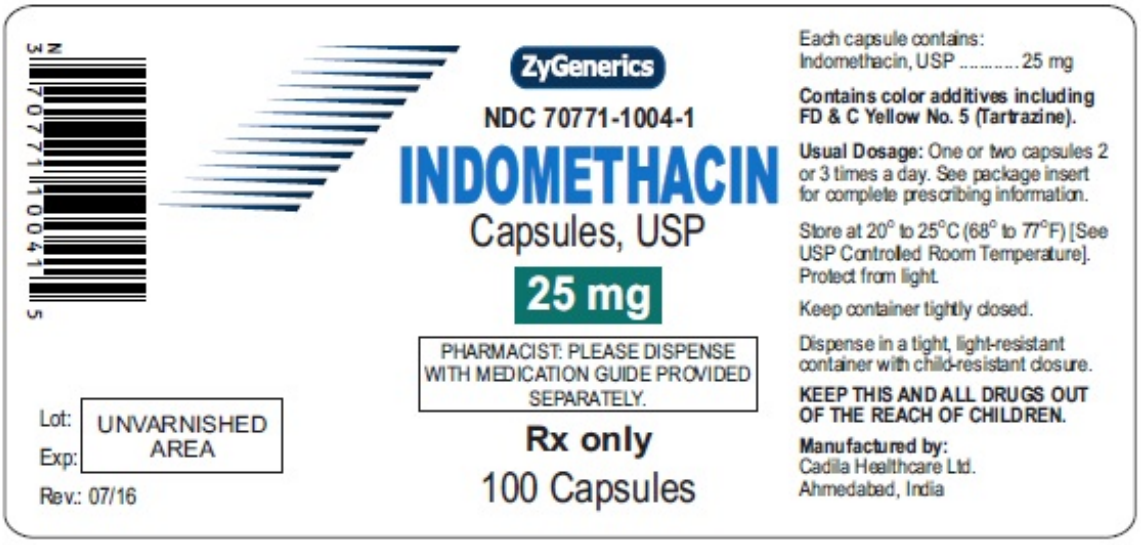
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1004-01

Indomethacin capsules USP, 25 mg

100 Capsules

Rx only

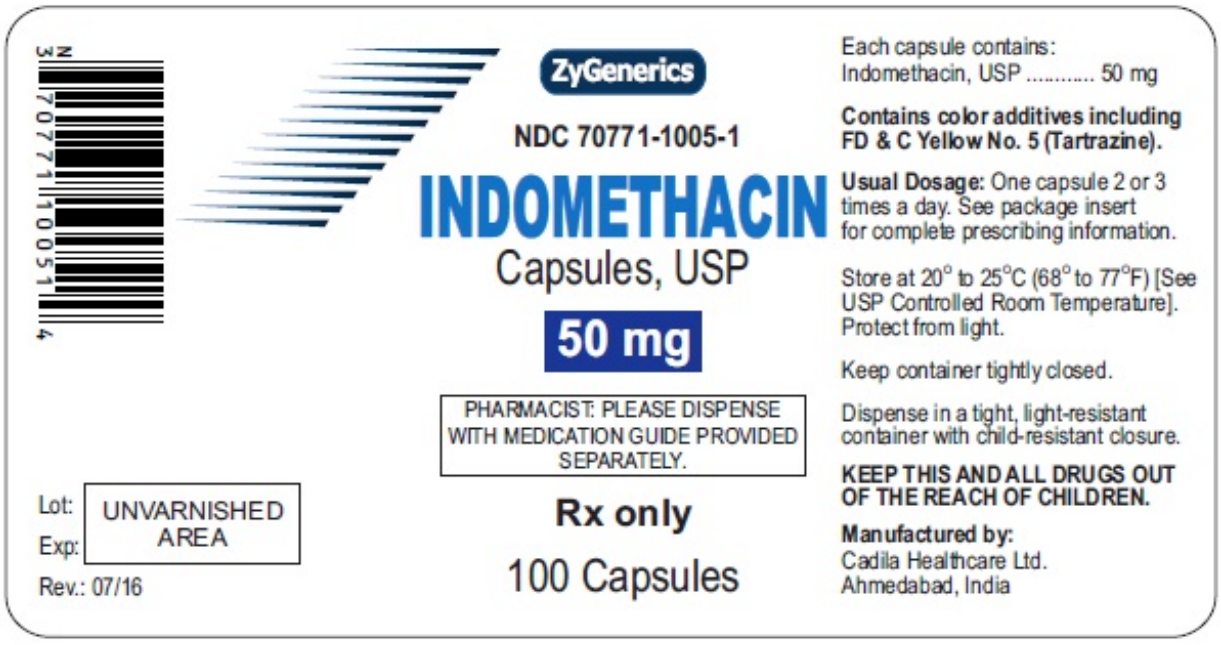


NDC 70771-1005-01

Indomethacin capsules USP, 50 mg

100 Capsules

Rx only



INDOMETHACIN

indomethacin capsule

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1004
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
INDOMETHACIN (UNII: XXE1CET956) (INDOMETHACIN - UNII:XXE1CET956)	INDOMETHACIN	50 mg

Inactive Ingredients	
Ingredient Name	**Strength**
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
GELATIN (UNII: 2G86QN327L)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POWDERED CELLULOSE (UNII: SMD1X3XO9M)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	GREEN (GREEN)	**Score**	no score
Shape	CAPSULE (CAPSULE)	**Size**	19mm
Flavor		**Imprint Code**	294;50mg
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1004-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	07/21/2016	
2	NDC:70771-1004-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	07/21/2016	
3	NDC:70771-1004-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	07/21/2016	
4	NDC:70771-1004-2	10 in 1 BLISTER PACK; Type 0: Not a Combination Product	07/21/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090403	07/21/2016	

INDOMETHACIN

indomethacin capsule

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1005
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
INDOMETHACIN (UNII: XXE1CET956) (INDOMETHACIN - UNII:XXE1CET956)	INDOMETHACIN	25 mg

Inactive Ingredients

Ingredient Name	Strength
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
GELATIN (UNII: 2G86QN327L)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POWDERED CELLULOSE (UNII: SMD1X3XO9M)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	GREEN (GREEN)	**Score**	no score
Shape	CAPSULE (CAPSULE)	**Size**	16mm
Flavor		**Imprint Code**	293;25mg
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1005-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	07/21/2016	
2	NDC:70771-1005-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	07/21/2016	
3	NDC:70771-1005-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	07/21/2016	
4	NDC:70771-1005-2	10 in 1 BLISTER PACK; Type 0: Not a Combination Product	07/21/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090403	07/21/2016	

Labeler - Cadila Healthcare Limited (918596198)

Registrant - Cadila Healthcare Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Cadila Healthcare Limited		918596198	ANALYSIS(70771-1004, 70771-1005) , MANUFACTURE(70771-1004, 70771-1005)

Revised: 8/2020 Cadila Healthcare Limited