DOXYCYCLINE HYCLATE- doxycycline hyclate capsule
Cadila Healthcare Limited

Doxycycline hyclate capsules

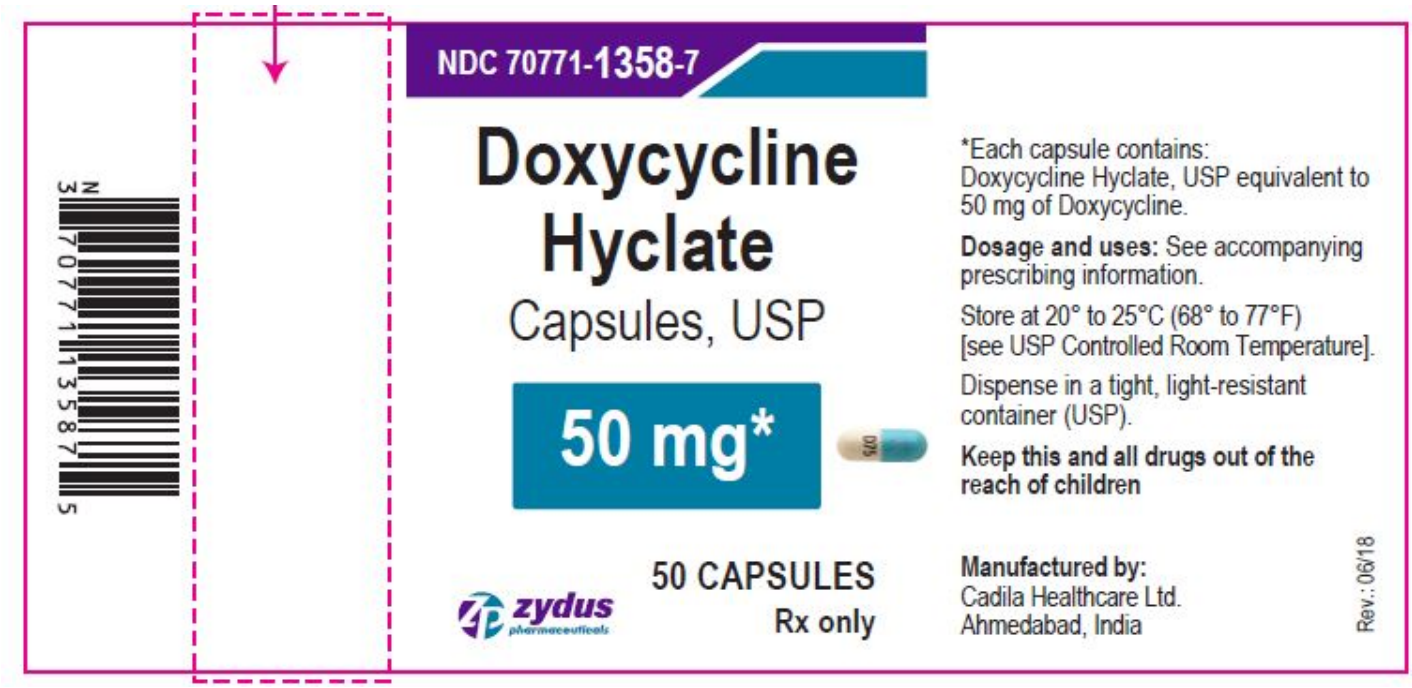
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1358-7

Doxycycline hyclate capsules, 50 mg

Rx only

50 capsules



NDC 70771-1359-7

Doxycycline hyclate capsules, 100 mg

Rx only

50 capsules

DOXYCYCLINE HYCLATE

doxycycline hyclate capsule

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1358
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DOXYCYCLINE HYCLATE (UNII: 19XTS3T51U) (DOXYCYCLINE ANHYDROUS - UNII:334895S862)	DOXYCYCLINE ANHYDROUS	50 mg

Inactive Ingredients	
Ingredient Name	**Strength**
ALCOHOL (UNII: 3K9958V90M)	
AMMONIA (UNII: 5138Q19F1X)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
GELATIN (UNII: 2G86QN327L)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	BLUE (BLUE) , WHITE (WHITE)	**Score**	no score
Shape	CAPSULE (CAPSULE)	**Size**	16mm
Flavor		**Imprint Code**	CHL;D75
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1358-7	50 in 1 BOTTLE; Type 0: Not a Combination Product	09/12/2018	
2	NDC:70771-1358-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	09/12/2018	
3	NDC:70771-1358-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	09/12/2018	
4	NDC:70771-1358-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	09/12/2018	
5	NDC:70771-1358-4	10 in 1 CARTON	09/12/2018	
5	NDC:70771-1358-2	10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA207774	09/12/2018	

DOXYCYCLINE HYCLATE

doxycycline hyclate capsule

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1359
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DOXYCYCLINE HYCLATE (UNII: 19XTS3T51U) (DOXYCYCLINE ANHYDROUS - UNII:334895S862)	DOXYCYCLINE ANHYDROUS	100 mg

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
AMMONIA (UNII: 5138Q19F1X)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	

BUTYL ALCOHOL (UNII: 8PJ61P6TS3)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
GELATIN (UNII: 2G86QN327L)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	BLUE (LIGHT BLUE) , BLUE (LIGHT BLUE)	**Score**	no score
Shape	CAPSULE (CAPSULE)	**Size**	20mm
Flavor		**Imprint Code**	CHL;D76
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1359-7	50 in 1 BOTTLE; Type 0: Not a Combination Product	09/12/2018	
2	NDC:70771-1359-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	09/12/2018	
3	NDC:70771-1359-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	09/12/2018	
4	NDC:70771-1359-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	09/12/2018	
5	NDC:70771-1359-4	10 in 1 CARTON	09/12/2018	
5	NDC:70771-1359-2	10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA207774	09/12/2018	

Labeler - Cadila Healthcare Limited (918596198)

Registrant - Cadila Healthcare Limited (863362789)

Establishment

Name	Address	ID/FEI	Business Operations
Cadila Healthcare Limited		863362789	ANALYSIS(70771-1358, 70771-1359) , MANUFACTURE(70771-1358, 70771-1359)