DOXYCYCLINE HYCLATE - doxycycline hyclate tablet, delayed release
Zydus Lifesciences Limited

Doxycycline Hyclate Delayed-release Tablets, USP

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1587-6 in bottle of 60 tablets

Doxycycline Hyclate Delayed-release Tablets USP, 75 mg

Rx only

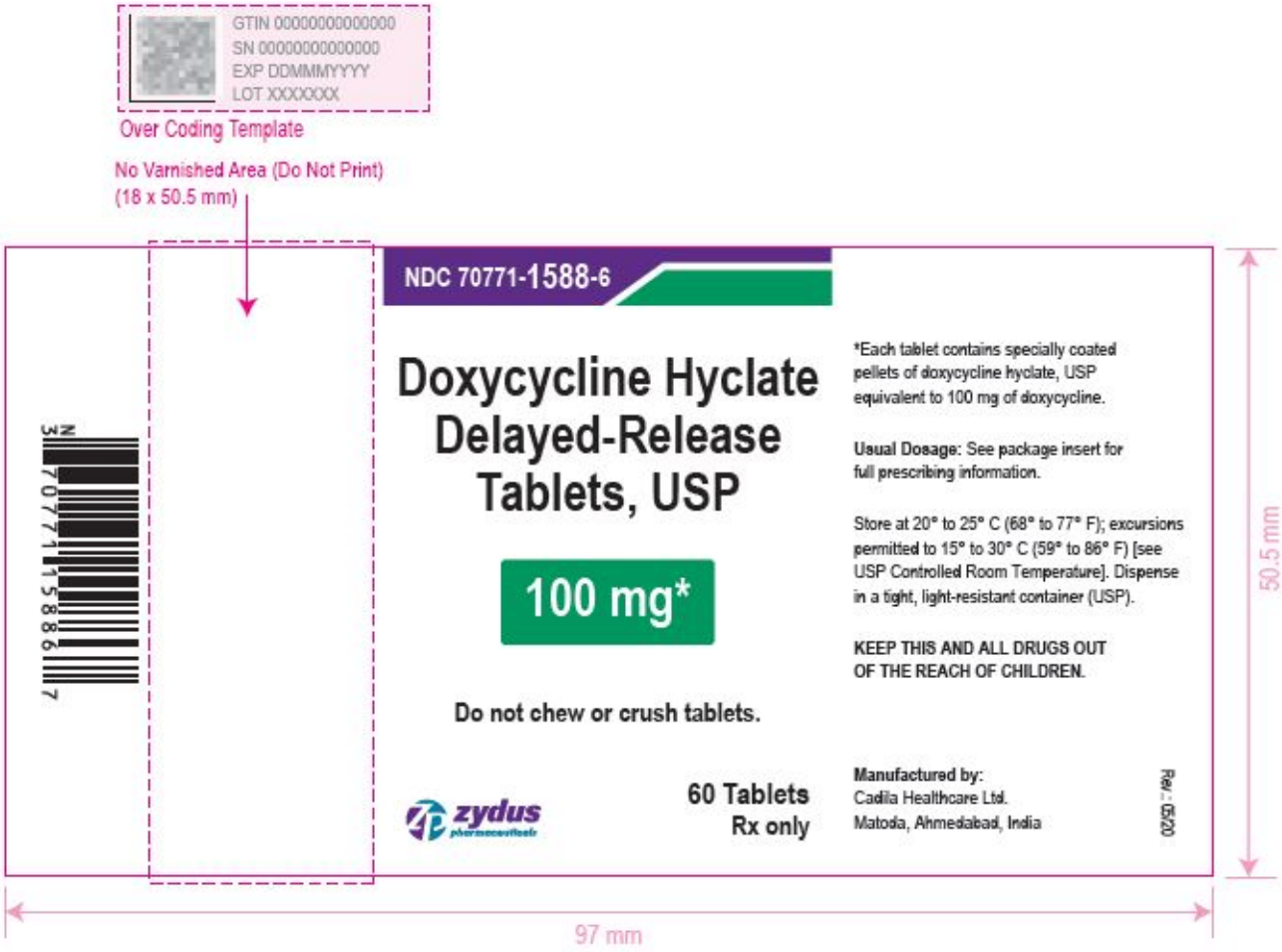
60 tablets

NDC 70771-1588-6 in bottle of 60 tablets

Doxycycline Hyclate Delayed-release Tablets USP, 100 mg

Rx only

60 tablets

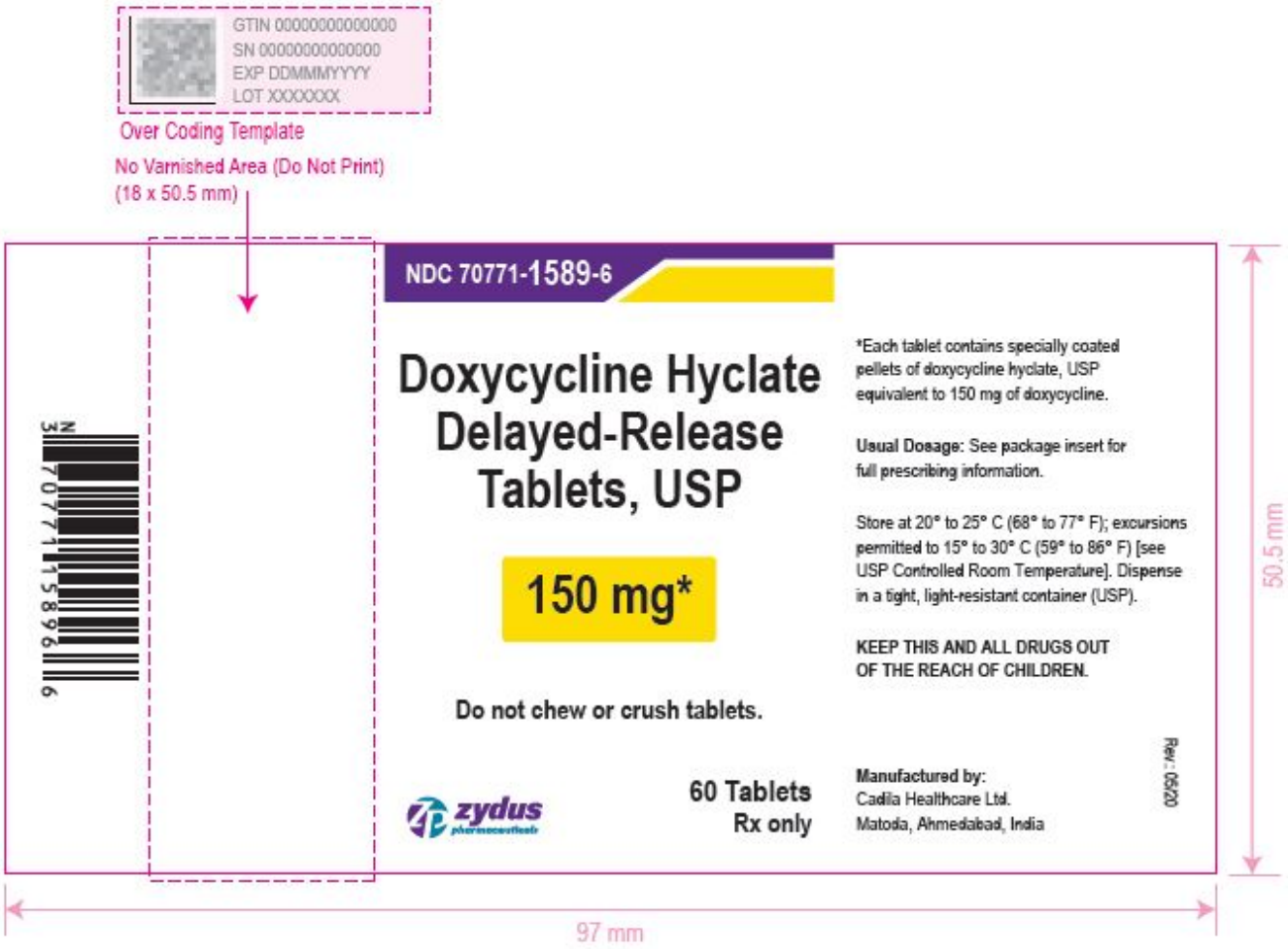


NDC 70771-1589-6 in bottle of 60 tablets

Doxycycline Hyclate Delayed-release Tablets USP, 150 mg

Rx only

60 tablets



DOXYCYCLINE HYCLATE

doxycycline hyclate tablet, delayed release

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1587
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DOXYCYCLINE HYCLATE (UNII: 19XTS3T51U) (DOXYCYCLINE ANHYDROUS - UNII:334895S862)	DOXYCYCLINE ANHYDROUS	75 mg

Inactive Ingredients	
Ingredient Name	**Strength**
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSPOVIDONE (UNII: 2S7830E561)	
HYPROMELLOSE PHTHALATE (24% PHTHALATE, 55 CST) (UNII: 87Y6436BKR)	

HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE)	**Score**	2 pieces
Shape	OVAL (OVAL)	**Size**	16mm
Flavor		**Imprint Code**	70;8
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1587-6	60 in 1 BOTTLE; Type 0: Not a Combination Product	12/21/2018	
2	NDC:70771-1587-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	12/21/2018	
3	NDC:70771-1587-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	12/21/2018	
4	NDC:70771-1587-4	10 in 1 CARTON	12/21/2018	
4	NDC:70771-1587-2	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	ANDA206772	12/21/2018	

DOXYCYCLINE HYCLATE

doxycycline hyclate tablet, delayed release

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1588
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

UNII:334895S862)	ANHYDROUS	100 mg

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSPOVIDONE (UNII: 2S7830E561)	
HYPROMELLOSE PHTHALATE (24% PHTHALATE, 55 CST) (UNII: 87Y6436BKR)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE)	**Score**	2 pieces
Shape	OVAL (OVAL)	**Size**	18mm
Flavor		**Imprint Code**	70;9
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1588-6	60 in 1 BOTTLE; Type 0: Not a Combination Product	12/21/2018	
2	NDC:70771-1588-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	12/21/2018	
3	NDC:70771-1588-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	12/21/2018	
4	NDC:70771-1588-4	10 in 1 CARTON	12/21/2018	
4	NDC:70771-1588-2	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	ANDA206772	12/21/2018	

DOXYCYCLINE HYCLATE

doxycycline hyclate tablet, delayed release

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1589
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DOXYCYCLINE HYCLATE (UNII: 19XTS3T51U) (DOXYCYCLINE ANHYDROUS - UNII:334895S862)	DOXYCYCLINE ANHYDROUS	150 mg

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSPOVIDONE (UNII: 2S7830E561)	
HYPROMELLOSE PHTHALATE (24% PHTHALATE, 55 CST) (UNII: 87Y6436BKR)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE)	**Score**	3 pieces
Shape	CAPSULE (CAPSULE)	**Size**	19mm
Flavor		**Imprint Code**	7;1;0
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1589-6	60 in 1 BOTTLE; Type 0: Not a Combination Product	12/21/2018	
2	NDC:70771-1589-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	12/21/2018	
3	NDC:70771-1589-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	12/21/2018	
4	NDC:70771-1589-4	10 in 1 CARTON	12/21/2018	
4	NDC:70771-1589-2	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	ANDA206772	12/21/2018	

Labeler - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		863362789	ANALYSIS(70771-1587, 70771-1588, 70771-1589) , MANUFACTURE(70771-1587, 70771-1588, 70771-1589)

Revised: 10/2022 Zydus Lifesciences Limited