

DOXYCYCLINE - doxycycline tablet, film coated
Zydus Lifesciences Limited

Doxycycline Tablets, USP

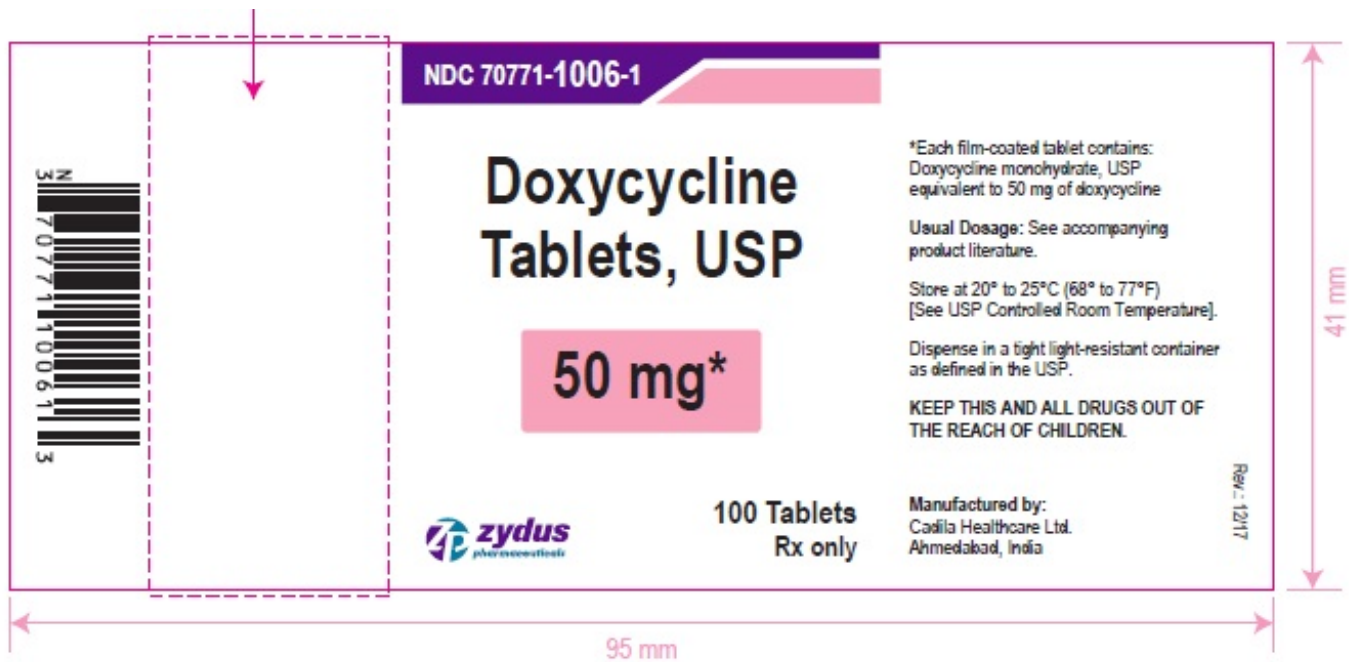
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1006-1

Doxycycline Tablets, USP - 50 mg

Rx only

100 Tablets

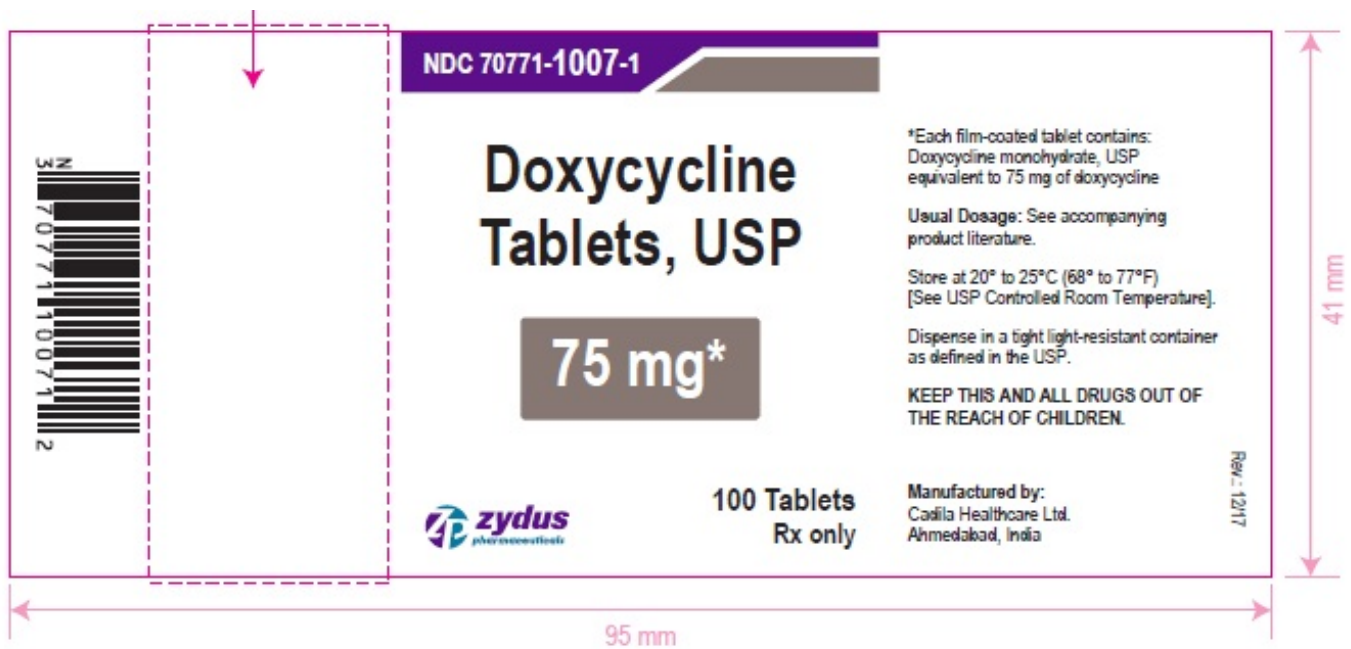


NDC 70771-1007-1

Doxycycline Tablets, USP - 75 mg

Rx only

100 Tablets

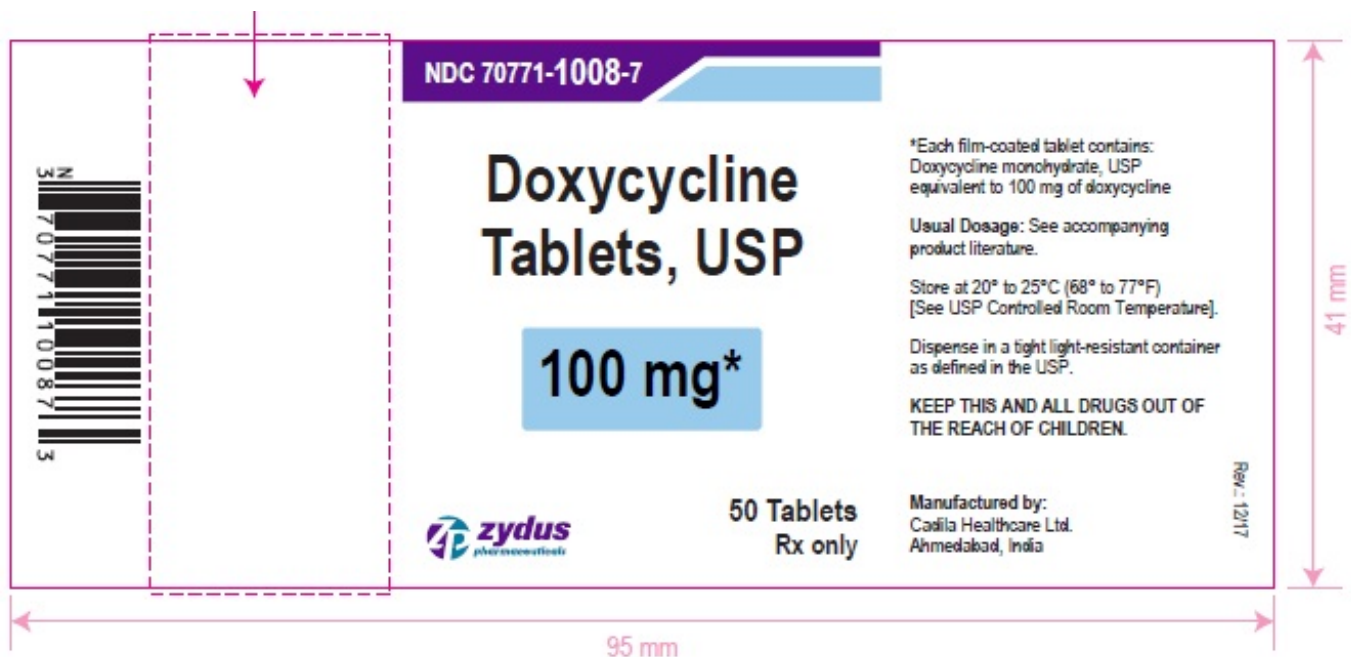


NDC 70771-1008-7

Doxycycline Tablets, USP - 100 mg

Rx only

50 Tablets



NDC 70771-1009-1

Doxycycline Tablets, USP - 150 mg

Rx only

100 Tablets



DOXYCYCLINE

doxycycline tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1006
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DOXYCYCLINE (UNII: N12000U13O) (DOXYCYCLINE ANHYDROUS - UNII:334895S862)	DOXYCYCLINE ANHYDROUS	50 mg

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSPVIDONE (UNII: 2S7830E561)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I3O)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	YELLOW (PALE YELLOW)	Score	no score
Shape	ROUND (biconvex, beveled edged)	Size	7mm
Flavor		Imprint Code	1121
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1006-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	01/11/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA209582	01/11/2018	

DOXYCYCLINE

doxycycline tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1007
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DOXYCYCLINE (UNII: N12000U13O) (DOXYCYCLINE ANHYDROUS - UNII:334895S862)	DOXYCYCLINE ANHYDROUS	75 mg

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSPVIDONE (UNII: 2S7830E561)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I3O)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

TRIETHYL CITRATE (UNII: 8Z96QXD6UM)

Product Characteristics

Color	ORANGE (CREAMISH ORANGE)	Score	no score
Shape	ROUND (biconvex, beveled edged)	Size	8mm
Flavor		Imprint Code	1122
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1007-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	01/11/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA209582	01/11/2018	

DOXYCYCLINE

doxycycline tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1008
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DOXYCYCLINE (UNII: N12000U13O) (DOXYCYCLINE ANHYDROUS - UNII:334895S862)	DOXYCYCLINE ANHYDROUS	100 mg

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSPVIDONE (UNII: 2S7830E561)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I3O)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	

SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
Product Characteristics				
Color	YELLOW (LEMON YELLOW TO BUFF COLORED)	Score	no score	
Shape	ROUND (biconvex, beveled edged)	Size	9mm	
Flavor		Imprint Code	1123	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1008-7	50 in 1 BOTTLE; Type 0: Not a Combination Product	01/11/2018	
2	NDC:70771-1008-8	250 in 1 BOTTLE; Type 0: Not a Combination Product	01/11/2018	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA209582	01/11/2018		

DOXYCYCLINE			
doxycycline tablet, film coated			
Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1009
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
DOXYCYCLINE (UNII: N12000U13O) (DOXYCYCLINE ANHYDROUS - UNII:334895S862)		DOXYCYCLINE ANHYDROUS	150 mg
Inactive Ingredients			
Ingredient Name			Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)			
CROSPVIDONE (UNII: 2S7830E561)			
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)			
FERRIC OXIDE RED (UNII: 1K09F3G675)			
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)			
HYPROMELLOSES (UNII: 3NXW29V3WO)			

LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

Product Characteristics

Color	ORANGE (DARK ORANGE TO CREAMISH ORANGE)	Score	2 pieces
Shape	ROUND (biconvex, beveled edged)	Size	11mm
Flavor		Imprint Code	1124
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1009-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	01/11/2018	
2	NDC:70771-1009-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	01/11/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA209582	01/11/2018	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		863362789	ANALYSIS(70771-1006, 70771-1007, 70771-1008, 70771-1009) , MANUFACTURE(70771-1006, 70771-1007, 70771-1008, 70771-1009)