DOXYCYCLINE - doxycycline capsule
Zydus Lifesciences Limited

Doxycycline Capsules, USP

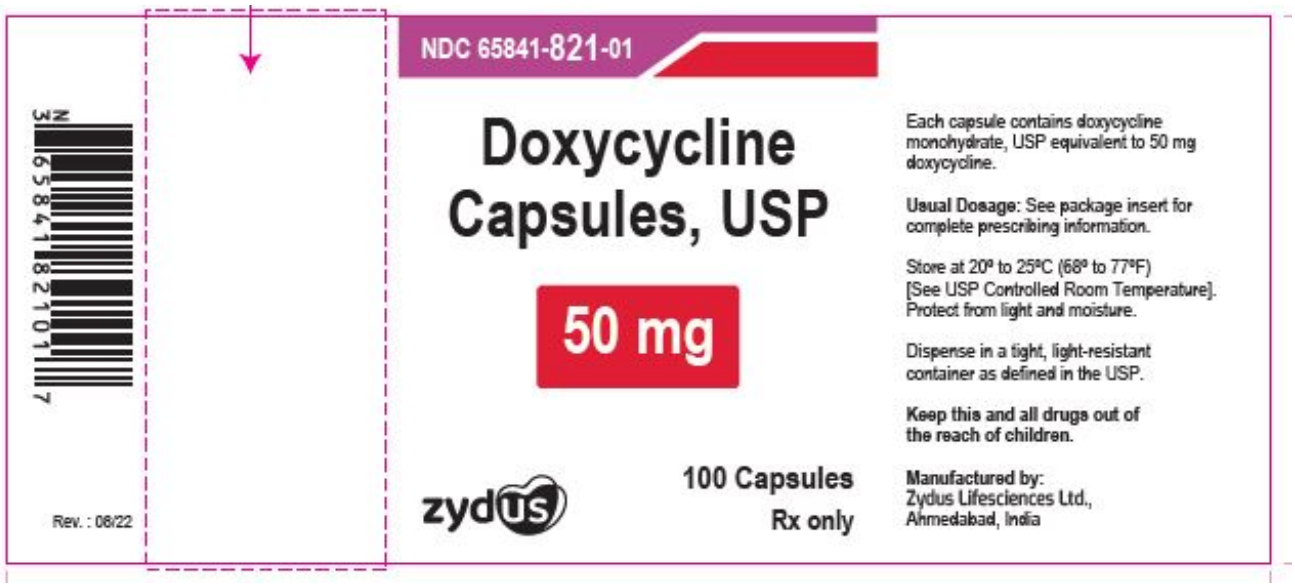
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 65841-821-01 in bottle of 100 Capsules

Doxycycline Capsules USP, 50 mg

Rx Only

100 Capsules



NDC 65841-822-01 in bottle of 100 Capsules

Doxycycline Capsules USP, 75 mg

Rx Only

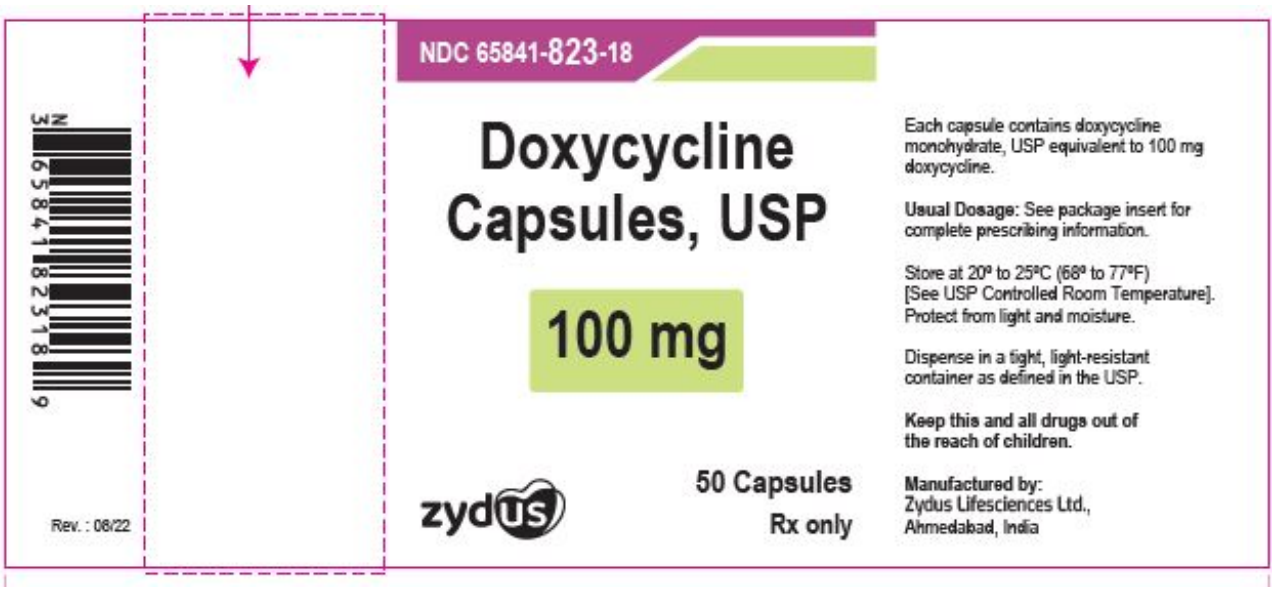
100 Capsules

NDC 65841-823-01 in bottle of 100 Capsules

Doxycycline Capsules USP, 100 mg

Rx Only

100 Capsules



DOXYCYCLINE

doxycycline capsule

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-821
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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
GELATIN (UNII: 2G86QN327L)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
AMMONIA (UNII: 5138Q19F1X)	

Product Characteristics

Color	YELLOW (OPAQUE YELLOW) , WHITE (OPAQUE WHITE)	**Score**	no score
Shape	CAPSULE (CAPSULE)	**Size**	16mm
Flavor		**Imprint Code**	782
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-821-06	30 in 1 BOTTLE; Type 0: Not a Combination Product	03/14/2016	
2	NDC:65841-821-18	50 in 1 BOTTLE; Type 0: Not a Combination Product	03/14/2016	
3	NDC:65841-821-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	03/14/2016	
4	NDC:65841-821-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	03/14/2016	
5	NDC:65841-821-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	03/14/2016	
6	NDC:65841-821-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	03/14/2016	
7	NDC:65841-821-77	10 in 1 CARTON	03/14/2016	
7	NDC:65841-821-30	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	ANDA205115	03/14/2016	

DOXYCYCLINE

doxycycline capsule

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-822
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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
GELATIN (UNII: 2G86QN327L)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 3 (UNII: PN2ZH5LOQY)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
AMMONIA (UNII: 5138Q19F1X)	

Product Characteristics

Color	ORANGE (OPAQUE ORANGE) , WHITE (OPAQUE WHITE)	**Score**	no score
Shape	CAPSULE (CAPSULE)	**Size**	18mm
Flavor		**Imprint Code**	706
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-822-06	30 in 1 BOTTLE; Type 0: Not a Combination Product	03/14/2016	
2	NDC:65841-822-18	50 in 1 BOTTLE; Type 0: Not a Combination Product	03/14/2016	
3	NDC:65841-822-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	03/14/2016	
4	NDC:65841-822-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	03/14/2016	
5	NDC:65841-822-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	03/14/2016	
6	NDC:65841-822-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	03/14/2016	
7	NDC:65841-822-77	10 in 1 CARTON	03/14/2016	
7	NDC:65841-822-30	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	ANDA205115	03/14/2016	

DOXYCYCLINE

doxycycline capsule

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-823
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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
GELATIN (UNII: 2G86QN327L)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 3 (UNII: PN2ZH5LOQY)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
AMMONIA (UNII: 5138Q19F1X)	

Product Characteristics

Color	YELLOW (OPAQUE YELLOW) , ORANGE (OPAQUE ORANGE)	**Score**	no score
Shape	CAPSULE (CAPSULE)	**Size**	19mm
Flavor		**Imprint Code**	707
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-823-06	30 in 1 BOTTLE; Type 0: Not a Combination Product	03/14/2016	
2	NDC:65841-823-18	50 in 1 BOTTLE; Type 0: Not a Combination Product	03/14/2016	
3	NDC:65841-823-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	03/14/2016	
4	NDC:65841-823-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	03/14/2016	
5	NDC:65841-823-21	250 in 1 BOTTLE; Type 0: Not a Combination Product	03/14/2016	
6	NDC:65841-823-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	03/14/2016	
7	NDC:65841-823-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	03/14/2016	
8	NDC:65841-823-77	10 in 1 CARTON	03/14/2016	
8	NDC:65841-823-30	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	ANDA205115	03/14/2016	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (863362789)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		863362789	ANALYSIS(65841-821, 65841-822, 65841-823) , MANUFACTURE(65841-821, 65841-822, 65841-823)

Revised: 8/2022

Zydus Lifesciences Limited