AMIODARONE HYDROCHLORIDE - amiodarone hydrochloride tablet
Zydus Lifesciences Limited

AMIODARONE HYDROCHLORIDE TABLETS

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 65841-840-06

Amiodarone Hydrochloride Tablets USP, 100 mg

30 Tablets

Rx only

NDC 65841-631-14 in bottle of 60 tablets

Amiodarone Hydrochloride Tablets, 200 mg

Rx only

NDC 65841-841-06

Amiodarone Hydrochloride Tablets USP, 400 mg

30 Tablets

Rx only

AMIODARONE HYDROCHLORIDE

amiodarone hydrochloride tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-840

Route of Administration	ORAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
AMIODARONE HYDROCHLORIDE (UNII: 976728SY6Z) (AMIODARONE - UNII:N3RQ532IUT)	AMIODARONE HYDROCHLORIDE	100 mg

Inactive Ingredients	
Ingredient Name	**Strength**
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
POVIDONE (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics			
Color	WHITE (OFF-WHITE)	**Score**	no score
Shape	ROUND (ROUND)	**Size**	8mm
Flavor		**Imprint Code**	297
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:65841-840-06	30 in 1 BOTTLE; Type 0: Not a Combination Product	02/09/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA079029	02/09/2023	

AMIODARONE HYDROCHLORIDE

amiodarone hydrochloride tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-631
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AMIODARONE HYDROCHLORIDE (UNII: 976728SY6Z) (AMIODARONE - UNII:N3RQ532IUT)	AMIODARONE HYDROCHLORIDE	200 mg

Inactive Ingredients

Ingredient Name	Strength
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
POVIDONE (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE)	**Score**	2 pieces
Shape	ROUND (ROUND)	**Size**	10mm
Flavor		**Imprint Code**	ZE;65
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-631-06	30 in 1 BOTTLE; Type 0: Not a Combination Product	08/10/2009	
2	NDC:65841-631-14	60 in 1 BOTTLE; Type 0: Not a Combination Product	08/10/2009	
3	NDC:65841-631-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	08/10/2009	
4	NDC:65841-631-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	08/10/2009	
5	NDC:65841-631-77	10 in 1 CARTON	08/10/2009	
5		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	ANDA079029	08/10/2009	

AMIODARONE HYDROCHLORIDE

amiodarone hydrochloride tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-841
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AMIODARONE HYDROCHLORIDE (UNII: 976728SY6Z) (AMIODARONE - UNII:N3RQ532IUT)	AMIODARONE HYDROCHLORIDE	400 mg

Inactive Ingredients

Ingredient Name	Strength
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
STARCH, CORN (UNII: O8232NY3SJ)	
POVIDONE (UNII: FZ989GH94E)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	

Product Characteristics

Color	YELLOW (PALE YELLOW TO YELLOW)	**Score**	2 pieces
Shape	ROUND (ROUND)	**Size**	13mm
Flavor		**Imprint Code**	2;98
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-841-06	30 in 1 BOTTLE; Type 0: Not a Combination Product	02/09/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA079029	02/09/2023	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		918596198	ANALYSIS(65841-631, 65841-840, 65841-841) , MANUFACTURE(65841-631, 65841-840, 65841-841)