

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 65841-631-14

Amiodarone Hydrochloride Tablets, USP

200 mg

Attention Pharmacist: Dispense with Medication Guide.

zydus 60 Tablets Rx only

Each tablet contains: Amiodarone hydrochloride, USP...200 mg

Usual Dosage: See package insert for complete prescribing information.

Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature]. Protect from light.

Dispense in a tight, light-resistant container.

Keep this and all drugs out of the reach of children.

Manufactured by: Zydus Lifesciences Ltd, India

Rev.: 08/22

95 mm

41 mm

NDC 65841-841-06

Amiodarone Hydrochloride Tablets USP, 400 mg

30 Tablets

Rx only

NDC 65841-841-06

Amiodarone Hydrochloride Tablets, USP

400 mg

PHARMACIST: Dispense the Medication Guide provided separately to each patient.

zydus 30 Tablets Rx only

Each tablet contains: Amiodarone hydrochloride, USP...400 mg

Usual Dosage: See package insert for complete Prescribing Information.

This package is child-resistant.

Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature]. Protect from light.

Dispense in a tight, light-resistant container.

Keep this and all drugs out of the reach of children.

Manufactured by: Cadila Healthcare Ltd, India

Rev.: 01/23

95 mm

41 mm

AMIODARONE HYDROCHLORIDE

amiodarone hydrochloride tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:65841-840
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Route of Administration	ORAL
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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)

Revised: 1/2023

Zydus Lifesciences Limited