CANDESARTAN CILEXETIL AND HYDROCHLOROTHIAZIDE- candesartan cilexetil and hydrochlorothiazide tablet
Zydus Lifesciences Limited

Candesartan Cilexetil and Hydrochlorothiazide Tablets USP, for oral use

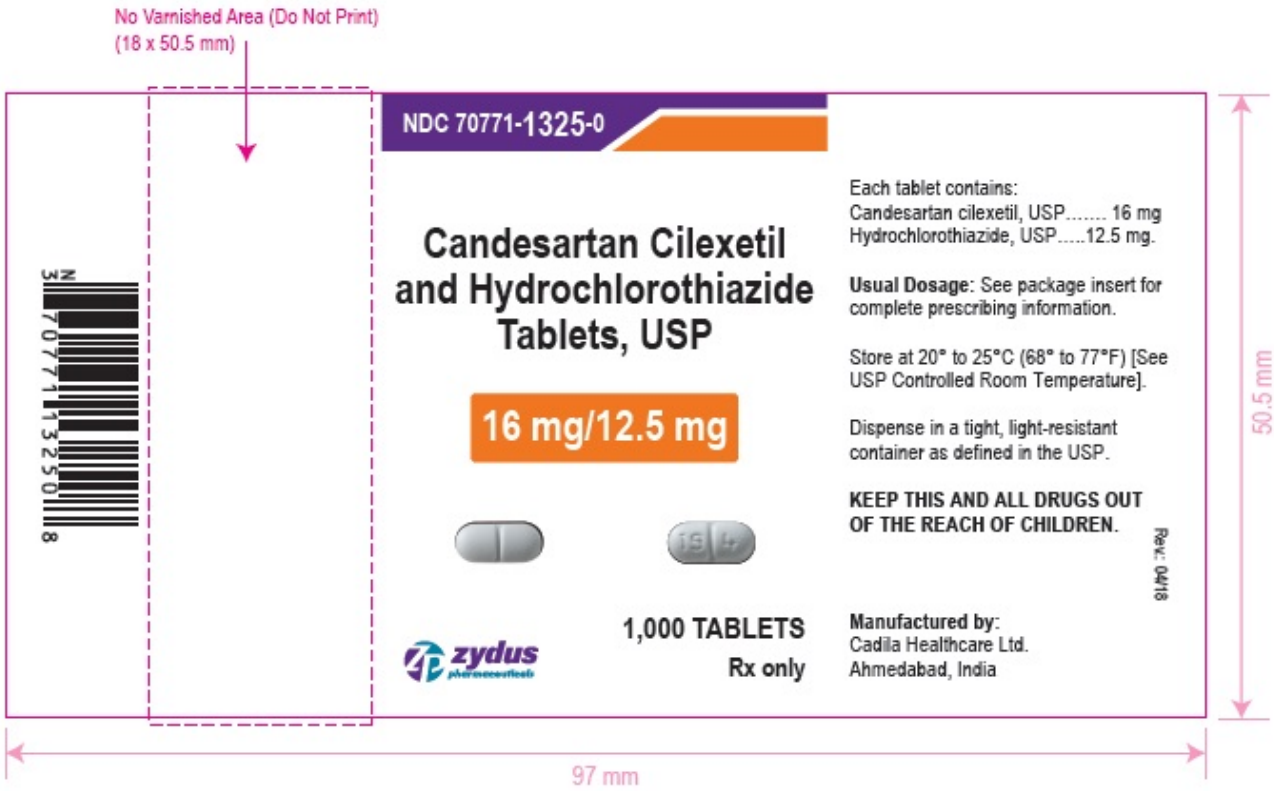
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1325-0 in bottle of 1000 tablets

Candesartan Cilexetil and Hydrochlorothiazide Tablets USP, 16 mg/12.5 mg

R_x only

1000 tablets



NDC 70771-1326-0 in bottle of 1000 tablets

Candesartan Cilexetil and Hydrochlorothiazide Tablets USP, 32 mg/12.5 mg

R_x only

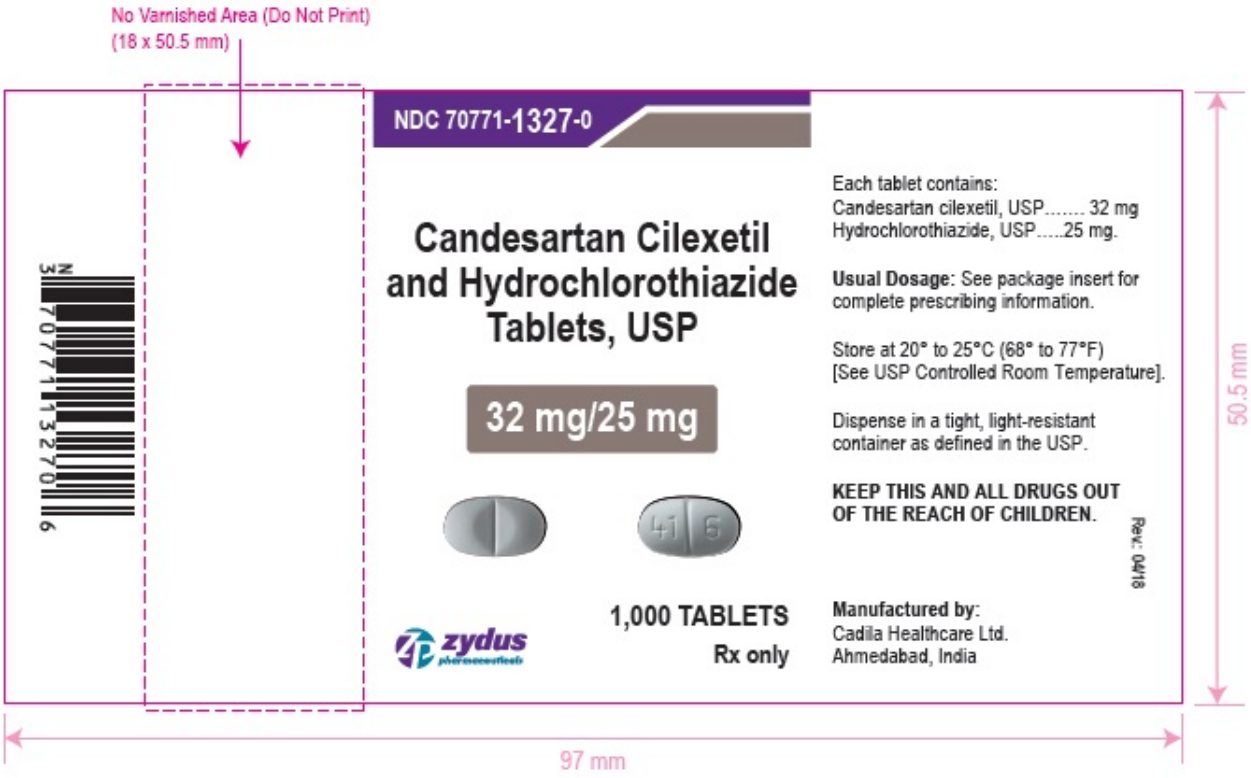
1000 tablets

NDC 70771-1327-0 in bottle of 1000 tablets

Candesartan Cilexetil and Hydrochlorothiazide Tablets USP, 32 mg/25 mg

R_x only

1000 tablets



CANDESARTAN CILEXETIL AND HYDROCHLOROTHIAZIDE

candesartan cilexetil and hydrochlorothiazide tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1325
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CANDESARTAN CILEXETIL (UNII: R85M2X0D68) (CANDESARTAN - UNII:S8Q36MD2XX)	CANDESARTAN CILEXETIL	16 mg
HYDROCHLOROTHIAZIDE (UNII: 0J48LPH2TH) (HYDROCHLOROTHIAZIDE - UNII:0J48LPH2TH)	HYDROCHLOROTHIAZIDE	12.5 mg

Inactive Ingredients	
Ingredient Name	**Strength**
CARBOXYMETHYLCELLULOSE CALCIUM (UNII: UTY7PDF93L)	
STARCH, CORN (UNII: O8232NY3SJ)	
GLYCERYL MONO- AND DICAPRYLOCAPRATE (UNII: U72Q2I8C85)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
HYDROXYPROPYL CELLULOSE (110000 WAMW) (UNII: 5Y0974F5PW)	

Product Characteristics			
Color	WHITE (WHITE TO OFF-WHITE)	**Score**	2 pieces
Shape	OVAL (OVAL)	**Size**	10mm
Flavor		**Imprint Code**	19;4
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1325-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	04/14/2018	
2	NDC:70771-1325-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	04/14/2018	
3	NDC:70771-1325-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	04/14/2018	
4	NDC:70771-1325-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	04/14/2018	
5	NDC:70771-1325-4	10 in 1 CARTON	04/14/2018	
5	NDC:70771-1325-2	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	ANDA203466	04/14/2018	

CANDESARTAN CILEXETIL AND HYDROCHLOROTHIAZIDE

candesartan cilexetil and hydrochlorothiazide tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1326
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CANDESARTAN CILEXETIL (UNII: R85M2X0D68) (CANDESARTAN - UNII:S8Q36MD2XX)	CANDESARTAN CILEXETIL	32 mg
HYDROCHLOROTHIAZIDE (UNII: 0J48LPH2TH) (HYDROCHLOROTHIAZIDE - UNII:0J48LPH2TH)	HYDROCHLOROTHIAZIDE	12.5 mg

Inactive Ingredients

Ingredient Name	Strength
CARBOXYMETHYLCELLULOSE CALCIUM (UNII: UTY7PDF93L)	

STARCH, CORN (UNII: O8232NY3SJ)	
GLYCERYL MONO- AND DICAPRYLOCAPRATE (UNII: U72Q2I8C85)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
HYDROXYPROPYL CELLULOSE (110000 WAMW) (UNII: 5Y0974F5PW)	

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE)	**Score**	2 pieces
Shape	OVAL (OVAL)	**Size**	11mm
Flavor		**Imprint Code**	19;5
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1326-4	10 in 1 CARTON	04/14/2018	
1	NDC:70771-1326-2	10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:70771-1326-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	04/14/2018	
3	NDC:70771-1326-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	04/14/2018	
4	NDC:70771-1326-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	04/14/2018	
5	NDC:70771-1326-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	04/14/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA203466	04/14/2018	

CANDESARTAN CILEXETIL AND HYDROCHLOROTHIAZIDE

candesartan cilexetil and hydrochlorothiazide tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1327
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CANDESARTAN CILEXETIL (UNII: R85M2X0D68) (CANDESARTAN - UNII:S8Q36MD2XX)	CANDESARTAN CILEXETIL	32 mg

HYDROCHLOROTHIAZIDE (UNII: 0J48LPH2TH) (HYDROCHLOROTHIAZIDE - UNII:0J48LPH2TH)	HYDROCHLOROTHIAZIDE	25 mg

Inactive Ingredients

Ingredient Name	Strength
CARBOXYMETHYLCELLULOSE CALCIUM (UNII: UTY7PDF93L)	
STARCH, CORN (UNII: O8232NY3SJ)	
GLYCERYL MONO- AND DICAPRYLOCAPRATE (UNII: U72Q2I8C85)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
HYDROXYPROPYL CELLULOSE (110000 WAMW) (UNII: 5Y0974F5PW)	

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE)	**Score**	2 pieces
Shape	OVAL (OVAL)	**Size**	11mm
Flavor		**Imprint Code**	41;6
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1327-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	04/14/2018	
2	NDC:70771-1327-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	04/14/2018	
3	NDC:70771-1327-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	04/14/2018	
4	NDC:70771-1327-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	04/14/2018	
5	NDC:70771-1327-4	10 in 1 CARTON	04/14/2018	
5	NDC:70771-1327-2	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	ANDA203466	04/14/2018	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations

Zydus Lifesciences Limited		918596198	ANALYSIS(70771-1325, 70771-1326, 70771-1327) , MANUFACTURE(70771-1325, 70771-1326, 70771-1327)