

CANDESARTAN CILEXETIL- candesartan cilexetil tablet
Cadila Healthcare Limited

CANDESARTAN CILEXETIL TABLETS

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL

NDC 70771-1204-5

Candesartan Cilexetil Tablets USP, 4 mg

Rx Only

500 tablets

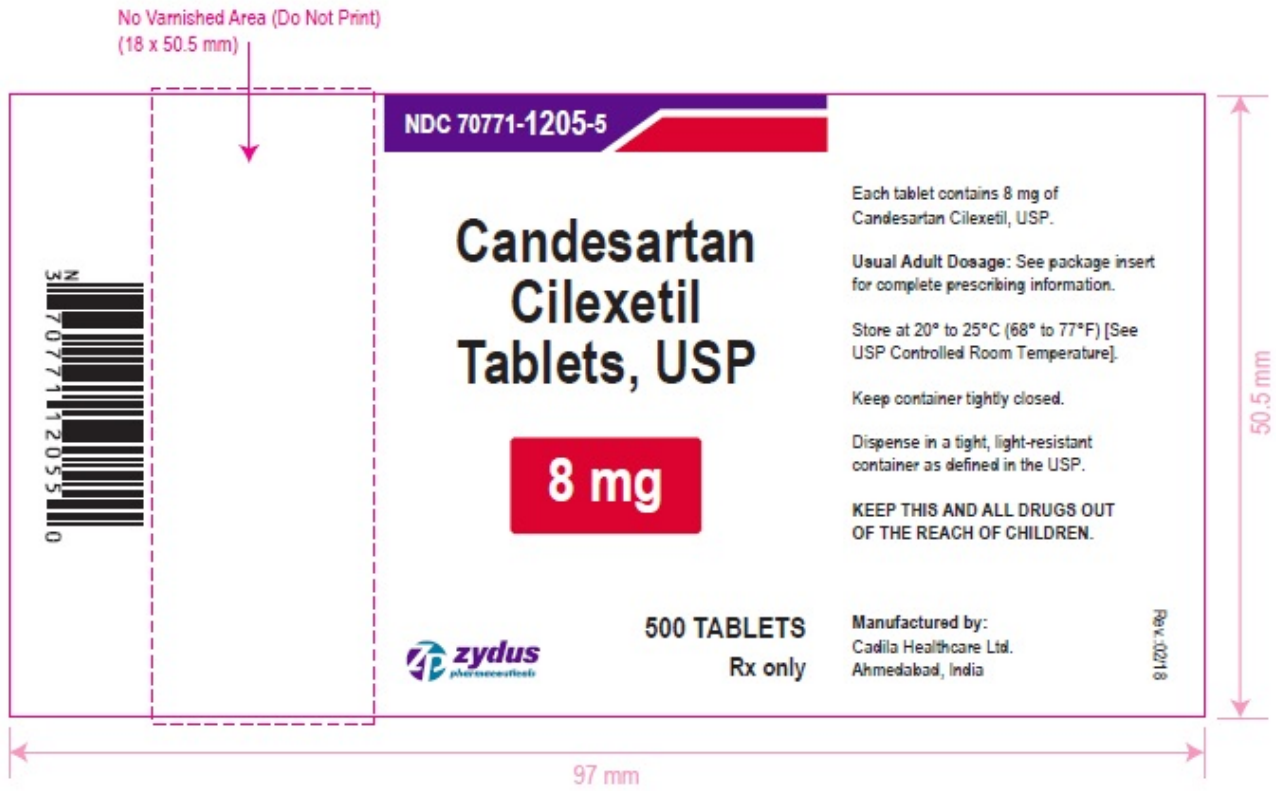


NDC 70771-1205-5

Candesartan Cilexetil Tablets USP, 8 mg

Rx Only

500 tablets

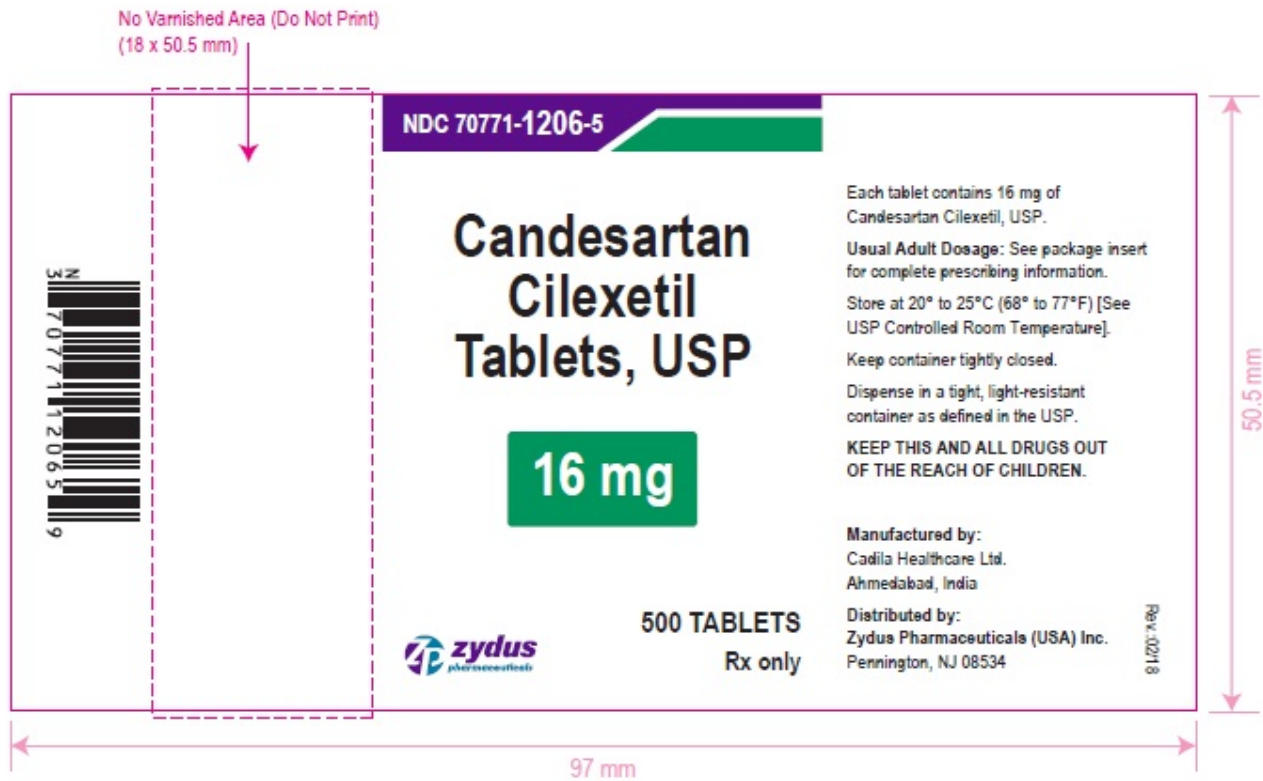


NDC 70771-1206-5

Candesartan Cilexetil Tablets USP, 16 mg

Rx Only

500 tablets

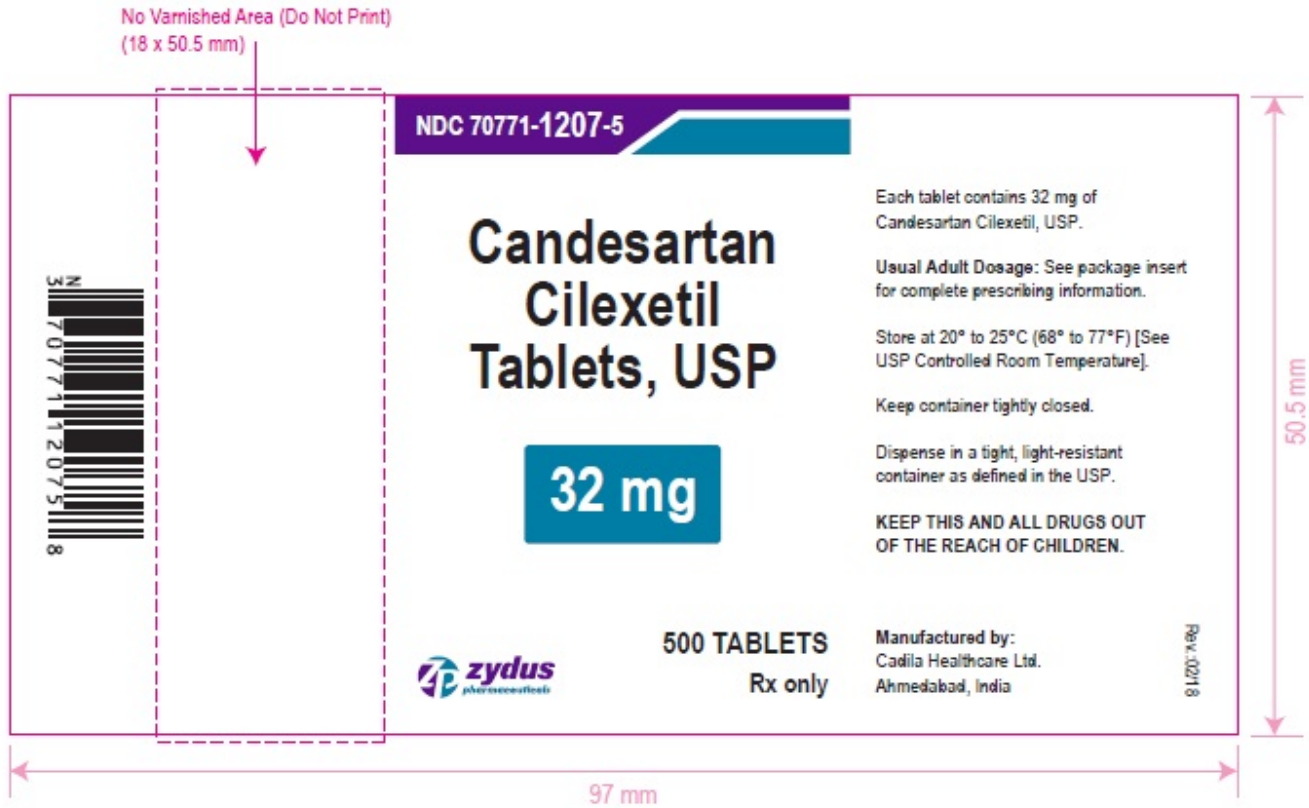


NDC 70771-1207-5

Candesartan Cilexetil Tablets USP, 32 mg

Rx Only

500 tablets



CANDESARTAN CILEXETIL

candesartan cilexetil tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1204
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CANDESARTAN CILEXETIL (UNII: R85M2X0D68) (CANDESARTAN - UNII:S8Q36MD2XX)	CANDESARTAN CILEXETIL	4 mg

Inactive Ingredients

Ingredient Name	Strength
CARBOXYMETHYLCELLULOSE CALCIUM (UNII: UTY7PDF93L)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
HYDROXYPROPYL CELLULOSE (110000 WAMW) (UNII: 5Y0974F5PW)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL 6000 (UNII: 30IQX730WE)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics			
Color	PINK (LIGHT PINK)	Score	2 pieces
Shape	ROUND (ROUND)	Size	7mm
Flavor		Imprint Code	ZE;58
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1204-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	02/22/2018	
2	NDC:70771-1204-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	02/22/2018	
3	NDC:70771-1204-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	02/22/2018	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091390	02/22/2018	

CANDESARTAN CILEXETIL			
candesartan cilexetil tablet			
Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1205
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
CANDESARTAN CILEXETIL (UNII: R85M2X0D68) (CANDESARTAN - UNII:S8Q36MD2XX)		CANDESARTAN CILEXETIL	8 mg
Inactive Ingredients			
Ingredient Name			Strength
CARBOXYMETHYLCELLULOSE CALCIUM (UNII: UTY7PDF93L)			
FERRIC OXIDE RED (UNII: 1K09F3G675)			
HYDROXYPROPYL CELLULOSE (110000 WAMW) (UNII: 5Y0974F5PW)			
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
POLYETHYLENE GLYCOL 6000 (UNII: 30IQX730WE)			
STARCH, CORN (UNII: O8232NY3SJ)			
Product Characteristics			
Color	PINK (PINK)	Score	2 pieces
Shape	ROUND (ROUND)	Size	7mm

Flavor		Imprint Code	ZE;59
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1205-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	02/22/2018	
2	NDC:70771-1205-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	02/22/2018	
3	NDC:70771-1205-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	02/22/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091390	02/22/2018	

CANDESARTAN CILEXETIL

candesartan cilexetil tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1206
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

Inactive Ingredients

Ingredient Name	Strength
CARBOXYMETHYLCELLULOSE CALCIUM (UNII: UTY7PDF93L)	
HYDROXYPROPYL CELLULOSE (110000 WAMW) (UNII: 5Y0974F5PW)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL 6000 (UNII: 30IQX730WE)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	WHITE (WHITE)	Score	2 pieces
Shape	ROUND (ROUND)	Size	7mm
Flavor		Imprint Code	ZE;60
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1206-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	02/22/2018	
2	NDC:70771-1206-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	02/22/2018	
3	NDC:70771-1206-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	02/22/2018	
4	NDC:70771-1206-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	02/22/2018	
5	NDC:70771-1206-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	02/22/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091390	02/22/2018	

CANDESARTAN CILEXETIL

candesartan cilexetil tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1207
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

Inactive Ingredients

Ingredient Name	Strength
CARBOXYMETHYLCELLULOSE CALCIUM (UNII: UTY7PDF93L)	
HYDROXYPROPYL CELLULOSE (110000 WAMW) (UNII: 5Y0974F5PW)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL 6000 (UNII: 30IQX730WE)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE)	Score	2 pieces
Shape	ROUND (ROUND)	Size	9mm
Flavor		Imprint Code	ZE;61
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1207-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	02/22/2018	
2	NDC:70771-1207-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	02/22/2018	
3	NDC:70771-1207-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	02/22/2018	
4	NDC:70771-1207-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	02/22/2018	
5	NDC:70771-1207-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	02/22/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091390	02/22/2018	

Labeler - Cadila Healthcare Limited (918596198)

Registrant - Cadila Healthcare Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Cadila Healthcare Limited		918596198	ANALYSIS(70771-1204, 70771-1205, 70771-1206, 70771-1207) , MANUFACTURE(70771-1204, 70771-1205, 70771-1206, 70771-1207)

Revised: 8/2020

Cadila Healthcare Limited