

IRBESARTAN- irbesartan tablet
Cadila Healthcare Limited

IRBESARTAN TABLETS

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1159-0 in bottles of 1000 tablets

Irbesartan Tablets USP, 75 mg

1000 Tablets

Rx Only

ZyGenerics

NDC 70771-1159-0

IRBESARTAN
Tablets, USP

75 mg

Rx only

1000 Tablets

Each tablet contains:
Irbesartan, USP 75 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].

Dispense in a tight container.

KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.

Manufactured by:
Cadila Healthcare Ltd.
Ahmedabad, India

Lot:
Exp:
Rev.: 12/17

NDC 70771-1160-0 in bottles of 1000 tablets

Irbesartan Tablets USP, 150 mg

1000 Tablets

Rx Only



ZyGenerics

NDC 70771-1160-0

IRBESARTAN

Tablets, USP

150 mg

Rx only

1000 Tablets

Each tablet contains:
Irbesartan, USP 150 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].

Dispense in a tight container.

KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.

Manufactured by:
Cadila Healthcare Ltd.
Ahmedabad, India

Lot:
Exp:
Rev.: 12/17

NDC 70771-1161-0 in bottles of 1000 tablets

Irbesartan Tablets USP, 300 mg

1000 Tablets

Rx Only



ZyGenerics

NDC 70771-1161-0

IRBESARTAN

Tablets, USP

300 mg

Rx only

1000 Tablets

Each tablet contains:
Irbesartan, USP 300 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].

Dispense in a tight container.

KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.

Manufactured by:
Cadila Healthcare Ltd.
Ahmedabad, India

Lot:
Exp:
Rev.: 12/17

IRBESARTAN

irbesartan tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1159
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IRBESARTAN (UNII: J0E2756Z7N) (IRBESARTAN - UNII:J0E2756Z7N)	IRBESARTAN	75 mg

Inactive Ingredients

Ingredient Name	Strength
CALCIUM STEARATE (UNII: 776XM7047L)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	
POLOXAMER 188 (UNII: LQA7B6G8JG)	

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE)	Score	no score
Shape	CAPSULE (CAPSULE)	Size	11mm

Flavor		Imprint Code	ZE53	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1159-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	12/08/2017	
2	NDC:70771-1159-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	12/08/2017	
3	NDC:70771-1159-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	12/08/2017	
4	NDC:70771-1159-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	12/08/2017	
5	NDC:70771-1159-4	10 in 1 CARTON	12/08/2017	
5	NDC:70771-1159-2	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	ANDA079213	12/08/2017		

IRBESARTAN

irbesartan tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1160
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
IRBESARTAN (UNII: J0E2756Z7N) (IRBESARTAN - UNII:J0E2756Z7N)	IRBESARTAN	150 mg	
Inactive Ingredients			
Ingredient Name	Strength		
CALCIUM STEARATE (UNII: 776XM7047L)			
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)			
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)			
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)			
POLOXAMER 188 (UNII: LQA7B6G8JG)			
STARCH, CORN (UNII: O8232NY3SJ)			
Product Characteristics			
Color	WHITE (WHITE TO OFF-WHITE)	Score	no score
Shape	CAPSULE (CAPSULE)	Size	13mm
Flavor		Imprint Code	ZE54
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1160-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	12/08/2017	
2	NDC:70771-1160-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	12/08/2017	
3	NDC:70771-1160-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	12/08/2017	
4	NDC:70771-1160-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	12/08/2017	
5	NDC:70771-1160-4	10 in 1 CARTON	12/08/2017	
5	NDC:70771-1160-2	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	ANDA079213	12/08/2017	

IRBESARTAN

irbesartan tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1161
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IRBESARTAN (UNII: J0E2756Z7N) (IRBESARTAN - UNII:J0E2756Z7N)	IRBESARTAN	300 mg

Inactive Ingredients

Ingredient Name	Strength
CALCIUM STEARATE (UNII: 776XM7047L)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLOXAMER 188 (UNII: LQA7B6G8JG)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE)	Score	no score
Shape	CAPSULE (CAPSULE)	Size	17mm
Flavor		Imprint Code	ZE55
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1161-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	12/08/2017	
2	NDC:70771-1161-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	12/08/2017	
3	NDC:70771-1161-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	12/08/2017	
4	NDC:70771-1161-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	12/08/2017	
5	NDC:70771-1161-4	10 in 1 CARTON	12/08/2017	
5	NDC:70771-1161-2	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	ANDA079213	12/08/2017	

Labeler - Cadila Healthcare Limited (918596198)

Registrant - Cadila Healthcare Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Cadila Healthcare Limited		918596198	ANALYSIS(70771-1159, 70771-1160, 70771-1161), MANUFACTURE(70771-1159, 70771-1160, 70771-1161)

Revised: 8/2020

Cadila Healthcare Limited