

**IRBESARTAN - irbesartan tablet**  
**Zydus Lifesciences Limited**

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**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

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

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>IRBESARTAN</b> (UNII: J0E2756Z7N) (IRBESARTAN - UNII:J0E2756Z7N)	IRBESARTAN	75 mg

### Inactive Ingredients

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

### Product Characteristics

<b>Color</b>	WHITE (WHITE TO OFF-WHITE)	<b>Score</b>	no score
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<b>Shape</b>	CAPSULE (CAPSULE)	<b>Size</b>	11mm
<b>Flavor</b>		<b>Imprint Code</b>	ZE53
<b>Contains</b>			

### 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

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:70771-1160
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IRBESARTAN (UNII: J0E2756Z 7N) (IRBESARTAN - UNII:J0E2756Z 7N)	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

<b>Color</b>	WHITE (WHITE TO OFF-WHITE)	<b>Score</b>	no score
<b>Shape</b>	CAPSULE (CAPSULE)	<b>Size</b>	13mm
<b>Flavor</b>		<b>Imprint Code</b>	ZE54
<b>Contains</b>			

## 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

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

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>IRBESARTAN</b> (UNII: J0E2756Z7N) (IRBESARTAN - UNII:J0E2756Z7N)	IRBESARTAN	300 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>CALCIUM STEARATE</b> (UNII: 776XM7047L)	
<b>CROSCARMELOSE SODIUM</b> (UNII: M28OL1HH48)	

<b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>POLOXAMER 188</b> (UNII: LQA7B6G8JG)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	

### Product Characteristics

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

### 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** - Zydus Lifesciences Limited (918596198)

**Registrant** - Zydus Lifesciences Limited (918596198)

### Establishment

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