

**CARVEDILOL- carvedilol tablet, film coated**  
**Zydus Lifesciences Limited**

-----  
**CARVEDILOL TABLETS**

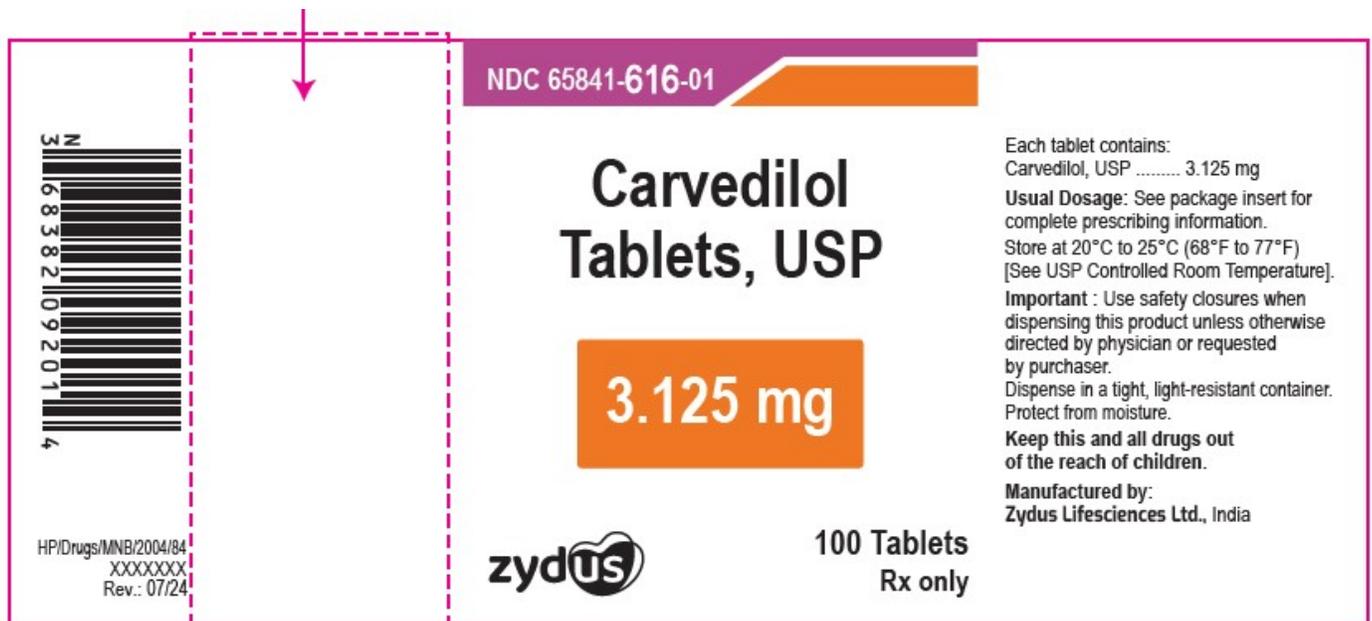
**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

NDC 65841-616-01 in bottle of 100 Tablets

Carvedilol Tablets USP, 3.125 mg

R<sub>x</sub> only

100 Tablets



NDC 65841-617-01 in bottle of 100 Tablets

Carvedilol Tablets USP, 6.25 mg

R<sub>x</sub> only

100 Tablets

NDC 65841-617-01

3 N  
68382109301  
1

HP/Drugs/MNB/2004/84  
XXXXXXX  
Rev.: 07/24

**Carvedilol  
Tablets, USP**

**6.25 mg**

zydUS

100 Tablets  
Rx only

Each tablet contains:  
Carvedilol, USP ..... 6.25 mg  
**Usual Dosage:** See package insert for complete prescribing information.  
Store at 20°C to 25°C (68°F to 77°F)  
[See USP Controlled Room Temperature].  
**Important :** Use safety closures when dispensing this product unless otherwise directed by physician or requested by purchaser.  
Dispense in a tight, light-resistant container.  
Protect from moisture.  
**Keep this and all drugs out of the reach of children.**  
**Manufactured by:**  
Zydus Lifesciences Ltd., India

NDC 65841-618-01 in bottle of 100 Tablets  
Carvedilol Tablets USP, 12.5 mg  
Rx only  
100 Tablets

NDC 65841-618-01

3 N  
68382109401  
8

HP/Drugs/MNB/2004/84  
XXXXXXX  
Rev.: 07/24

**Carvedilol  
Tablets, USP**

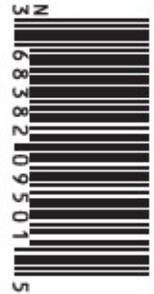
**12.5 mg**

zydUS

100 Tablets  
Rx only

Each tablet contains:  
Carvedilol, USP ..... 12.5 mg  
**Usual Dosage:** See package insert for complete prescribing information.  
Store at 20°C to 25°C (68°F to 77°F)  
[See USP Controlled Room Temperature].  
**Important :** Use safety closures when dispensing this product unless otherwise directed by physician or requested by purchaser.  
Dispense in a tight, light-resistant container.  
Protect from moisture.  
**Keep this and all drugs out of the reach of children.**  
**Manufactured by:**  
Zydus Lifesciences Ltd., India

NDC 65841-619-01 in bottle of 100 Tablets  
Carvedilol Tablets USP, 25 mg  
Rx only  
100 Tablets



HP/Drugs/MNB/2004/84  
XXXXXXX  
Rev.: 07/24

NDC 65841-619-01

# Carvedilol Tablets, USP

25 mg



100 Tablets  
Rx only

Each tablet contains:  
Carvedilol, USP ..... 25 mg

**Usual Dosage:** See package insert for complete prescribing information.

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

**Important :** Use safety closures when dispensing this product unless otherwise directed by physician or requested by purchaser.

Dispense in a tight, light-resistant container.  
Protect from moisture.

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

**Manufactured by:**  
Zydus Lifesciences Ltd., India

## CARVEDILOL

carvedilol tablet, film coated

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:65841-616
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>CARVEDILOL</b> (UNII: 0K47UL67F2) (CARVEDILOL - UNII:0K47UL67F2)	CARVEDILOL	3.125 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>CROSPVIDONE</b> (UNII: 2S7830E561)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POVIDONE K30</b> (UNII: U725QWY32X)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

### Product Characteristics

<b>Color</b>	WHITE (WHITE TO OFF-WHITE)	<b>Score</b>	no score
<b>Shape</b>	ROUND (ROUND)	<b>Size</b>	4mm
<b>Flavor</b>		<b>Imprint Code</b>	Z;1

**Contains****Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-616-17	28 in 1 BOTTLE; Type 0: Not a Combination Product	09/05/2007	
2	NDC:65841-616-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	09/05/2007	
3	NDC:65841-616-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	09/05/2007	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077614	09/05/2007	

**CARVEDILOL**

carvedilol tablet, film coated

**Product Information**

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:65841-617
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>CARVEDILOL</b> (UNII: 0K47UL67F2) (CARVEDILOL - UNII:0K47UL67F2)	CARVEDILOL	6.25 mg

**Inactive Ingredients**

Ingredient Name	Strength
<b>CROSPVIDONE</b> (UNII: 2S7830E561)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POVIDONE K30</b> (UNII: U725QWY32X)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

**Product Characteristics**

<b>Color</b>	WHITE (WHITE TO OFF-WHITE)	<b>Score</b>	no score
--------------	----------------------------	--------------	----------

<b>Shape</b>	ROUND (ROUND)	<b>Size</b>	6mm
<b>Flavor</b>		<b>Imprint Code</b>	ZC40
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-617-17	28 in 1 BOTTLE; Type 0: Not a Combination Product	09/05/2007	
2	NDC:65841-617-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	09/05/2007	
3	NDC:65841-617-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	09/05/2007	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077614	09/05/2007	

## CARVEDILOL

carvedilol tablet, film coated

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:65841-618
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CARVEDILOL (UNII: 0K47UL67F2) (CARVEDILOL - UNII:0K47UL67F2)	CARVEDILOL	12.5 mg

### Inactive Ingredients

Ingredient Name	Strength
CROSPROVIDONE (UNII: 2S7830E561)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE K30 (UNII: U725QWY32X)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

## Product Characteristics

<b>Color</b>	WHITE (WHITE TO OFF-WHITE)	<b>Score</b>	no score
<b>Shape</b>	ROUND (ROUND)	<b>Size</b>	8mm
<b>Flavor</b>		<b>Imprint Code</b>	ZC41
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-618-17	28 in 1 BOTTLE; Type 0: Not a Combination Product	09/05/2007	
2	NDC:65841-618-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	09/05/2007	
3	NDC:65841-618-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	09/05/2007	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077614	09/05/2007	

## CARVEDILOL

carvedilol tablet, film coated

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:65841-619
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CARVEDILOL (UNII: 0K47UL67F2) (CARVEDILOL - UNII:0K47UL67F2)	CARVEDILOL	25 mg

### Inactive Ingredients

Ingredient Name	Strength
CROSPVIDONE (UNII: 2S7830E561)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE K30 (UNII: U725QWY32X)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

## Product Characteristics

<b>Color</b>	WHITE (WHITE TO OFF-WHITE)	<b>Score</b>	no score
<b>Shape</b>	ROUND (ROUND)	<b>Size</b>	10mm
<b>Flavor</b>		<b>Imprint Code</b>	ZC42
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-619-17	28 in 1 BOTTLE; Type 0: Not a Combination Product	09/05/2007	
2	NDC:65841-619-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	09/05/2007	
3	NDC:65841-619-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	09/05/2007	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077614	09/05/2007	

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

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

## Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		918596198	ANALYSIS(65841-616, 65841-617, 65841-618, 65841-619) , MANUFACTURE(65841-616, 65841-617, 65841-618, 65841-619)

## Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		677605858	ANALYSIS(65841-616, 65841-617, 65841-618, 65841-619) , MANUFACTURE(65841-616, 65841-617, 65841-618, 65841-619)

## Establishment

Name	Address	ID/FEI	Business Operations
Zydus Pharmaceuticals Limited		650173735	MANUFACTURE(65841-616, 65841-617, 65841-618, 65841-619) , ANALYSIS(65841-616, 65841-617, 65841-618, 65841-619)