

**RAMIPRIL - ramipril capsule**  
**Zydus Lifesciences Limited**

**RAMIPRIL CAPSULES**

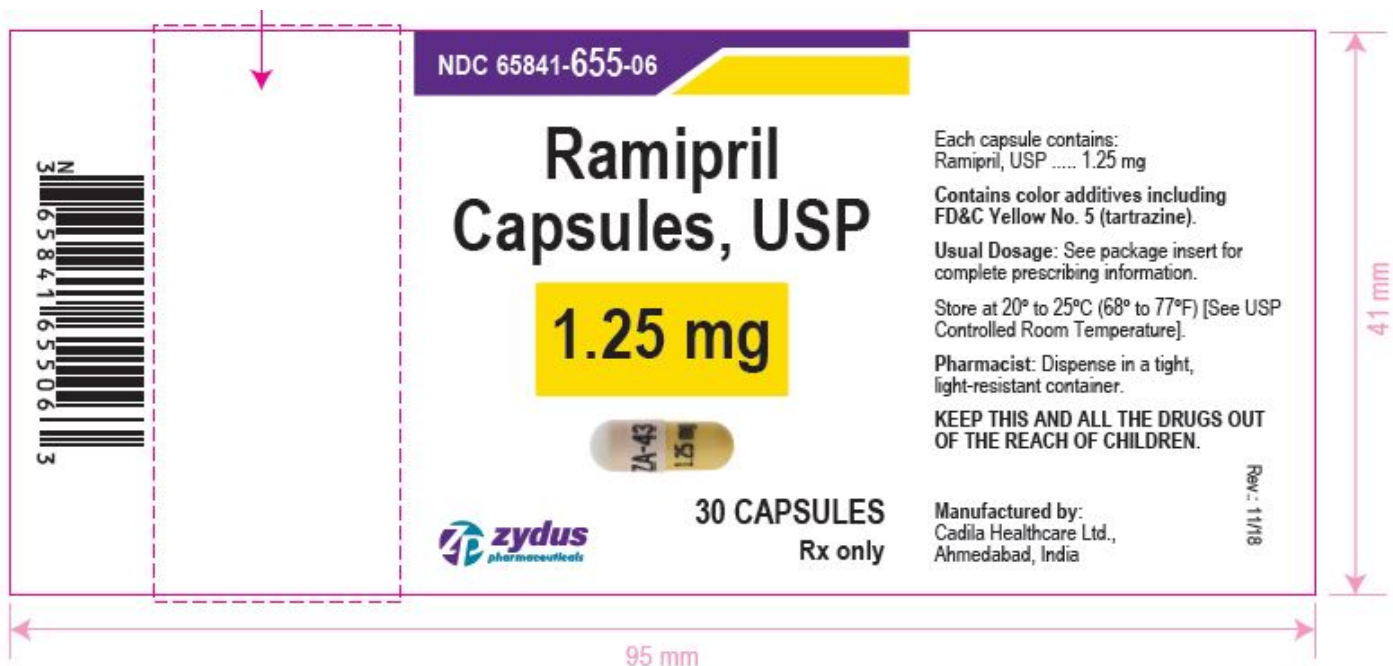
**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

NDC 65841-655-06 in bottle of 30 Capsules

Ramipril Capsules, 1.25 mg

R<sub>x</sub> only

30 Capsules

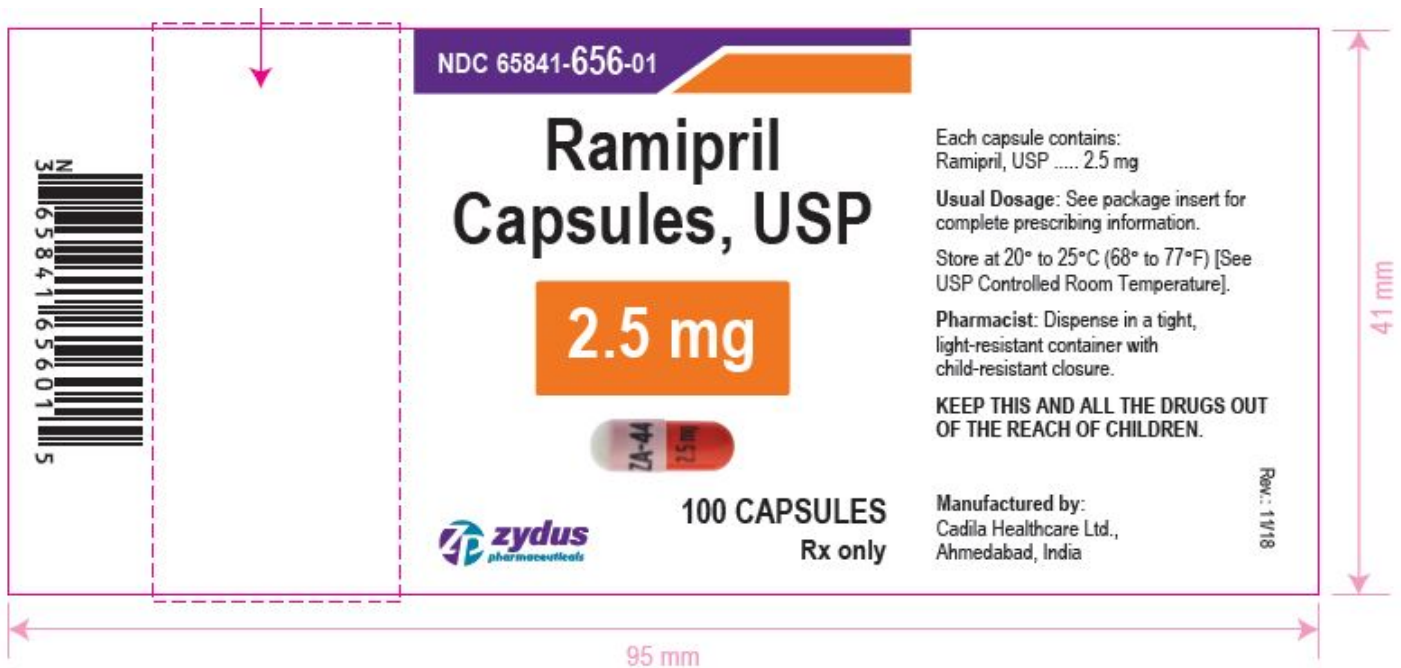


NDC 65841-656-01 in bottle of 100 Capsules

Ramipril Capsules, 2.5 mg

R<sub>x</sub> only

100 Capsules

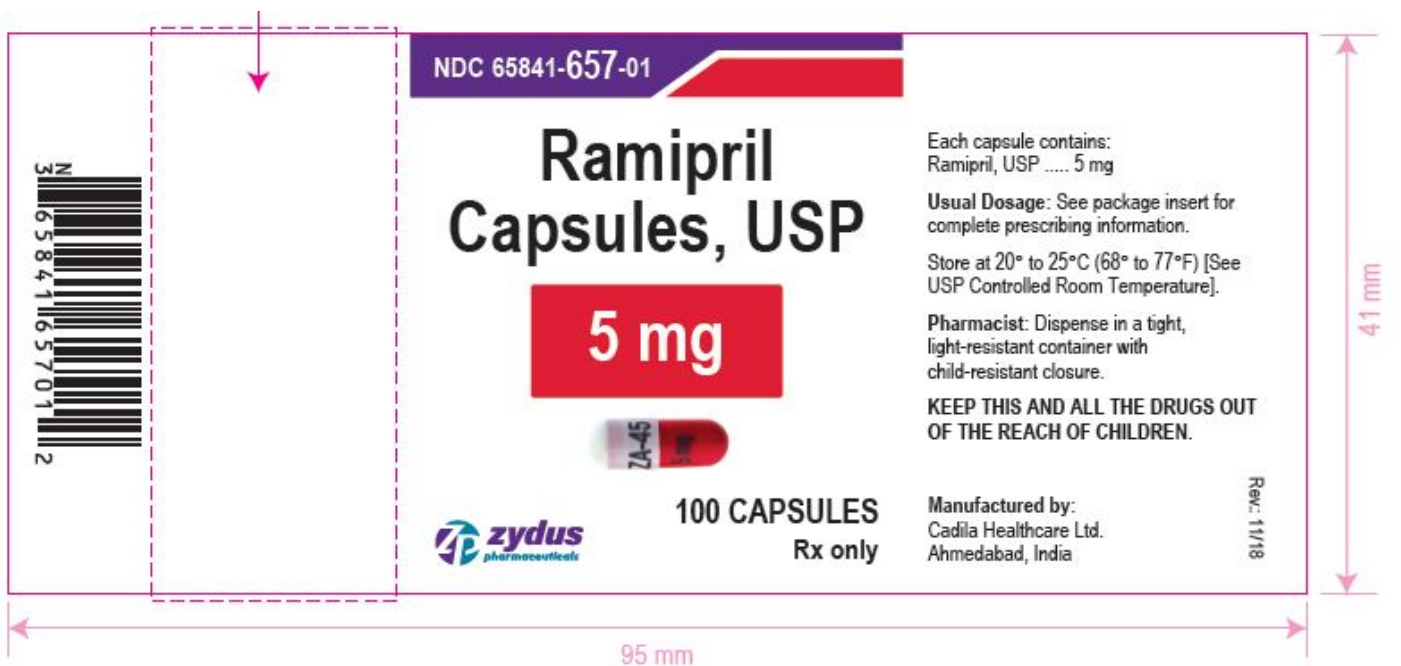


NDC 65841-657-01 in bottle of 100 Capsules

Ramipril Capsules, 5 mg

R<sub>x</sub> only

100 Capsules

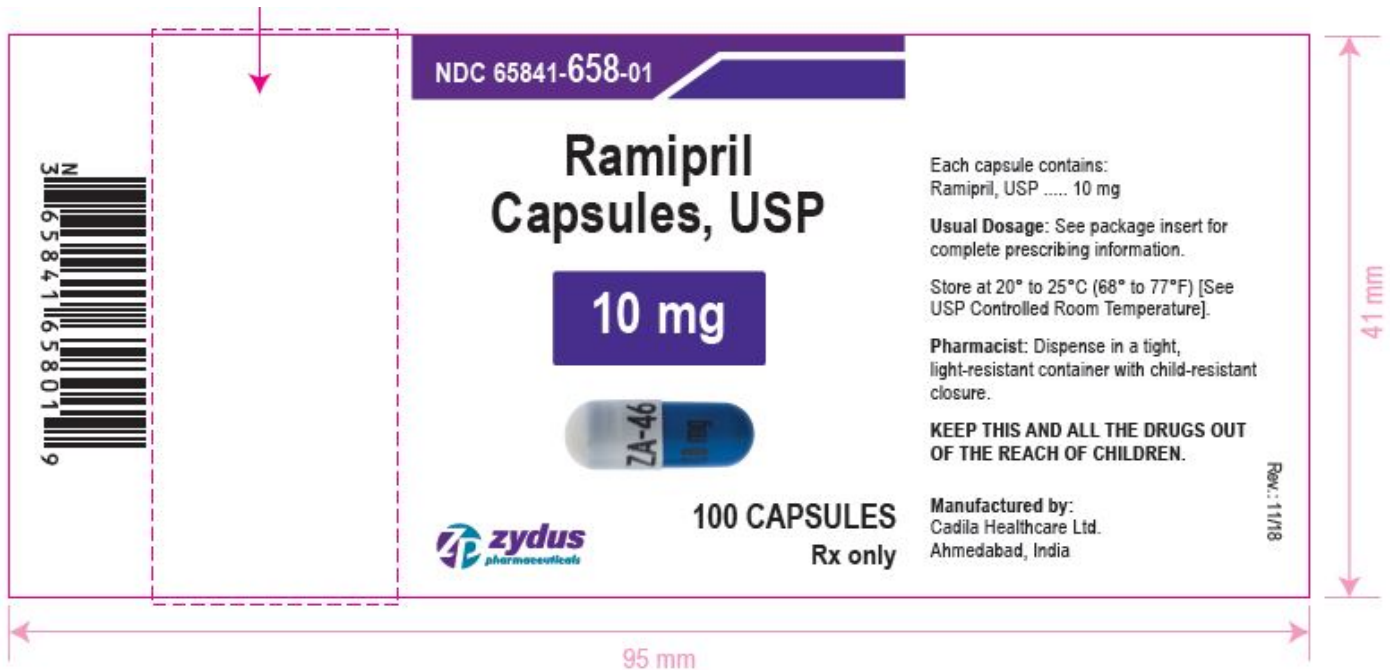


NDC 65841-658-01 in bottle of 100 Capsules

Ramipril Capsules, 10 mg

R<sub>x</sub> only

100 Capsules



## RAMIPRIL

ramipril capsule

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:65841-655
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
RAMIPRIL (UNII: L35JN3I7SJ) (RAMIPRILAT - UNII:6N5U4QFC3G)	RAMIPRIL	1.25 mg

### Inactive Ingredients

Ingredient Name	Strength
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
STARCH, CORN (UNII: O8232NY3SJ)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	

### Product Characteristics

<b>Color</b>	WHITE (WHITE) , YELLOW (YELLOW)	<b>Score</b>	no score
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<b>Shape</b>	CAPSULE (CAPSULE)	<b>Size</b>	14mm	
<b>Flavor</b>		<b>Imprint Code</b>	ZA;43;1;25mg	
<b>Contains</b>				
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-655-06	30 in 1 BOTTLE; Type 0: Not a Combination Product	11/20/2010	
2	NDC:65841-655-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	11/20/2010	
3	NDC:65841-655-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	11/20/2010	
4	NDC:65841-655-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	11/20/2010	
5	NDC:65841-655-30	10 in 1 CARTON	11/20/2010	
5		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
<b>Marketing Information</b>				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA078832	11/20/2010		

<b>RAMIPRIL</b>			
ramipril capsule			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:65841-656
<b>Route of Administration</b>	ORAL		
<b>Active Ingredient/Active Moiety</b>			
<b>Ingredient Name</b>		<b>Basis of Strength</b>	<b>Strength</b>
RAMIPRIL (UNII: L35JN3I7SJ) (RAMIPRILAT - UNII:6N5U4QFC3G)		RAMIPRIL	2.5 mg
<b>Inactive Ingredients</b>			
<b>Ingredient Name</b>			<b>Strength</b>
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)			
FD&C RED NO. 40 (UNII: WZB9127XOA)			
GELATIN (UNII: 2G86QN327L)			
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)			
STARCH, CORN (UNII: O8232NY3SJ)			
FERROSO FERRIC OXIDE (UNII: XM0M87F357)			

## Product Characteristics

<b>Color</b>	WHITE (WHITE) , ORANGE (ORANGE)	<b>Score</b>	no score
<b>Shape</b>	CAPSULE (CAPSULE)	<b>Size</b>	14mm
<b>Flavor</b>		<b>Imprint Code</b>	ZA;44;2;5mg
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-656-06	30 in 1 BOTTLE; Type 0: Not a Combination Product	11/20/2010	
2	NDC:65841-656-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	11/20/2010	
3	NDC:65841-656-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	11/20/2010	
4	NDC:65841-656-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	11/20/2010	
5	NDC:65841-656-30	10 in 1 CARTON	11/20/2010	
5		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	ANDA078832	11/20/2010	

## RAMIPRIL

ramipril capsule

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:65841-657
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
RAMIPRIL (UNII: L35JN317SJ) (RAMIPRILAT - UNII:6N5U4QFC3G)	RAMIPRIL	5 mg

### Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	

<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>FERROSFERRIC OXIDE</b> (UNII: XM0M87F357)	

### Product Characteristics

<b>Color</b>	WHITE (WHITE) , RED (RED)	<b>Score</b>	no score
<b>Shape</b>	CAPSULE (CAPSULE)	<b>Size</b>	14mm
<b>Flavor</b>		<b>Imprint Code</b>	ZA;45;5mg
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-657-06	30 in 1 BOTTLE; Type 0: Not a Combination Product	11/20/2010	
2	NDC:65841-657-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	11/20/2010	
3	NDC:65841-657-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	11/20/2010	
4	NDC:65841-657-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	11/20/2010	
5	NDC:65841-657-30	10 in 1 CARTON	11/20/2010	
5		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	ANDA078832	11/20/2010	

## RAMIPRIL

ramipril capsule

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:65841-658
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>RAMIPRIL</b> (UNII: L35JN3I7SJ) (RAMIPRILAT - UNII:6N5U4QFC3G)	RAMIPRIL	10 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>D&amp;C RED NO. 28</b> (UNII: 7671P0Y5NH)	
<b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>STARCH, CORN</b> (UNII: O8232NY3S)	
<b>FERROSO FERRIC OXIDE</b> (UNII: XM0M87F357)	

## Product Characteristics

<b>Color</b>	WHITE (WHITE) , BLUE (BLUE)	<b>Score</b>	no score
<b>Shape</b>	CAPSULE (CAPSULE)	<b>Size</b>	14mm
<b>Flavor</b>		<b>Imprint Code</b>	ZA;46;10mg
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-658-06	30 in 1 BOTTLE; Type 0: Not a Combination Product	11/20/2010	
2	NDC:65841-658-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	11/20/2010	
3	NDC:65841-658-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	11/20/2010	
4	NDC:65841-658-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	11/20/2010	
5	NDC:65841-658-30	10 in 1 CARTON	11/20/2010	
5		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	ANDA078832	11/20/2010	

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

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

## Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences		918596198	ANALYSIS(65841-655, 65841-656, 65841-657, 65841-658) , MANUFACTURE(65841-655, 65841-656, 65841-657, 65841-658)

Limited

MANUFACTURE(03041-033, 03041-036, 03041-037, 03041-038)

Revised: 10/2022

Zydus Lifesciences Limited