RAMIPRIL - ramipril tablet
Zydus Lifesciences Limited

Ramipril Tablets

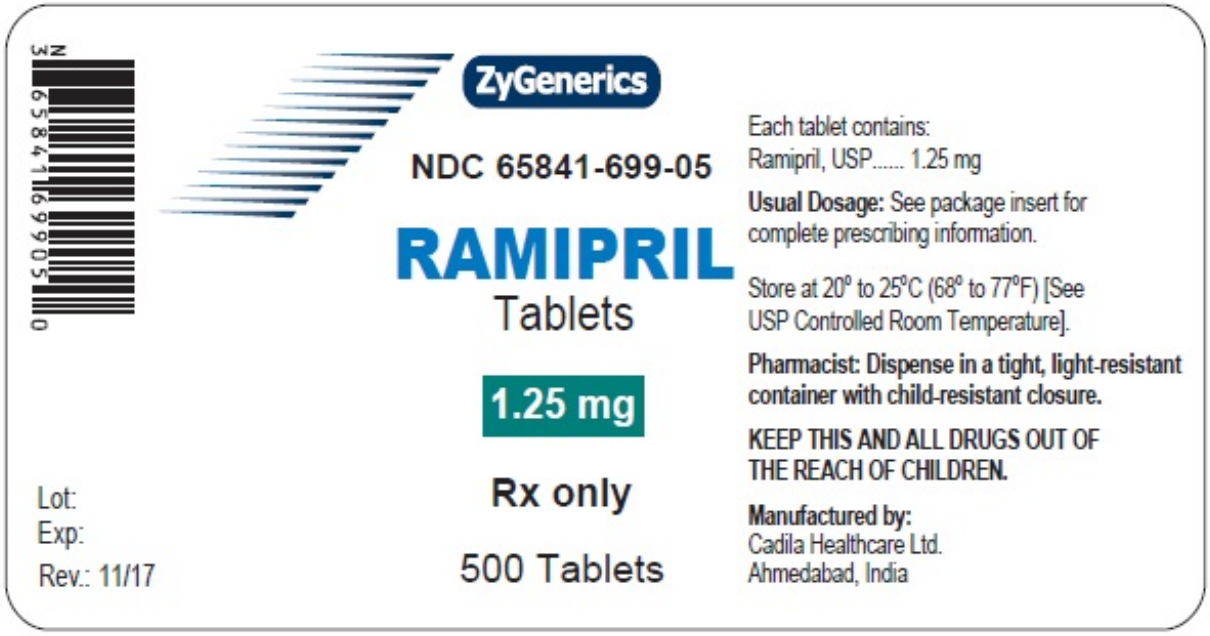
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 65841-699-05 in bottle of 500 tablets

Ramipril Tablets, 1.25 mg

Rx only

500 tablets

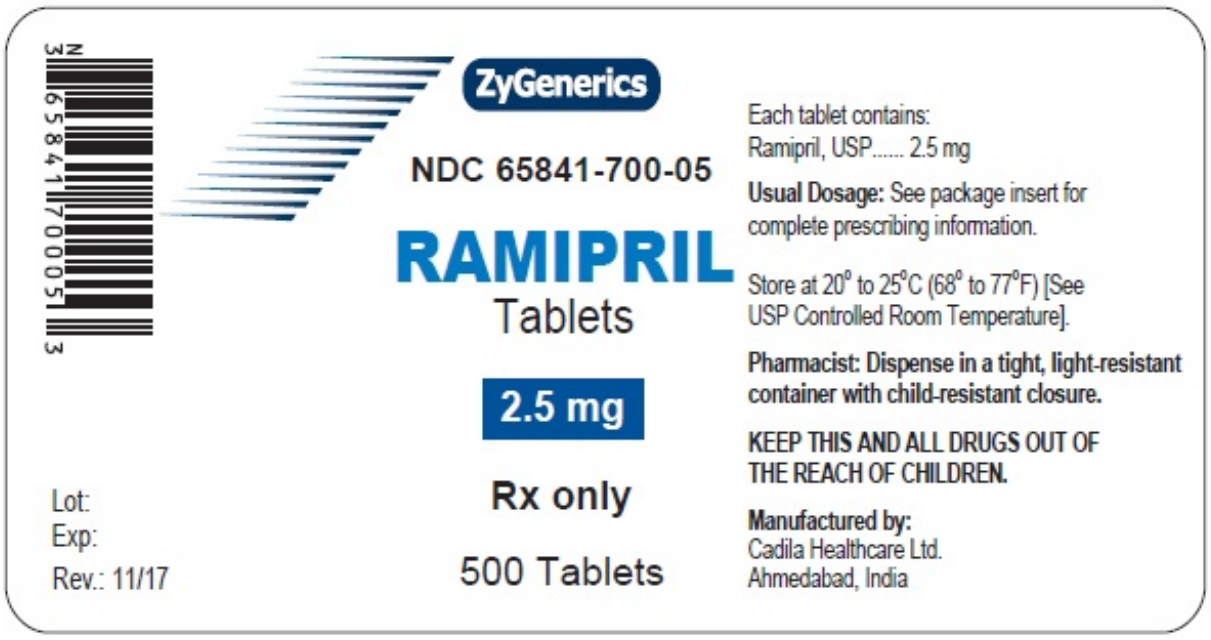


NDC 65841-700-05 in bottle of 500 tablets

Ramipril Tablets, 2.5 mg

Rx only

500 tablets

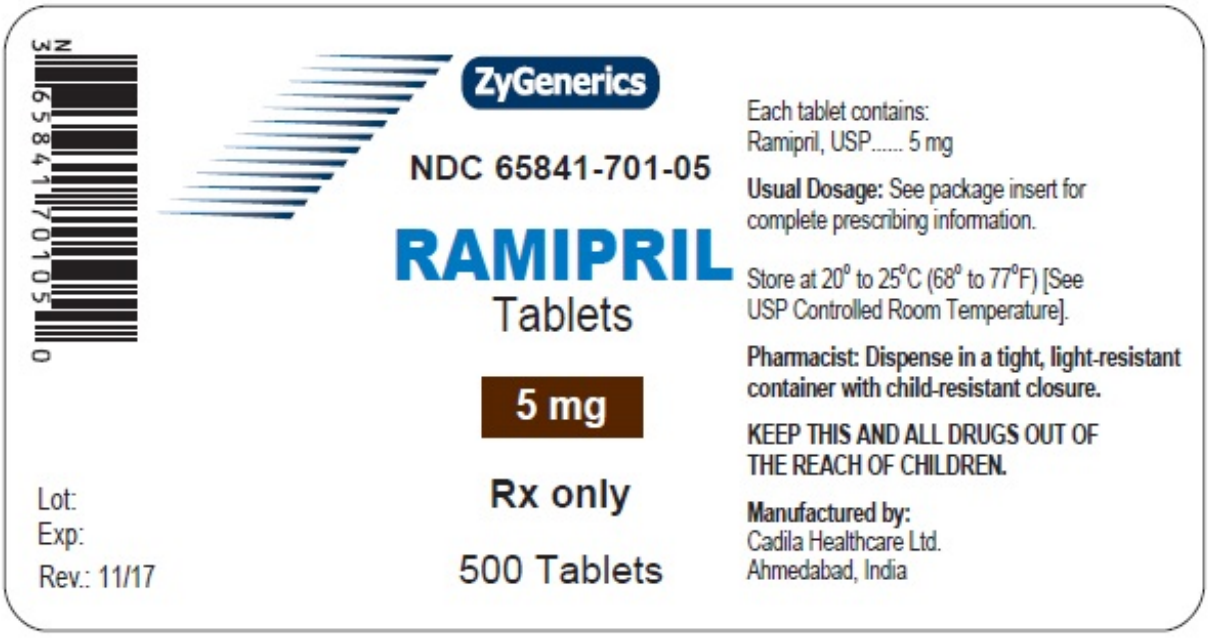


NDC 65841-701-05 in bottle of 500 tablets

Ramipril Tablets, 5 mg

Rx only

500 tablets

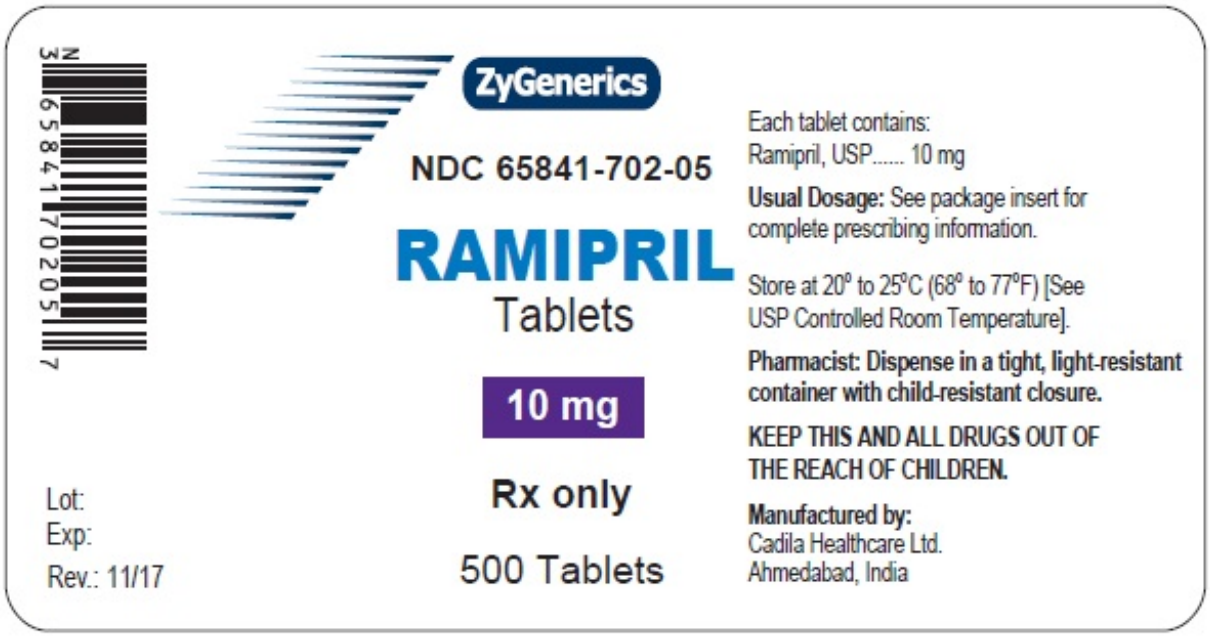


NDC 65841-702- 05 in bottle of 500 tablets

Ramipril Tablets, 10 mg

Rx only

500 tablets



RAMIPRIL

ramipril tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-699
Route of Administration	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**
HYPROMELLOSES (UNII: 3NXW29V3WO)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI)	

Product Characteristics			
Color	YELLOW (YELLOW)	**Score**	no score
Shape	CAPSULE (CAPSULE)	**Size**	8mm
Flavor		**Imprint Code**	374

Contains	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-699-06	30 in 1 BOTTLE; Type 0: Not a Combination Product	12/05/2017	
2	NDC:65841-699-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	12/05/2017	
3	NDC:65841-699-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	12/05/2017	
4	NDC:65841-699-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	12/05/2017	
5	NDC:65841-699-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	12/05/2017	
6	NDC:65841-699-77	10 in 1 CARTON	12/05/2017	
6		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	ANDA090697	12/05/2017	

RAMIPRIL

ramipril tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-700
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
RAMIPRIL (UNII: L35JN3I7SJ) (RAMIPRILAT - UNII:6N5U4QFC3G)	RAMIPRIL	2.5 mg

Inactive Ingredients

Ingredient Name	Strength
HYPROMELLOSES (UNII: 3NXW29V3WO)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI)	

Product Characteristics			
Color	ORANGE (PEACH)	**Score**	no score
Shape	CAPSULE (CAPSULE)	**Size**	8mm
Flavor		**Imprint Code**	375
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-700-06	30 in 1 BOTTLE; Type 0: Not a Combination Product	12/05/2017	
2	NDC:65841-700-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	12/05/2017	
3	NDC:65841-700-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	12/05/2017	
4	NDC:65841-700-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	12/05/2017	
5	NDC:65841-700-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	12/05/2017	
6	NDC:65841-700-77	10 in 1 CARTON	12/05/2017	
6		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	ANDA090697	12/05/2017	

RAMIPRIL

ramipril tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-701
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
RAMIPRIL (UNII: L35JN3I7SJ) (RAMIPRILAT - UNII:6N5U4QFC3G)	RAMIPRIL	5 mg

Inactive Ingredients

Ingredient Name	Strength
HYPROMELLOSES (UNII: 3NXW29V3WO)	

CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI)	

Product Characteristics

Color	RED (PINK TO RED)	**Score**	no score
Shape	CAPSULE (CAPSULE)	**Size**	8mm
Flavor		**Imprint Code**	376
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-701-06	30 in 1 BOTTLE; Type 0: Not a Combination Product	12/05/2017	
2	NDC:65841-701-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	12/05/2017	
3	NDC:65841-701-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	12/05/2017	
4	NDC:65841-701-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	12/05/2017	
5	NDC:65841-701-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	12/05/2017	
6	NDC:65841-701-77	10 in 1 CARTON	12/05/2017	
6		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	ANDA090697	12/05/2017	

RAMIPRIL

ramipril tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-702
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
HYPROMELLOSES (UNII: 3NXW29V3WO)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI)	

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE)	**Score**	no score
Shape	CAPSULE (CAPSULE)	**Size**	8mm
Flavor		**Imprint Code**	377
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-702-06	30 in 1 BOTTLE; Type 0: Not a Combination Product	12/05/2017	
2	NDC:65841-702-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	12/05/2017	
3	NDC:65841-702-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	12/05/2017	
4	NDC:65841-702-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	12/05/2017	
5	NDC:65841-702-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	12/05/2017	
6	NDC:65841-702-77	10 in 1 CARTON	12/05/2017	
6		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	ANDA090697	12/05/2017	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		918596198	ANALYSIS(65841-699, 65841-700, 65841-701, 65841-702) , MANUFACTURE(65841-699, 65841-700, 65841-701, 65841-702)