LOSARTAN POTASSIUM- losartan potassium tablet, film coated
Cadila Healthcare Limited

LOSARTAN POTASSIUM TABLETS

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

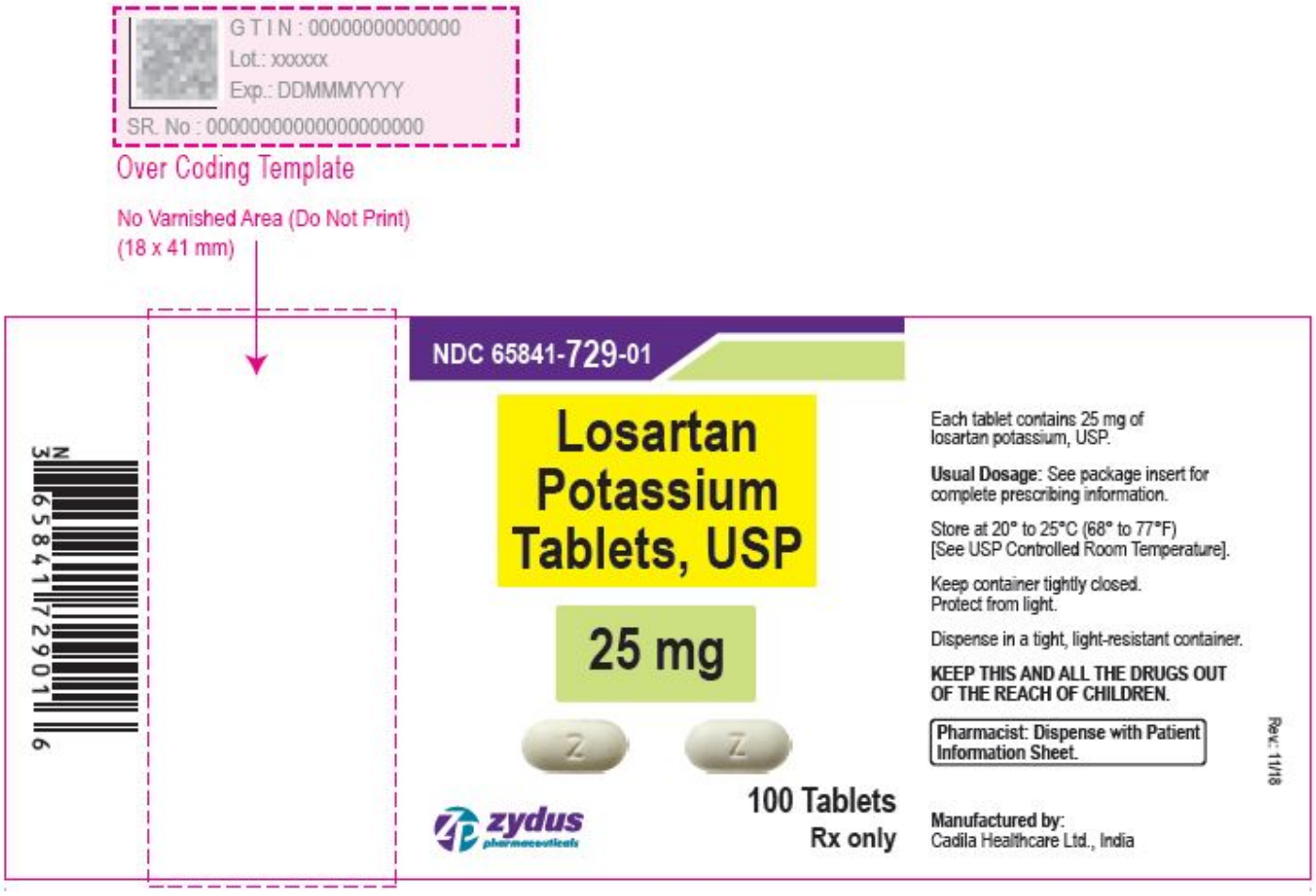
NDC 65841-729-01

Losartan Potassium Tablets USP, 25 mg

Rx Only

100 Tablets

Zydus



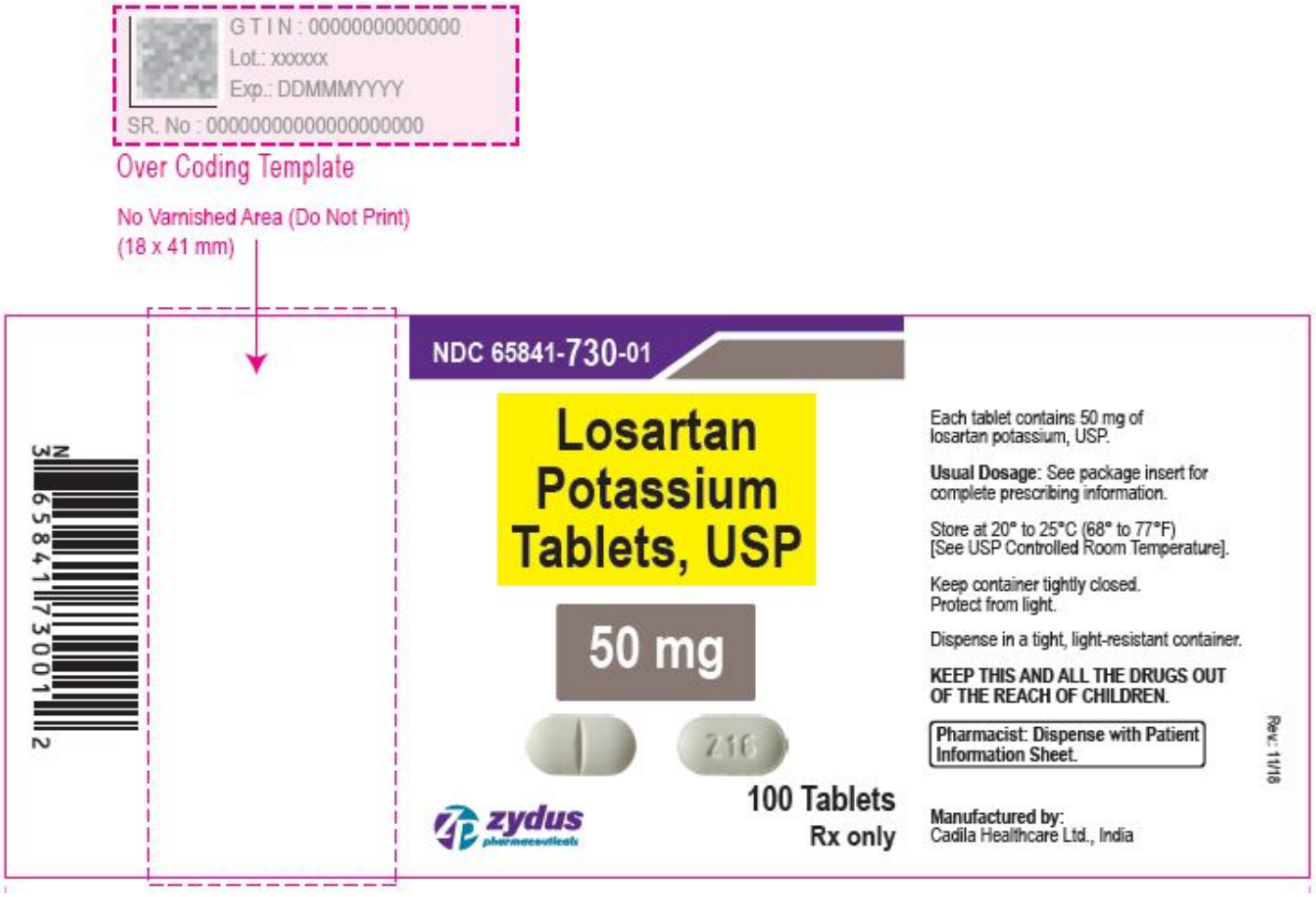
NDC 65841-730-01

Losartan Potassium Tablets USP, 50 mg

Rx Only

100 Tablets

Zydus



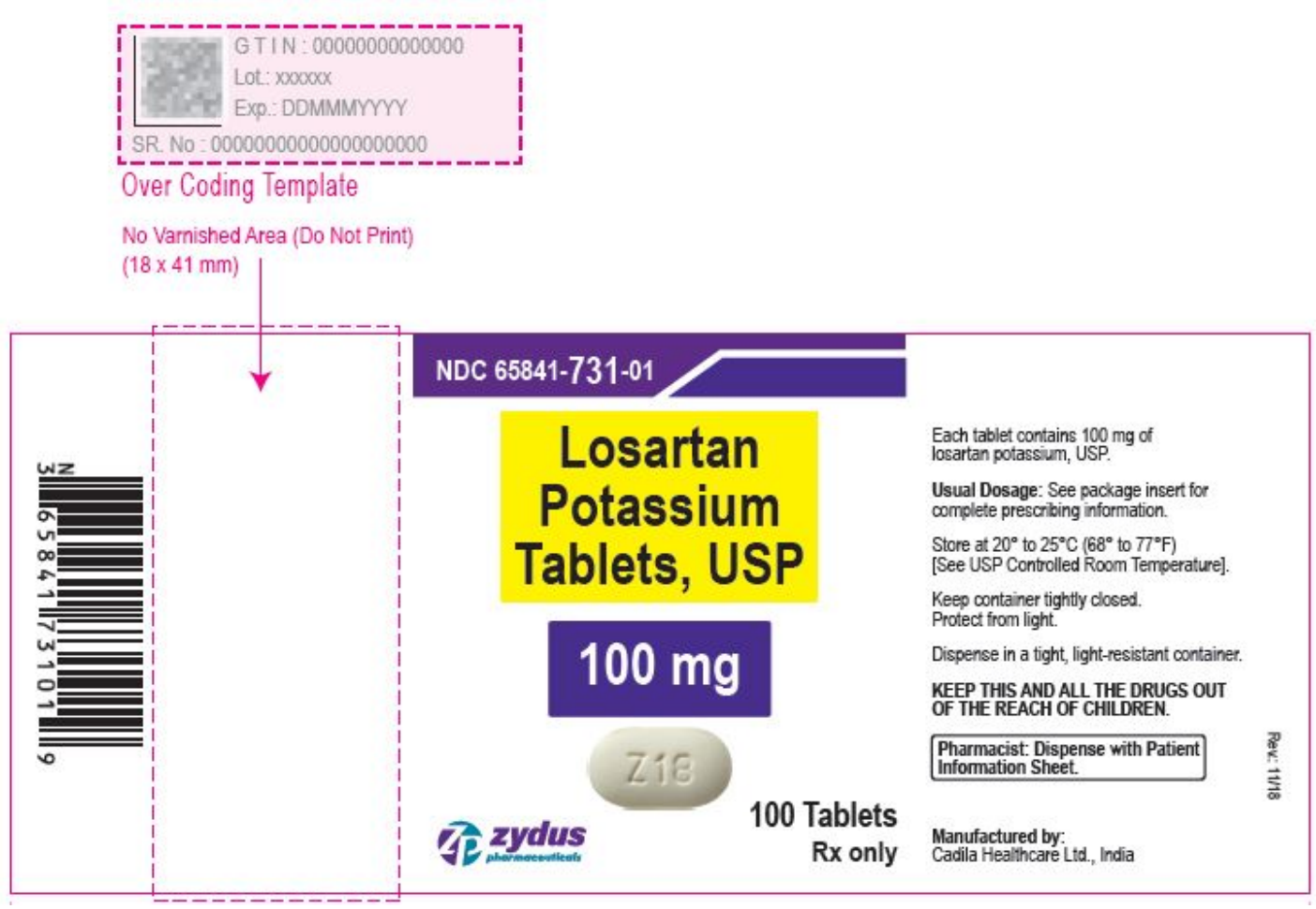
NDC 65841-731-01

Losartan Potassium Tablets USP, 100 mg

Rx Only

100 Tablets

Zydus



LOSARTAN POTASSIUM

losartan potassium tablet, film coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-729
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LOSARTAN POTASSIUM (UNII: 3ST302B24A) (LOSARTAN - UNII:JMS50MPO89)	LOSARTAN POTASSIUM	25 mg

Inactive Ingredients	
Ingredient Name	**Strength**
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
HYDROXYPROPYL CELLULOSE, LOW SUBSTITUTED (UNII: 2165RE0K14)	
STARCH, CORN (UNII: O8232NY3SJ)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	

Product Characteristics			
Color	WHITE (WHITE TO OFF-WHITE)	**Score**	no score
Shape	CAPSULE (CAPSULE)	**Size**	8mm
Flavor		**Imprint Code**	Z;2
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-729-06	30 in 1 BOTTLE; Type 0: Not a Combination Product	10/04/2010	
2	NDC:65841-729-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	10/04/2010	
3	NDC:65841-729-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	10/04/2010	
4	NDC:65841-729-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	10/04/2010	
5	NDC:65841-729-24	10000 in 1 BOTTLE; Type 0: Not a Combination Product	10/04/2010	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078243	10/04/2010	

LOSARTAN POTASSIUM

losartan potassium tablet, film coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-730
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LOSARTAN POTASSIUM (UNII: 3ST302B24A) (LOSARTAN - UNII:JMS50MPO89)	LOSARTAN POTASSIUM	50 mg

Inactive Ingredients

Ingredient Name	Strength
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
HYDROXYPROPYL CELLULOSE, LOW SUBSTITUTED (UNII: 2165RE0K14)	
STARCH, CORN (UNII: O8232NY3SJ)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE)	**Score**	2 pieces
Shape	CAPSULE (CAPSULE)	**Size**	11mm
Flavor		**Imprint Code**	Z16
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-730-06	30 in 1 BOTTLE; Type 0: Not a Combination Product	10/04/2010	
2	NDC:65841-730-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	10/04/2010	
3	NDC:65841-730-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	10/04/2010	
4	NDC:65841-730-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	10/04/2010	
5	NDC:65841-730-24	10000 in 1 BOTTLE; Type 0: Not a Combination Product	10/04/2010	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078243	10/04/2010	

LOSARTAN POTASSIUM

losartan potassium tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-731
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LOSARTAN POTASSIUM (UNII: 3ST302B24A) (LOSARTAN - UNII:JMS50MPO89)	LOSARTAN POTASSIUM	100 mg

Inactive Ingredients

Ingredient Name	Strength
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	

MAGNESIUM STEARATE (UNII: 70097M6I30)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
HYDROXYPROPYL CELLULOSE, LOW SUBSTITUTED (UNII: 2165RE0K14)	
STARCH, CORN (UNII: O8232NY3SJ)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE)	**Score**	no score
Shape	CAPSULE (CAPSULE)	**Size**	12mm
Flavor		**Imprint Code**	Z18
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-731-06	30 in 1 BOTTLE; Type 0: Not a Combination Product	10/04/2010	
2	NDC:65841-731-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	10/04/2010	
3	NDC:65841-731-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	10/04/2010	
4	NDC:65841-731-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	10/04/2010	
5	NDC:65841-731-77	10 in 1 CARTON	10/04/2010	
5	NDC:65841-731-30	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	ANDA078243	10/04/2010	

Labeler - Cadila Healthcare Limited (918596198)

Registrant - Cadila Healthcare Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
CADILA HEALTHCARE LIMITED		677605858	ANALYSIS(65841-729, 65841-730, 65841-731) , MANUFACTURE(65841-729, 65841-730, 65841-731)

Establishment

Name	Address	ID/FEI	Business Operations
Cadila Healthcare Limited		918596198	ANALYSIS(65841-729, 65841-730, 65841-731) , MANUFACTURE(65841-729, 65841-730, 65841-731)