

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



Over Coding Template

No Varnished Area (Do Not Print)
(18 x 41 mm)

NDC 65841-729-01

Losartan Potassium Tablets, USP

25 mg

100 Tablets
Rx only

z ydus pharmaceuticals

Each tablet contains 25 mg of losartan potassium, USP.

Usual Dosage: See package insert for complete prescribing information.

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

Keep container tightly closed. Protect from light.

Dispense in a tight, light-resistant container.

KEEP THIS AND ALL THE DRUGS OUT OF THE REACH OF CHILDREN.

Pharmacist: Dispense with Patient Information Sheet.

Manufactured by:
Cadila Healthcare Ltd., India

Rev: 11/18

NDC 65841-730-01

Losartan Potassium Tablets USP, 50 mg

Rx Only

100 Tablets

Zydus

GTIN : 00000000000000
Lot: xxxxxx
Exp.: DDMMYYYY
SR. No : 000000000000000000

Over Coding Template

No Varnished Area (Do Not Print)
(18 x 41 mm)

NDC 65841-730-01

Losartan Potassium Tablets, USP

50 mg

100 Tablets
Rx only

Each tablet contains 50 mg of losartan potassium, USP.

Usual Dosage: See package insert for complete prescribing information.

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

Keep container tightly closed.
Protect from light.

Dispense in a tight, light-resistant container.

KEEP THIS AND ALL THE DRUGS OUT OF THE REACH OF CHILDREN.

Pharmacist: Dispense with Patient Information Sheet.

Manufactured by:
Cadila Healthcare Ltd., India

Rev: 1/18

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pharmaceuticals

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NDC 65841-731-01

Losartan Potassium Tablets USP, 100 mg

Rx Only

100 Tablets

Zydus



Over Coding Template

No Varnished Area (Do Not Print)
 (18 x 41 mm)

NDC 65841-731-01

Losartan Potassium Tablets, USP

100 mg

100 Tablets
Rx only

Each tablet contains 100 mg of losartan potassium, USP.

Usual Dosage: See package insert for complete prescribing information.

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

Keep container tightly closed. Protect from light.

Dispense in a tight, light-resistant container.

KEEP THIS AND ALL THE DRUGS OUT OF THE REACH OF CHILDREN.

Pharmacist: Dispense with Patient Information Sheet.

Manufactured by:
Cadila Healthcare Ltd., India

Rev: 1/18

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)

