LOSARTAN POTASSIUM AND HYDROCHLOROTHIAZIDE - losartan potassium and hydrochlorothiazide tablet, film coated
Zydus Lifesciences Limited

LOSARTAN POTASSIUM and HYDROCHLOROTHIAZIDE TABLETS

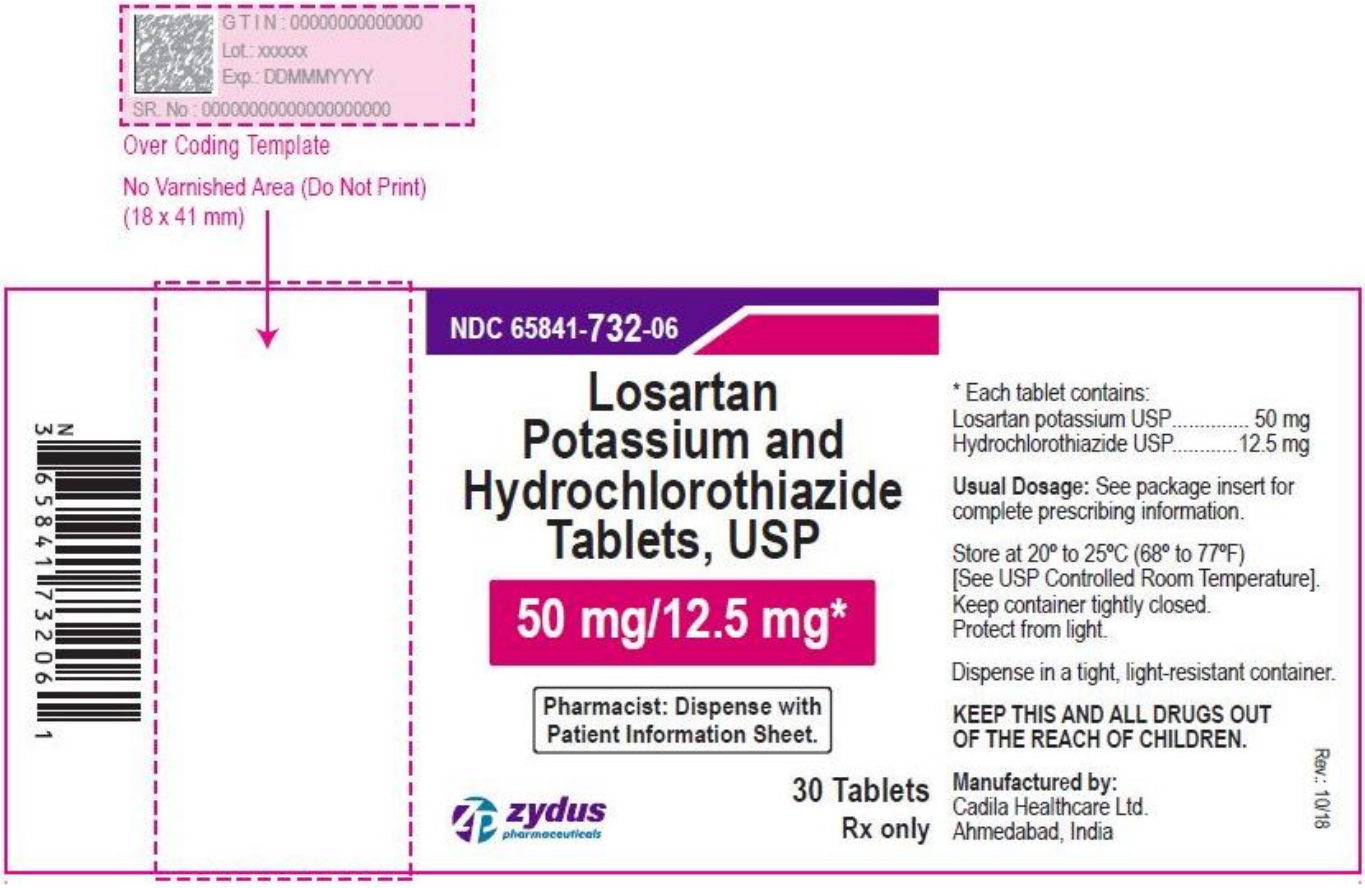
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 65841-732-06

Losartan Potassium and Hydrochlorothiazide Tablets USP, 50 mg/12.5 mg

30 Tablets

Rx Only

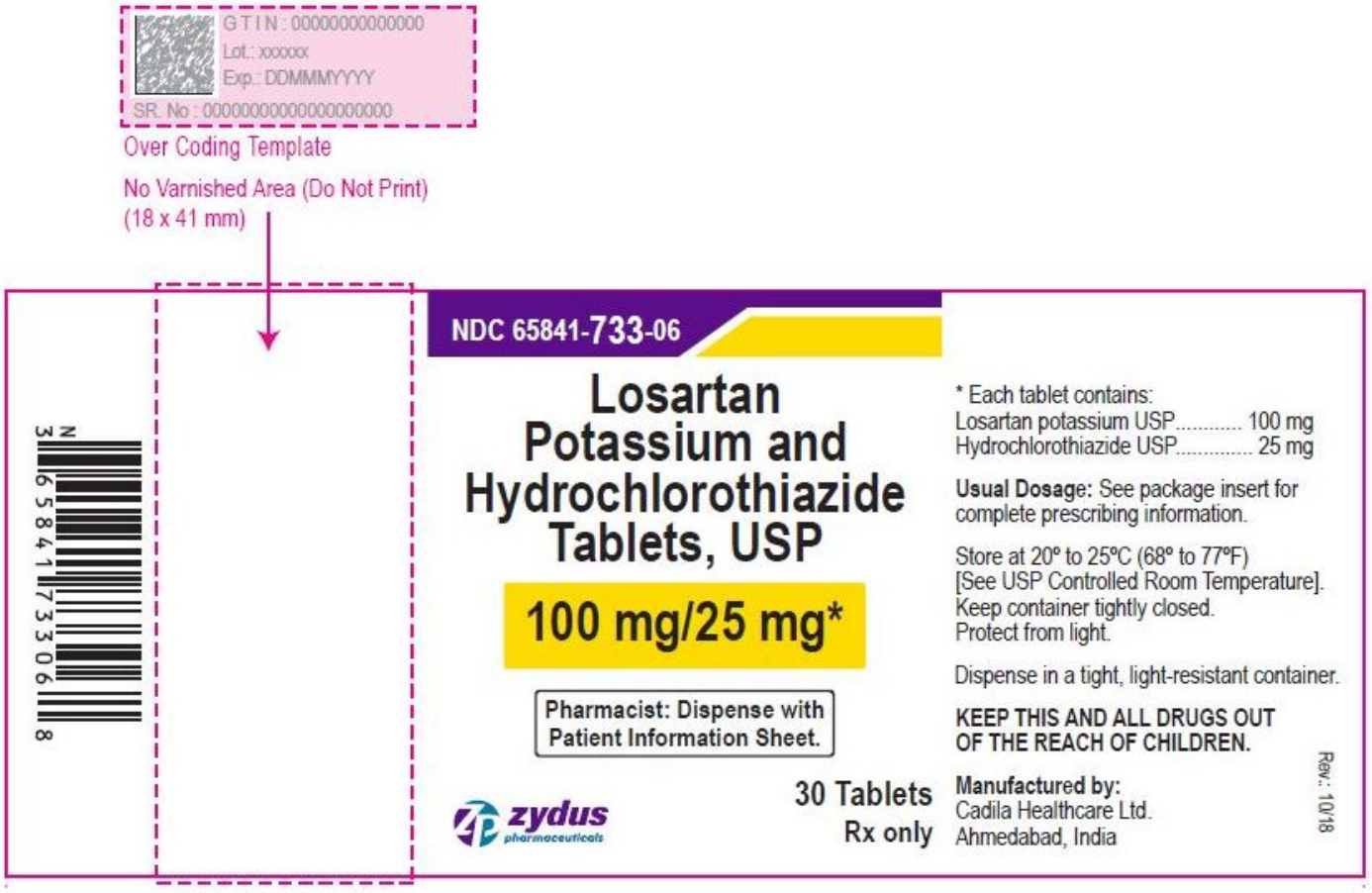


NDC 65841-733-06

Losartan Potassium and Hydrochlorothiazide Tablets USP, 100 mg/25 mg

30 Tablets

Rx Only



LOSARTAN POTASSIUM AND HYDROCHLOROTHIAZIDE

losartan potassium and hydrochlorothiazide tablet, film coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-732
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
HYDROCHLOROTHIAZIDE (UNII: 0J48LPH2TH) (HYDROCHLOROTHIAZIDE - UNII:0J48LPH2TH)	HYDROCHLOROTHIAZIDE	12.5 mg
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: 3WQ0SDW1A)	

Product Characteristics

Color	WHITE (WHITE TO OFF WHITE)	**Score**	no score
Shape	CAPSULE (CAPSULE)	**Size**	12mm
Flavor		**Imprint Code**	ZD18
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-732-40	5000 in 1 BOTTLE; Type 0: Not a Combination Product	04/10/2010	
2	NDC:65841-732-06	30 in 1 BOTTLE; Type 0: Not a Combination Product	04/10/2010	
3	NDC:65841-732-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	04/10/2010	
4	NDC:65841-732-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	04/10/2010	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078385	04/10/2010	

LOSARTAN POTASSIUM AND HYDROCHLOROTHIAZIDE

losartan potassium and hydrochlorothiazide tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-733
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROCHLOROTHIAZIDE (UNII: 0J48LPH2TH) (HYDROCHLOROTHIAZIDE - UNII:0J48LPH2TH)	HYDROCHLOROTHIAZIDE	25 mg
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: 3WQ0SDW1A)	

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE)	**Score**	no score
Shape	CAPSULE (CAPSULE)	**Size**	13mm
Flavor		**Imprint Code**	ZD19
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-733-06	30 in 1 BOTTLE; Type 0: Not a Combination Product	04/10/2010	
2	NDC:65841-733-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	04/10/2010	
3	NDC:65841-733-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	04/10/2010	
4	NDC:65841-733-23	4000 in 1 BOTTLE; Type 0: Not a Combination Product	04/10/2010	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078385	04/10/2010	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		918596198	ANALYSIS(65841-732, 65841-733) , MANUFACTURE(65841-732, 65841-733)