VALSARTAN AND HYDROCHLOROTHIAZIDE- valsartan and hydrochlorothiazide tablet, film coated
Cadila Healthcare Limited

VALSARTAN AND HYDROCHLOROTHIAZIDE TABLETS

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Valsartan and Hydrochlorothiazide Tablets USP, 80/12.5 mg

NDC 70771-1485-0 in bottle of 1000 tablets

1000 tablets

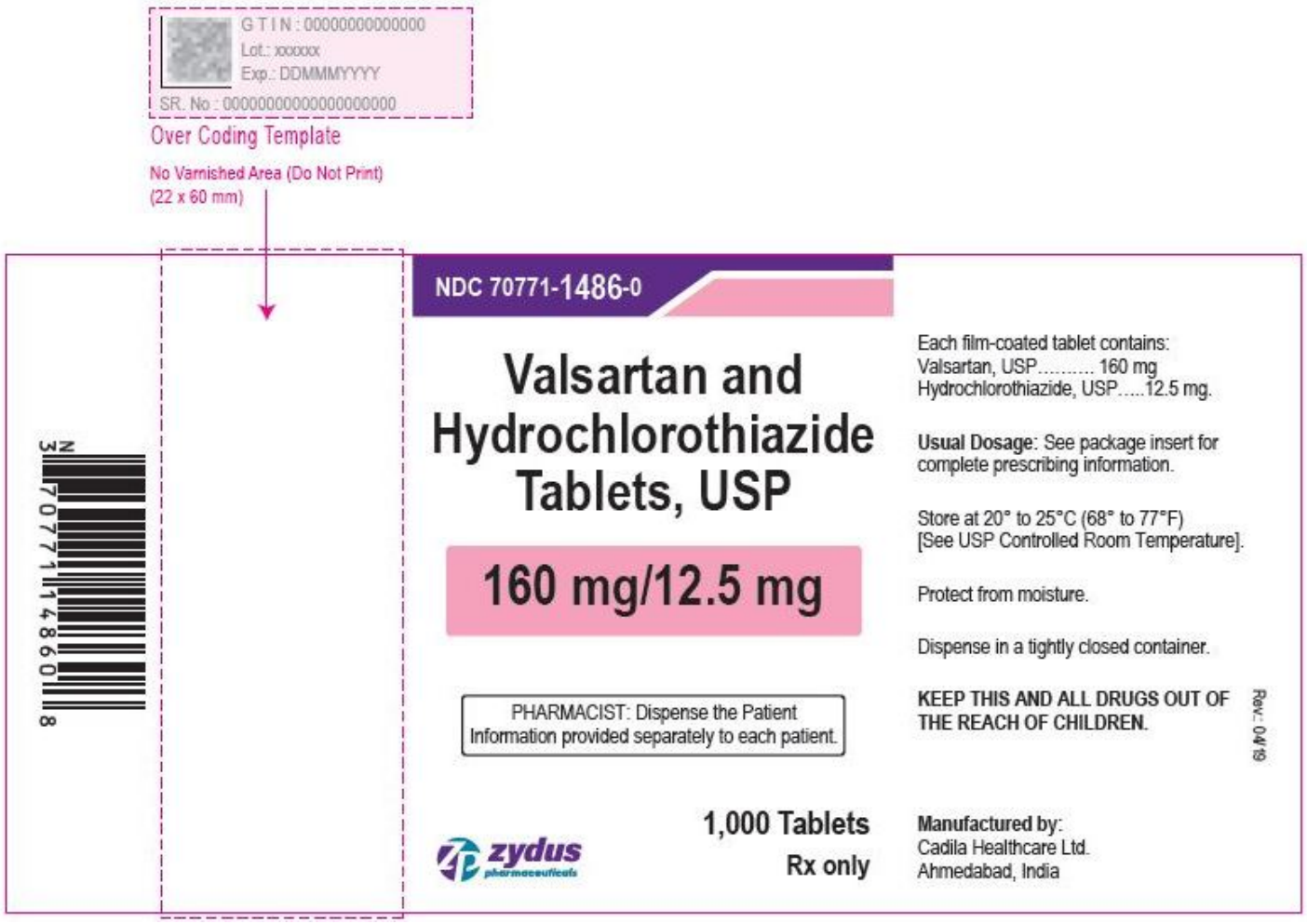
Rx only

Valsartan and Hydrochlorothiazide Tablets USP, 160/12.5 mg

NDC 70771-1486-0 in bottle of 1000 tablets

1000 tablets

Rx only

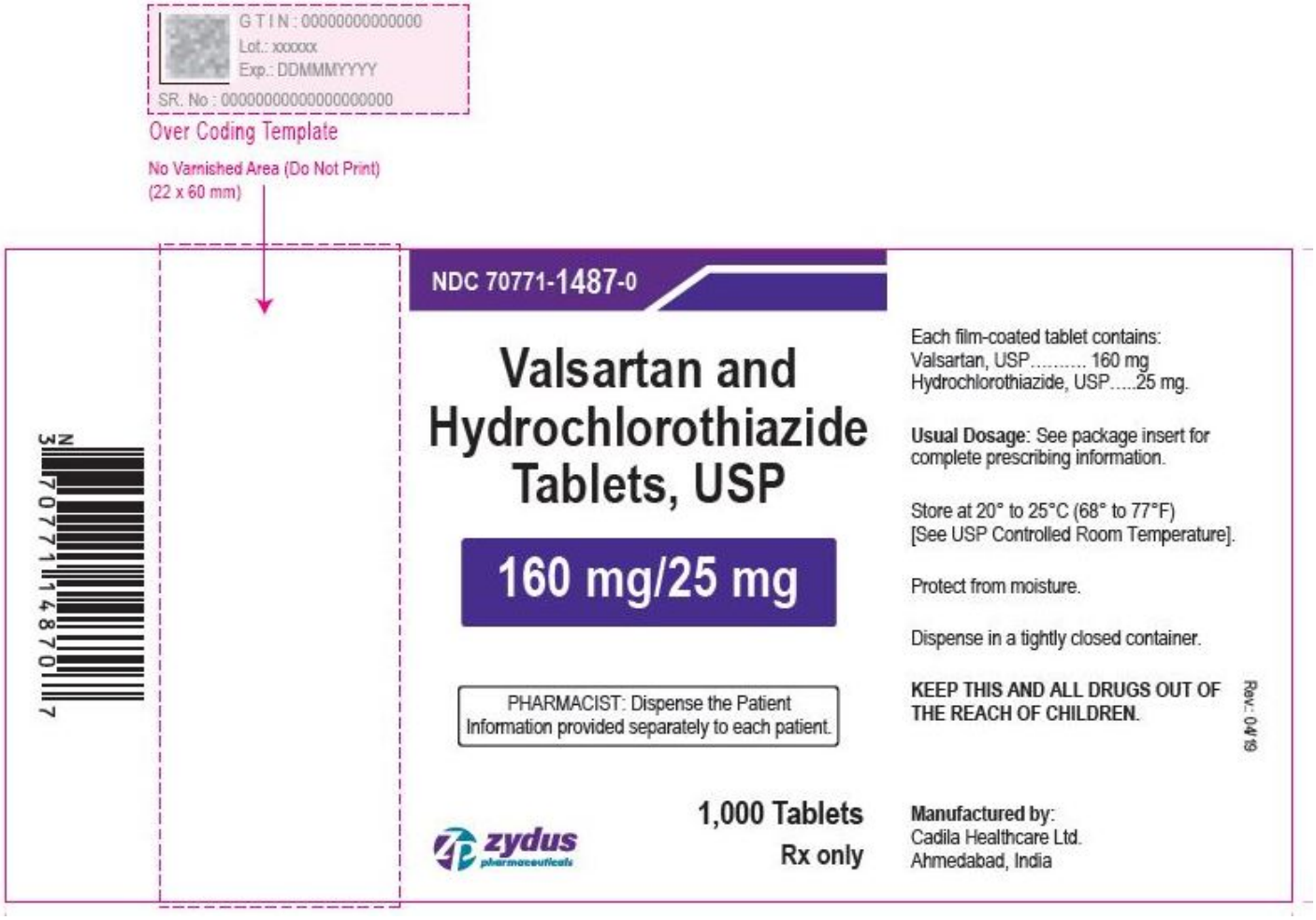


Valsartan and Hydrochlorothiazide Tablets USP, 160/25 mg

NDC 70771-1487-0 in bottle of 1000 tablets

1000 tablets

Rx only

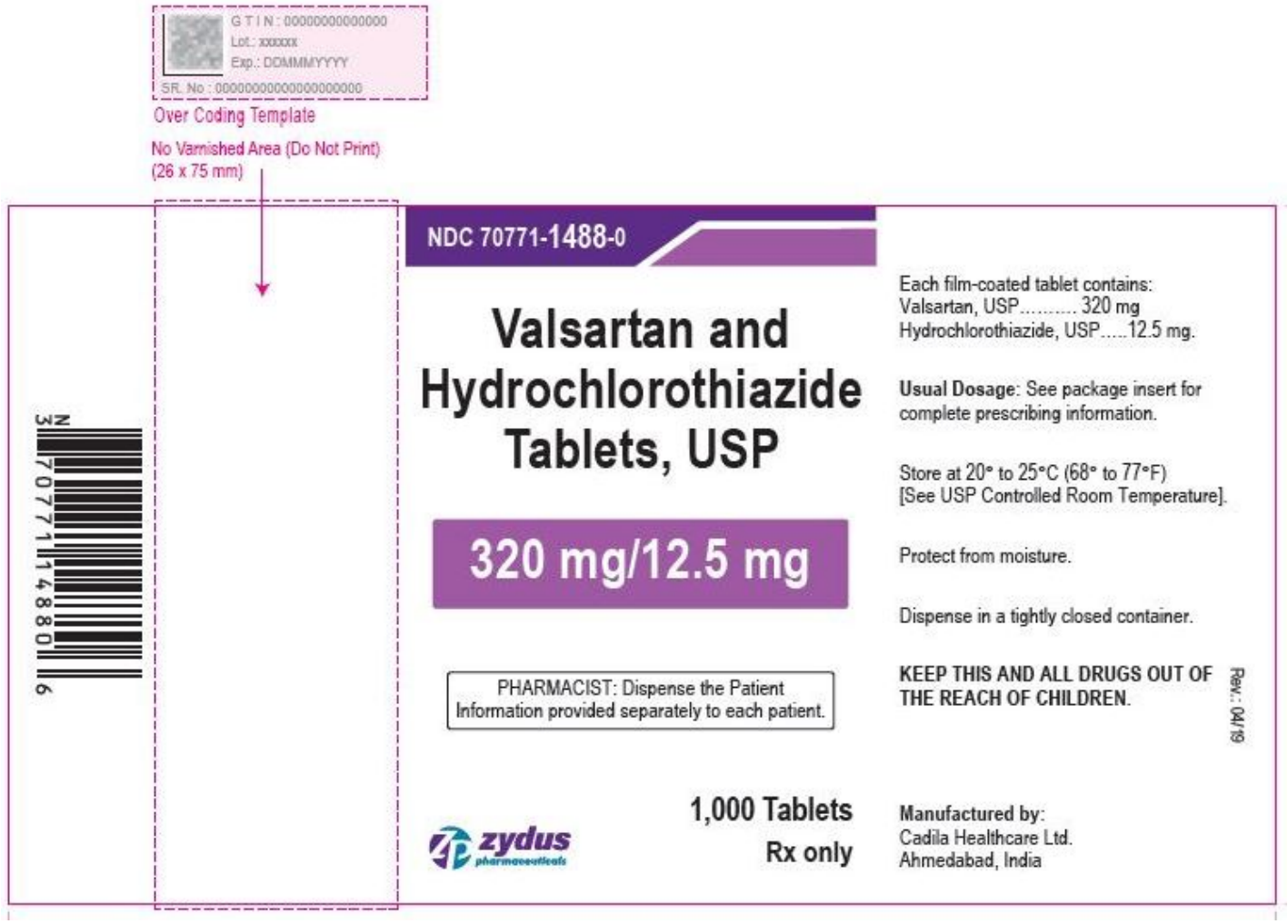


Valsartan and Hydrochlorothiazide Tablets USP, 320/12.5 mg

NDC 70771-1488-0 in bottle of 1000 tablets

1000 tablets

Rx only

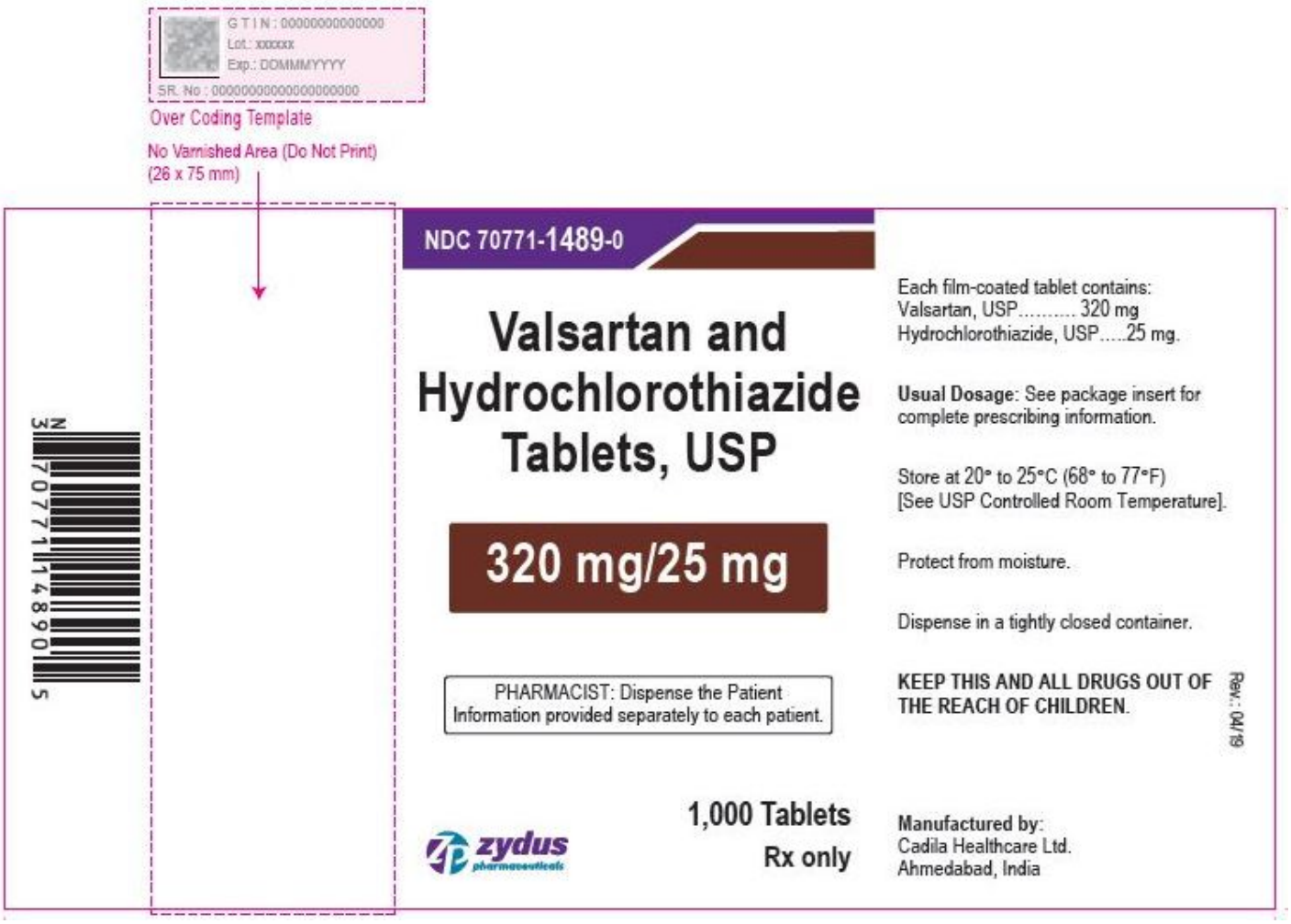


Valsartan and Hydrochlorothiazide Tablets USP, 320/25 mg

NDC 70771-1489-0 in bottle of 1000 tablets

1000 tablets

Rx only



VALSARTAN AND HYDROCHLOROTHIAZIDE

valsartan and hydrochlorothiazide tablet, film coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1485
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
VALSARTAN (UNII: 80M03YXJ7I) (VALSARTAN - UNII:80M03YXJ7I)	VALSARTAN	80 mg
HYDROCHLOROTHIAZIDE (UNII: 0J48LPH2TH) (HYDROCHLOROTHIAZIDE - UNII:0J48LPH2TH)	HYDROCHLOROTHIAZIDE	12.5 mg

Inactive Ingredients	
Ingredient Name	**Strength**
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSPOVIDONE (UNII: 2S7830E561)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL 4000 (UNII: 4R4HFI6D95)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	PINK (PINK)	**Score**	no score
Shape	OVAL (OVAL)	**Size**	12mm
Flavor		**Imprint Code**	279
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1485-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	02/12/2020	
2	NDC:70771-1485-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	02/12/2020	
3	NDC:70771-1485-4	10 in 1 CARTON	02/12/2020	
3		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	ANDA203000	02/12/2020	

VALSARTAN AND HYDROCHLOROTHIAZIDE

valsartan and hydrochlorothiazide tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1486
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
VALSARTAN (UNII: 80M03YXJ7I) (VALSARTAN - UNII:80M03YXJ7I)	VALSARTAN	160 mg
HYDROCHLOROTHIAZIDE (UNII: 0J48LPH2TH) (HYDROCHLOROTHIAZIDE - UNII:0J48LPH2TH)	HYDROCHLOROTHIAZIDE	12.5 mg

Inactive Ingredients

Ingredient Name	Strength
HYPROMELLOSES (UNII: 3NXW29V3WO)	

FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TALC (UNII: 7SEV7J4R1U)	
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSPOVIDONE (UNII: 2S7830E561)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
POLYETHYLENE GLYCOL 4000 (UNII: 4R4HFI6D95)	

Product Characteristics

Color	BROWN (brownish red)	**Score**	no score
Shape	OVAL (OVAL)	**Size**	17mm
Flavor		**Imprint Code**	280
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1486-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	02/12/2020	
2	NDC:70771-1486-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	02/12/2020	
3	NDC:70771-1486-4	10 in 1 CARTON	02/12/2020	
3		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	ANDA203000	02/12/2020	

VALSARTAN AND HYDROCHLOROTHIAZIDE

valsartan and hydrochlorothiazide tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1487
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
VALSARTAN (UNII: 80M03YXJ7I) (VALSARTAN - UNII:80M03YXJ7I)	VALSARTAN	160 mg
HYDROCHLOROTHIAZIDE (UNII: 0J48LPH2TH) (HYDROCHLOROTHIAZIDE - UNII:0J48LPH2TH)	HYDROCHLOROTHIAZIDE	25 mg

Inactive Ingredients	
Ingredient Name	**Strength**
HYPROMELLOSES (UNII: 3NXW29V3WO)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TALC (UNII: 7SEV7J4R1U)	
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSPOVIDONE (UNII: 2S7830E561)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
POLYETHYLENE GLYCOL 4000 (UNII: 4R4HFI6D95)	

Product Characteristics			
Color	BROWN (BROWN)	**Score**	no score
Shape	OVAL (oval)	**Size**	17mm
Flavor		**Imprint Code**	282
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:70771-1487-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	02/12/2020	
2	NDC:70771-1487-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	02/12/2020	
3	NDC:70771-1487-4	10 in 1 CARTON	02/12/2020	
3		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	ANDA203000	02/12/2020	

VALSARTAN AND HYDROCHLOROTHIAZIDE

valsartan and hydrochlorothiazide tablet, film coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1488
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**

VALSARTAN (UNII: 80M03YXJ7I) (VALSARTAN - UNII:80M03YXJ7I)	VALSARTAN	320 mg
HYDROCHLOROTHIAZIDE (UNII: 0J48LPH2TH) (HYDROCHLOROTHIAZIDE - UNII:0J48LPH2TH)	HYDROCHLOROTHIAZIDE	12.5 mg

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSPOVIDONE (UNII: 2S7830E561)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL 4000 (UNII: 4R4HFI6D95)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	PINK (pink)	**Score**	no score
Shape	OVAL (oval)	**Size**	21mm
Flavor		**Imprint Code**	281
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1488-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	02/12/2020	
2	NDC:70771-1488-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	02/12/2020	
3	NDC:70771-1488-4	10 in 1 CARTON	02/12/2020	
3		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	ANDA203000	02/12/2020	

VALSARTAN AND HYDROCHLOROTHIAZIDE

valsartan and hydrochlorothiazide tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1489
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
VALSARTAN (UNII: 80M03YXJ7I) (VALSARTAN - UNII:80M03YXJ7I)	VALSARTAN	320 mg
HYDROCHLOROTHIAZIDE (UNII: 0J48LPH2TH) (HYDROCHLOROTHIAZIDE - UNII:0J48LPH2TH)	HYDROCHLOROTHIAZIDE	25 mg

Inactive Ingredients

Ingredient Name	Strength
HYPROMELLOSES (UNII: 3NXW29V3WO)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 4000 (UNII: 4R4HFI6D95)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TALC (UNII: 7SEV7J4R1U)	
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSPOVIDONE (UNII: 2S7830E561)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	

Product Characteristics

Color	BROWN (BROWN)	**Score**	no score
Shape	OVAL (OVAL)	**Size**	21mm
Flavor		**Imprint Code**	283
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1489-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	02/12/2020	
2	NDC:70771-1489-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	02/12/2020	
3	NDC:70771-1489-4	10 in 1 CARTON	02/12/2020	
3		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	ANDA203000	02/12/2020	

Labeler - Cadila Healthcare Limited (918596198)

Registrant - Cadila Healthcare Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Cadila Healthcare Limited		918596198	ANALYSIS(70771-1485, 70771-1486, 70771-1487, 70771-1488, 70771-1489) , MANUFACTURE(70771-1485, 70771-1486, 70771-1487, 70771-1488, 70771-1489)