

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

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

Over Coding Template
No Varnished Area (Do Not Print)
(22 x 60 mm)

NDC 70771-1485-0

Valsartan and Hydrochlorothiazide Tablets, USP

80 mg/12.5 mg

PHARMACIST: Dispense the Patient Information provided separately to each patient.

zydus pharmaceuticals

1,000 Tablets
Rx only

Manufactured by:
Cadila Healthcare Ltd.
Ahmedabad, India

Each film-coated tablet contains:
Valsartan, USP..... 80 mg
Hydrochlorothiazide, USP.....12.5 mg.

Usual Dosage: See package insert for complete prescribing information.

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

Protect from moisture.

Dispense in a tightly closed container.

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

Rev: 04/19

Valsartan and Hydrochlorothiazide Tablets USP, 160/12.5 mg

NDC 70771-1486-0 in bottle of 1000 tablets

1000 tablets

Rx only

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

Over Coding Template

No Varnished Area (Do Not Print)
(22 x 60 mm)

NDC 70771-1486-0

Valsartan and Hydrochlorothiazide Tablets, USP

160 mg/12.5 mg

PHARMACIST: Dispense the Patient Information provided separately to each patient.

1,000 Tablets
Rx only

Manufactured by:
Cadila Healthcare Ltd.
Ahmedabad, India

Each film-coated tablet contains:
Valsartan, USP 160 mg
Hydrochlorothiazide, USP 12.5 mg.

Usual Dosage: See package insert for complete prescribing information.

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

Protect from moisture.

Dispense in a tightly closed container.

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

Rev: 04/19

Valsartan and Hydrochlorothiazide Tablets USP, 160/25 mg

NDC 70771-1487-0 in bottle of 1000 tablets

1000 tablets

Rx only

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

Over Coding Template

No Varnished Area (Do Not Print)
(22 x 60 mm)

NDC 70771-1487-0

Valsartan and Hydrochlorothiazide Tablets, USP

160 mg/25 mg

PHARMACIST: Dispense the Patient Information provided separately to each patient.

1,000 Tablets
Rx only

Each film-coated tablet contains:
Valsartan, USP..... 160 mg
Hydrochlorothiazide, USP.....25 mg.

Usual Dosage: See package insert for complete prescribing information.

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

Protect from moisture.

Dispense in a tightly closed container.

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

Manufactured by:
Cadila Healthcare Ltd.
Ahmedabad, India

Rev: 04/19

Valsartan and Hydrochlorothiazide Tablets USP, 320/12.5 mg

NDC 70771-1488-0 in bottle of 1000 tablets

1000 tablets

Rx only

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

Over Coding Template

No Varnished Area (Do Not Print)
(26 x 75 mm)

NDC 70771-1488-0

Valsartan and Hydrochlorothiazide Tablets, USP

320 mg/12.5 mg

PHARMACIST: Dispense the Patient Information provided separately to each patient.

1,000 Tablets Rx only

Manufactured by:
Cadila Healthcare Ltd.
Ahmedabad, India

Each film-coated tablet contains:
Valsartan, USP 320 mg
Hydrochlorothiazide, USP 12.5 mg.

Usual Dosage: See package insert for complete prescribing information.

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

Protect from moisture.

Dispense in a tightly closed container.

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

Rev: 04/19

Valsartan and Hydrochlorothiazide Tablets USP, 320/25 mg

NDC 70771-1489-0 in bottle of 1000 tablets

1000 tablets

Rx only

GTIN: 00000000000000
 Lot: 000000
 Exp.: 00MMYYYY
 SR. No.: 000000000000000000

Over Coding Template

No Varnished Area (Do Not Print)
 (26 x 75 mm)

NDC 70771-1489-0

Valsartan and Hydrochlorothiazide Tablets, USP

320 mg/25 mg

PHARMACIST: Dispense the Patient Information provided separately to each patient.



1,000 Tablets
 Rx only

Each film-coated tablet contains:
 Valsartan, USP..... 320 mg
 Hydrochlorothiazide, USP.....25 mg.

Usual Dosage: See package insert for complete prescribing information.

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

Protect from moisture.

Dispense in a tightly closed container.

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

Rev: 04/19

Manufactured by:
 Cadila Healthcare Ltd.
 Ahmedabad, India

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)	
CROSPVIDONE (UNII: 2S7830E561)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL 4000 (UNII: 4R4HF16D95)	
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)
CROSPVIDONE (UNII: 2S7830E561)
FERROSFERRIC OXIDE (UNII: XM0M87F357)
POLYETHYLENE GLYCOL 4000 (UNII: 4R4HF16D95)

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)	
CROSPVIDONE (UNII: 2S7830E561)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
POLYETHYLENE GLYCOL 4000 (UNII: 4R4HF16D95)	

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
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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)				
CROSPVIDONE (UNII: 2S7830E561)				
FERRIC OXIDE RED (UNII: 1K09F3G675)				
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)				
HYPROMELLOSES (UNII: 3NXW29V3WO)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
POLYETHYLENE GLYCOL 4000 (UNII: 4R4HF16D95)				
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: 4R4HF16D95)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TALC (UNII: 7SEV7J4R1U)	
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSPVIDONE (UNII: 2S7830E561)	
FERROSFERRIC 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)

Revised: 9/2020

Cadila Healthcare Limited