TELMISARTAN AND HYDROCHLOROTHIAZIDE - telmisartan and hydrochlorothiazide tablet
Zydus Lifesciences Limited

TELMISARTAN AND HYDROCHLORTHIAZIDE TABLETS

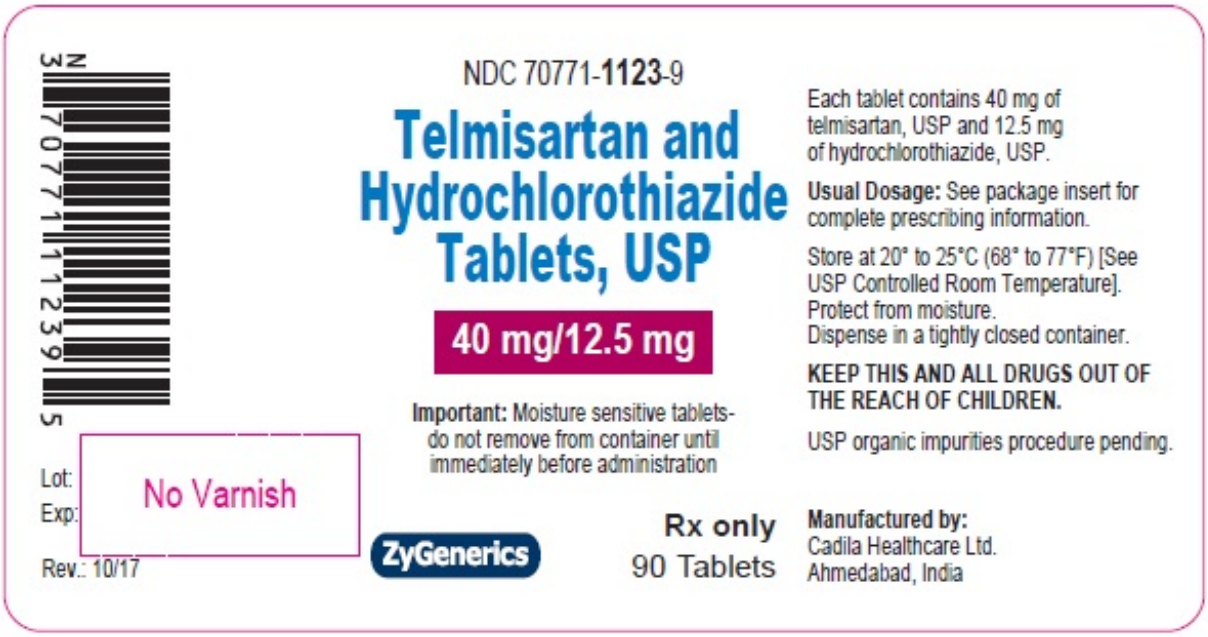
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1123-9 in bottle of 90 tablets

Telmisartan and Hydrochlorthaizide Tablets USP, 40 mg/12.5 mg

R_x only

90 tablets

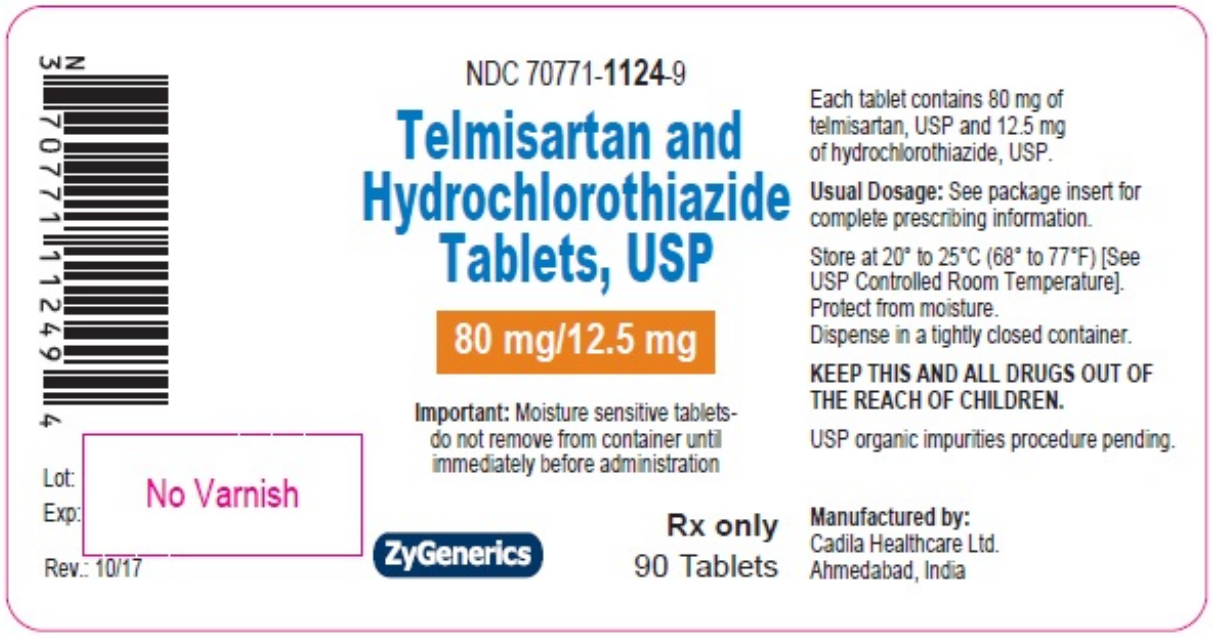


NDC 70771-1124-9 in bottle of 90 tablets

Telmisartan and Hydrochlorthaizide Tablets USP, 80 mg/12.5 mg

R_x only

90 tablets

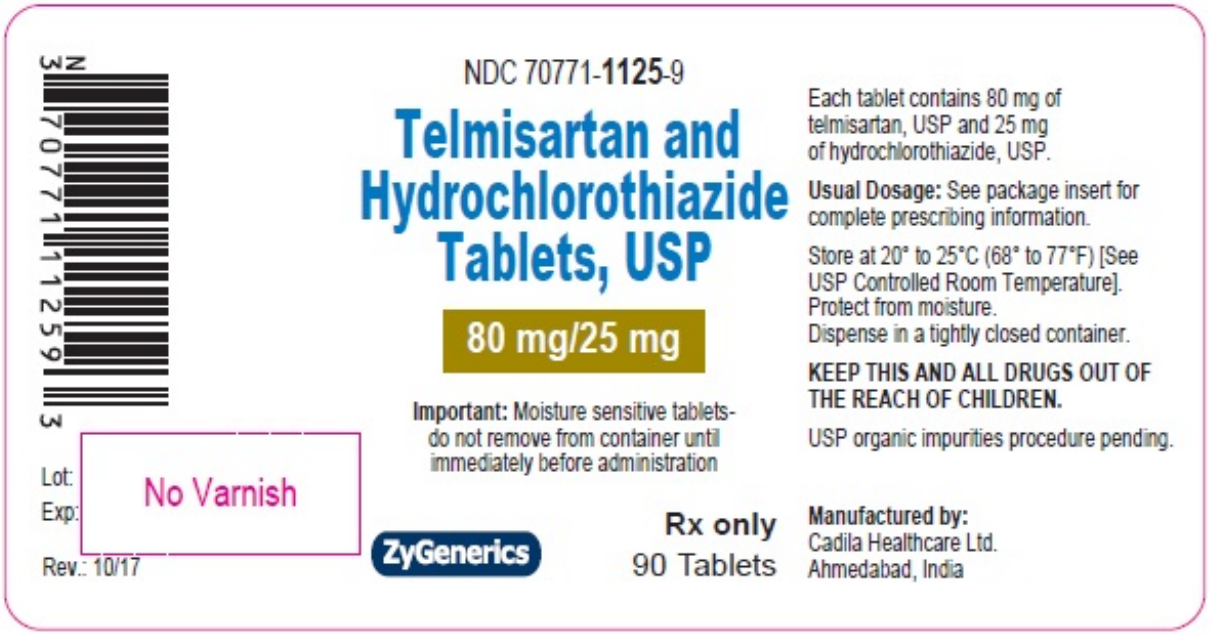


NDC 70771-1125-9 in bottle of 90 tablets

Telmisartan and Hydrochlorthaizide Tablets USP, 80 mg/25 mg

R_x only

90 tablets



TELMISARTAN AND HYDROCHLOROTHIAZIDE telmisartan and hydrochlorothiazide tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1123
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TELMISARTAN (UNII: U5SYW473RQ) (TELMISARTAN - UNII:U5SYW473RQ)	TELMISARTAN	40 mg
HYDROCHLOROTHIAZIDE (UNII: 0J48LPH2TH) (HYDROCHLOROTHIAZIDE - UNII:0J48LPH2TH)	HYDROCHLOROTHIAZIDE	12.5 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSPOVIDONE (UNII: 2S7830E561)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
MEGLUMINE (UNII: 6HG8UB2MUY)	
POVIDONE (UNII: FZ989GH94E)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI)	
SORBITOL (UNII: 506T60A25R)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics

Color	BROWN (Mottled Light brown to Mottled Brown) , WHITE (WHITE TO OFF WHITE)	**Score**	no score
Shape	OVAL (Oblong Shaped)	**Size**	15mm
Flavor		**Imprint Code**	513
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1123-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	10/12/2017	
2	NDC:70771-1123-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	10/12/2017	
3	NDC:70771-1123-8	3 in 1 CARTON	10/12/2017	
3	NDC:70771-1123-2	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	ANDA204221	10/12/2017	

TELMISARTAN AND HYDROCHLOROTHIAZIDE

telmisartan and hydrochlorothiazide tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1124
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TELMISARTAN (UNII: U5SYW473RQ) (TELMISARTAN - UNII:U5SYW473RQ)	TELMISARTAN	80 mg
HYDROCHLOROTHIAZIDE (UNII: 0J48LPH2TH) (HYDROCHLOROTHIAZIDE - UNII:0J48LPH2TH)	HYDROCHLOROTHIAZIDE	12.5 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSPOVIDONE (UNII: 2S7830E561)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
MEGLUMINE (UNII: 6HG8UB2MUY)	
POVIDONE (UNII: FZ989GH94E)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI)	
SORBITOL (UNII: 506T60A25R)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics

Color	BROWN (Mottled Light brown to Mottled Brown) , WHITE (WHITE TO OFF WHITE)	**Score**	no score
Shape	OVAL (Oblong Shaped)	**Size**	17mm
Flavor		**Imprint Code**	514
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1	NDC:70771-1124-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	10/12/2017	
2	NDC:70771-1124-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	10/12/2017	
3	NDC:70771-1124-8	3 in 1 CARTON	10/12/2017	
3	NDC:70771-1124-2	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	ANDA204221	10/12/2017	

TELMISARTAN AND HYDROCHLOROTHIAZIDE

telmisartan and hydrochlorothiazide tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1125
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TELMISARTAN (UNII: U5SYW473RQ) (TELMISARTAN - UNII:U5SYW473RQ)	TELMISARTAN	80 mg
HYDROCHLOROTHIAZIDE (UNII: 0J48LPH2TH) (HYDROCHLOROTHIAZIDE - UNII:0J48LPH2TH)	HYDROCHLOROTHIAZIDE	25 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSPOVIDONE (UNII: 2S7830E561)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
MEGLUMINE (UNII: 6HG8UB2MUY)	
POVIDONE (UNII: FZ989GH94E)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI)	
SORBITOL (UNII: 506T60A25R)	
TALC (UNII: 7SEV7J4R1U)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	

Product Characteristics

Color	BROWN (Mottled Light brown to Mottled Brown) , YELLOW (YELLOW)	**Score**	no score
Shape	OVAL (Oblong Shaped)	**Size**	17mm
Flavor		**Imprint Code**	515
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1125-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	10/12/2017	
2	NDC:70771-1125-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	10/12/2017	
3	NDC:70771-1125-8	3 in 1 CARTON	10/12/2017	
3	NDC:70771-1125-2	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	ANDA204221	10/12/2017	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		918596198	ANALYSIS(70771-1123, 70771-1124, 70771-1125) , MANUFACTURE(70771-1123, 70771-1124, 70771-1125)

Revised: 10/2022 Zydus Lifesciences Limited