TELMISARTAN - telmisartan tablet
Zydus Lifesciences Limited

TELMISARTAN TABLETS

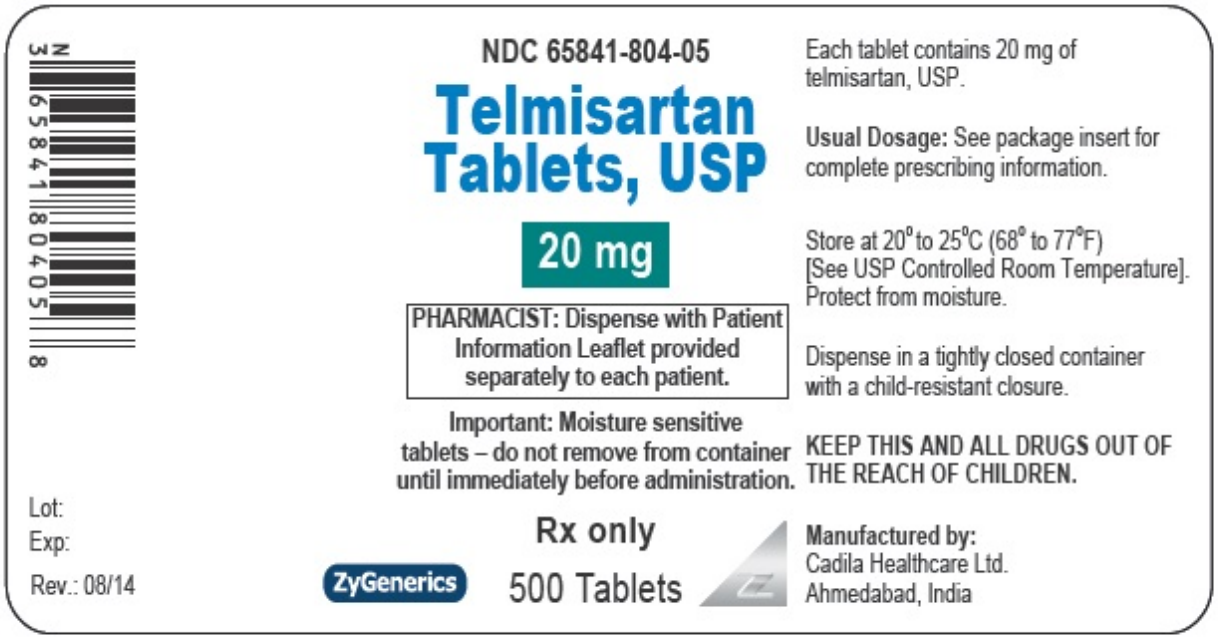
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 65841-804-05 in bottle of 500 tablets

Telmisartan Tablets USP, 20 mg

R_x only

500 tablets



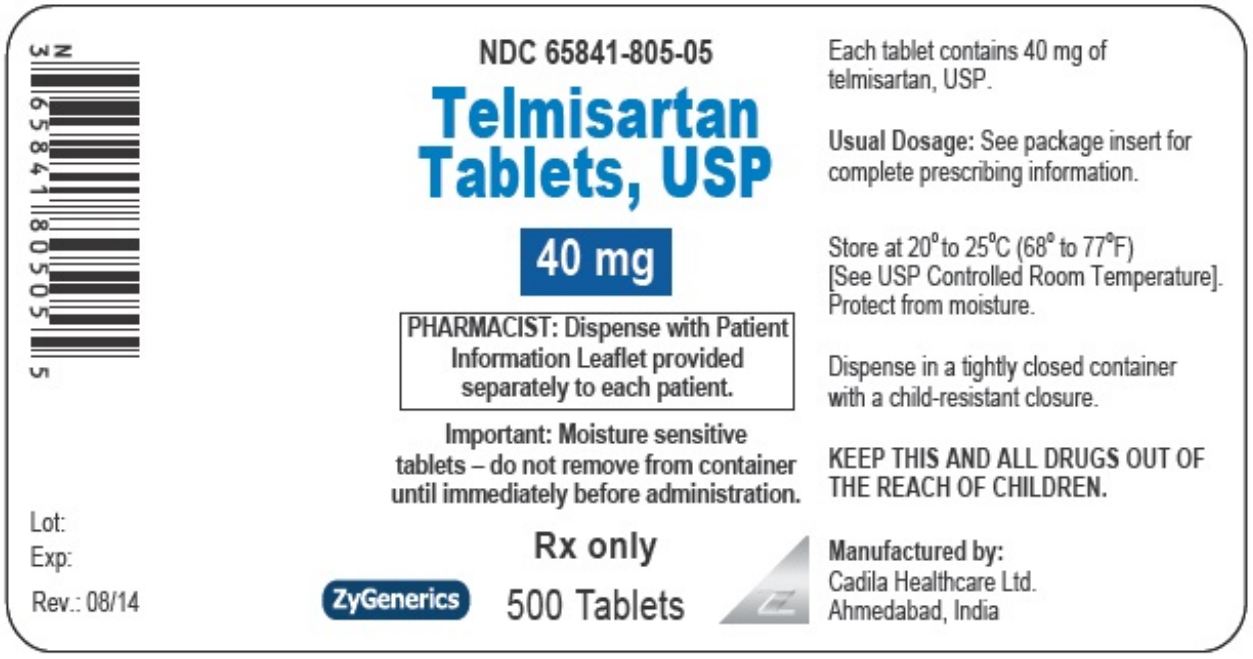
97 X 50.5 mm

NDC 65841-805-05 in bottle of 500 tablets

Telmisartan Tablets USP, 40 mg

R_x only

500 tablets

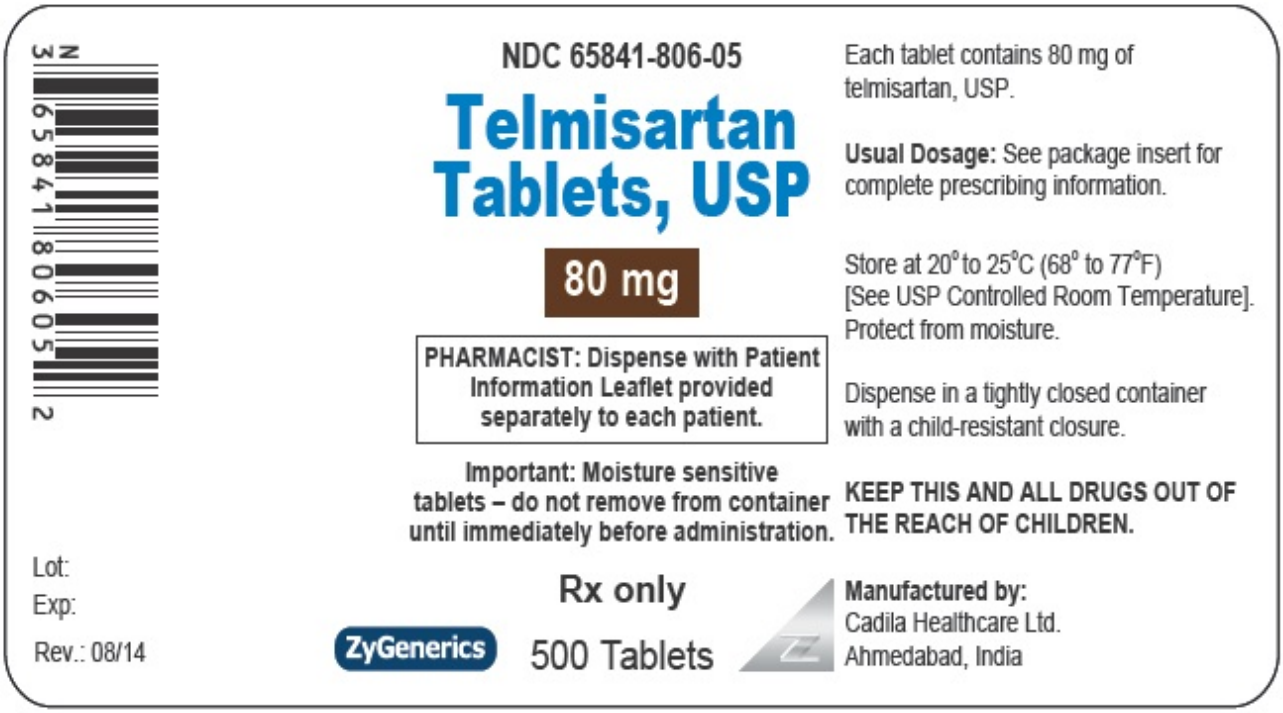


NDC 65841-806-05 in bottle of 500 tablets

Telmisartan Tablets USP, 80 mg

R_x only

500 tablets



TELMISARTAN

telmisartan tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-804
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
TELMISARTAN (UNII: U5SYW473RQ) (TELMISARTAN - UNII:U5SYW473RQ)	TELMISARTAN	20 mg

Inactive Ingredients	
Ingredient Name	**Strength**
FERRIC OXIDE RED (UNII: 1K09F3G675)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MEGLUMINE (UNII: 6HG8UB2MUY)	
POVIDONE (UNII: FZ989GH94E)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics			
Color	BROWN (MOTTLED LIGHT BROWN TO MOTTLED BROWN)	**Score**	no score
Shape	ROUND (ROUND)	**Size**	7mm
Flavor		**Imprint Code**	471
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:65841-804-06	30 in 1 BOTTLE; Type 0: Not a Combination Product	08/27/2014	
2	NDC:65841-804-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	08/27/2014	
3	NDC:65841-804-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	08/27/2014	
4	NDC:65841-804-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	08/27/2014	
5	NDC:65841-804-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	08/27/2014	
6	NDC:65841-804-78	30 in 1 CARTON	08/27/2014	
6	NDC:65841-804-30	1 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	ANDA203325	08/27/2014	

TELMISARTAN

telmisartan tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-805
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TELMISARTAN (UNII: U5SYW473RQ) (TELMISARTAN - UNII:U5SYW473RQ)	TELMISARTAN	40 mg

Inactive Ingredients

Ingredient Name	Strength
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
MEGLUMINE (UNII: 6HG8UB2MUY)	
POVIDONE (UNII: FZ989GH94E)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
SORBITOL (UNII: 506T60A25R)	
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

Product Characteristics

Color	BROWN (MOTTLED LIGHT BROWN TO MOTTLED BROWN)	**Score**	no score
Shape	OVAL (OBLONG)	**Size**	12mm
Flavor		**Imprint Code**	472
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-805-06	30 in 1 BOTTLE; Type 0: Not a Combination Product	08/27/2014	
2	NDC:65841-805-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	08/27/2014	
3	NDC:65841-805-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	08/27/2014	
4	NDC:65841-805-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	08/27/2014	
	NDC:65841-805	1000 in 1 BOTTLE; Type 0: Not a Combination		

5	NDC:65841-805-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	08/27/2014	
6	NDC:65841-805-78	30 in 1 CARTON	08/27/2014	
6	NDC:65841-805-30	1 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	ANDA203325	08/27/2014	

TELMISARTAN

telmisartan tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-806
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TELMISARTAN (UNII: U5SYW473RQ) (TELMISARTAN - UNII:U5SYW473RQ)	TELMISARTAN	80 mg

Inactive Ingredients

Ingredient Name	Strength
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
MEGLUMINE (UNII: 6HG8UB2MUY)	
POVIDONE (UNII: FZ989GH94E)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
SORBITOL (UNII: 506T60A25R)	
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

Product Characteristics

Color	BROWN (MOTTLED LIGHT BROWN TO MOTTLED BROWN)	**Score**	no score
Shape	OVAL (OBLONG)	**Size**	18mm
Flavor		**Imprint Code**	473
Contains			

Packaging

#	Item Code	Package Description	Marketing Start	Marketing End

#	Item Code	Package Description	Date	Date
1	NDC:65841-806-06	30 in 1 BOTTLE; Type 0: Not a Combination Product	08/27/2014	
2	NDC:65841-806-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	08/27/2014	
3	NDC:65841-806-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	08/27/2014	
4	NDC:65841-806-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	08/27/2014	
5	NDC:65841-806-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	08/27/2014	
6	NDC:65841-806-78	30 in 1 CARTON	08/27/2014	
6	NDC:65841-806-30	1 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	ANDA203325	08/27/2014	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		918596198	ANALYSIS(65841-804, 65841-805, 65841-806) , MANUFACTURE(65841-804, 65841-805, 65841-806)

Revised: 10/2022 Zydus Lifesciences Limited