

**TELMISARTAN- telmisartan tablet**  
**Cadila Healthcare Limited**

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**TELMISARTAN TABLETS**

**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

NDC 65841-804-05 in bottle of 500 tablets

Telmisartan Tablets USP, 20 mg

R<sub>x</sub> only

500 tablets

**NDC 65841-804-05**

**Telmisartan  
Tablets, USP**

**20 mg**

**PHARMACIST: Dispense with Patient  
Information Leaflet provided  
separately to each patient.**

**Important: Moisture sensitive  
tablets – do not remove from container  
until immediately before administration.**

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

Each tablet contains 20 mg of  
telmisartan, USP.

**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  
with a child-resistant closure.

Lot:  
Exp:  
Rev.: 08/14

**ZyGenerics** **Rx only** **500 Tablets**

**Manufactured by:**  
Cadila Healthcare Ltd.  
Ahmedabad, India

97 X 50.5 mm

NDC 65841-805-05 in bottle of 500 tablets

Telmisartan Tablets USP, 40 mg

R<sub>x</sub> only

500 tablets



NDC 65841-805-05

# Telmisartan Tablets, USP

**40 mg**

**PHARMACIST:** Dispense with Patient Information Leaflet provided separately to each patient.

**Important:** Moisture sensitive tablets – do not remove from container until immediately before administration.

Lot:  
Exp:  
Rev.: 08/14



**Rx only**  
500 Tablets



Each tablet contains 40 mg of telmisartan, USP.

**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 with a child-resistant closure.

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

**Manufactured by:**  
Cadila Healthcare Ltd.  
Ahmedabad, India

NDC 65841-806-05 in bottle of 500 tablets

Telmisartan Tablets USP, 80 mg

R<sub>x</sub> only

500 tablets



NDC 65841-806-05

# Telmisartan Tablets, USP

**80 mg**

**PHARMACIST:** Dispense with Patient Information Leaflet provided separately to each patient.

**Important:** Moisture sensitive tablets – do not remove from container until immediately before administration.

Lot:  
Exp:  
Rev.: 08/14



**Rx only**  
500 Tablets



Each tablet contains 80 mg of telmisartan, USP.

**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 with a child-resistant closure.

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

**Manufactured by:**  
Cadila Healthcare Ltd.  
Ahmedabad, India

## 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**

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:65841-805
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
TELMISARTAN (UNII: U5SYW473RQ) (TELMISARTAN - UNII:U5SYW473RQ)	TELMISARTAN	40 mg

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
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**

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

**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	
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**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ANDA	ANDA203325	08/27/2014	

**TELMISARTAN**

telmisartan tablet

**Product Information**

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:65841-806
<b>Route of Administration</b>	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**

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

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End 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** - Cadila Healthcare Limited (918596198)

**Registrant** - Cadila Healthcare Limited (918596198)

**Establishment**

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

Revised: 9/2020

Cadila Healthcare Limited