TADALAFIL - tadalafil tablet, film coated
Cadila Healthcare Limited

TADALAFIL TABLETS

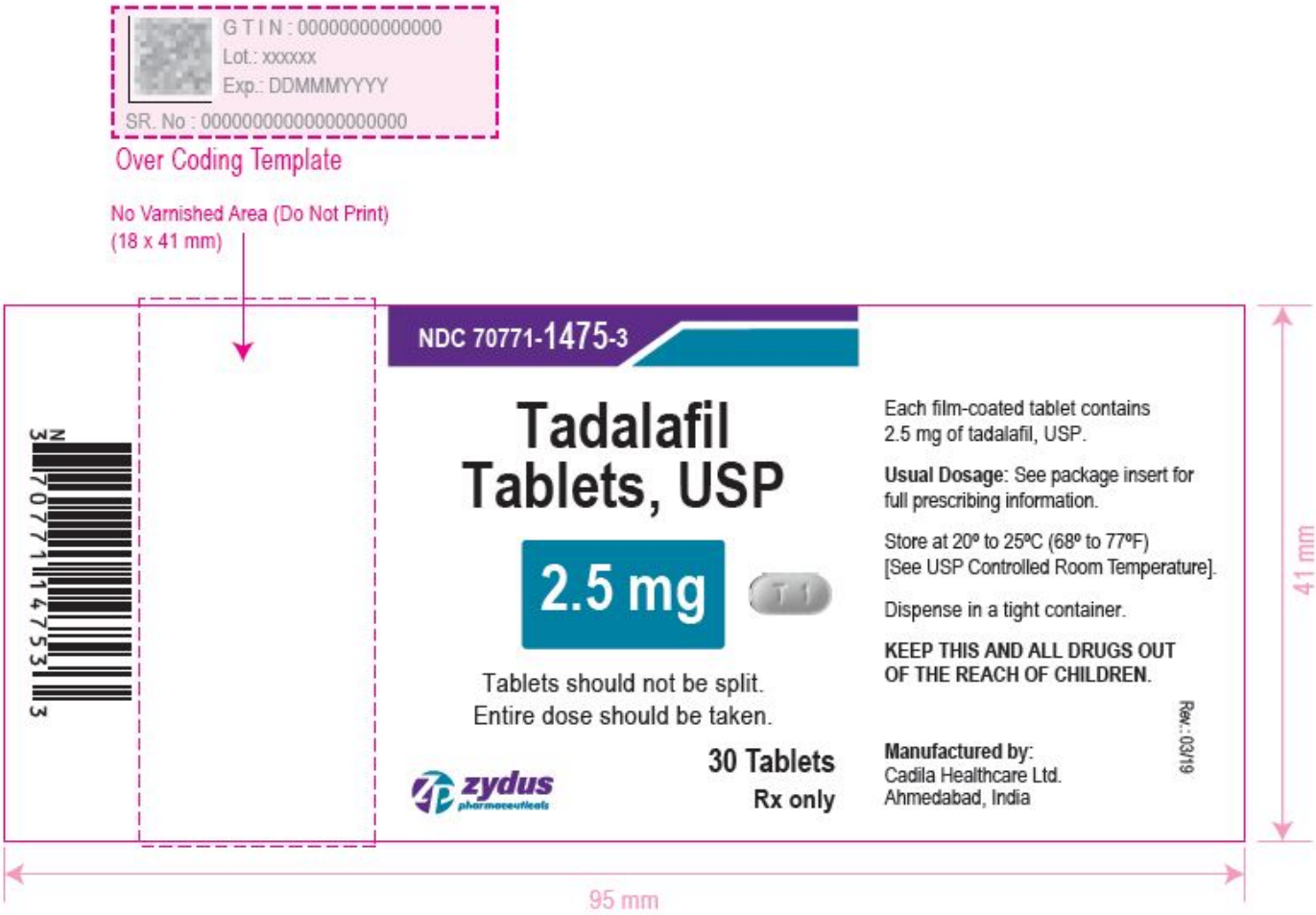
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1475-3 in bottle of 30 tablets

Tadalafil Tablets USP, 2.5 mg

Rx Only

30 tablets

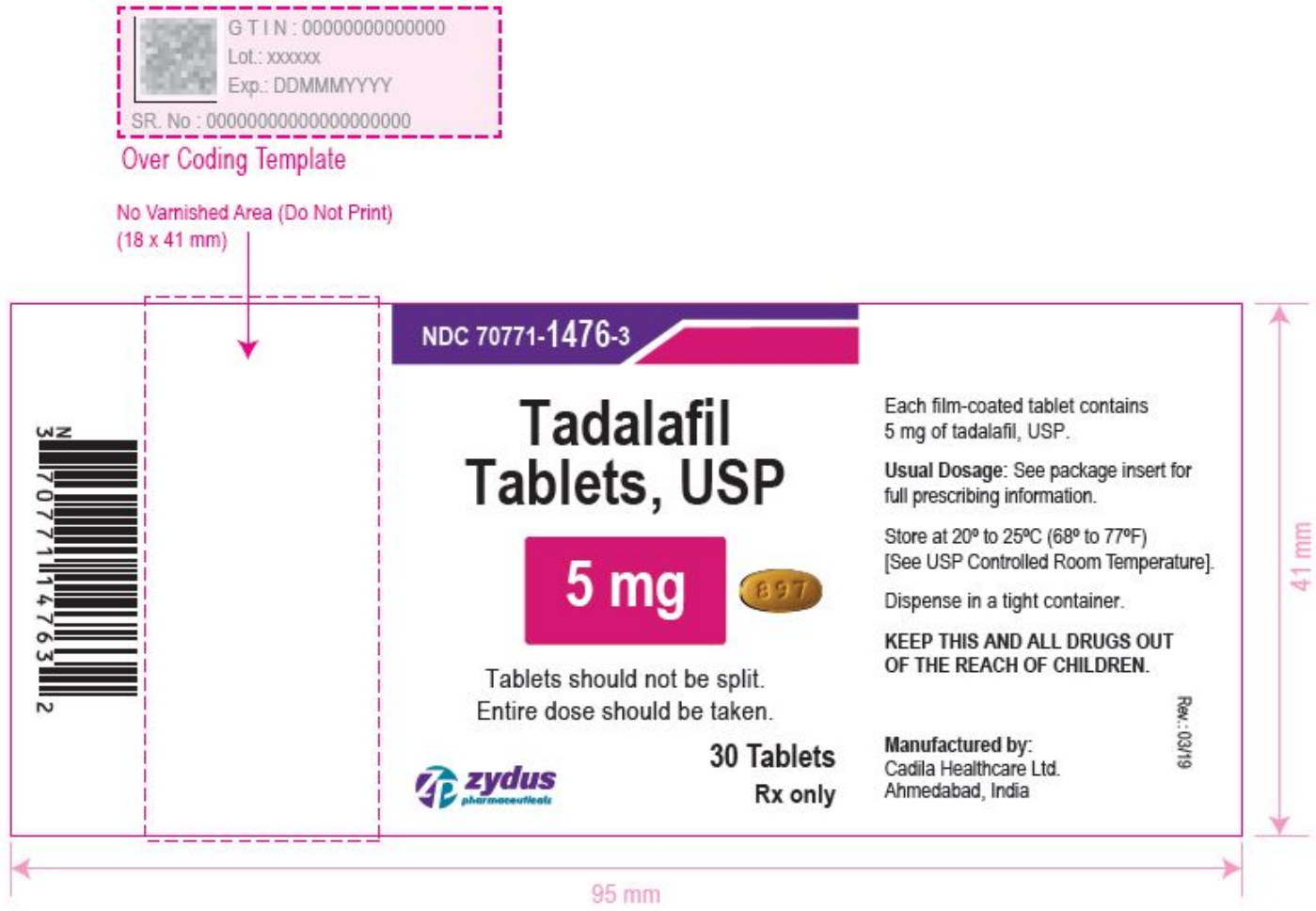


NDC 70771-1476-3 in bottle of 30 tablets

Tadalafil Tablets USP, 5 mg

Rx Only

30 tablets

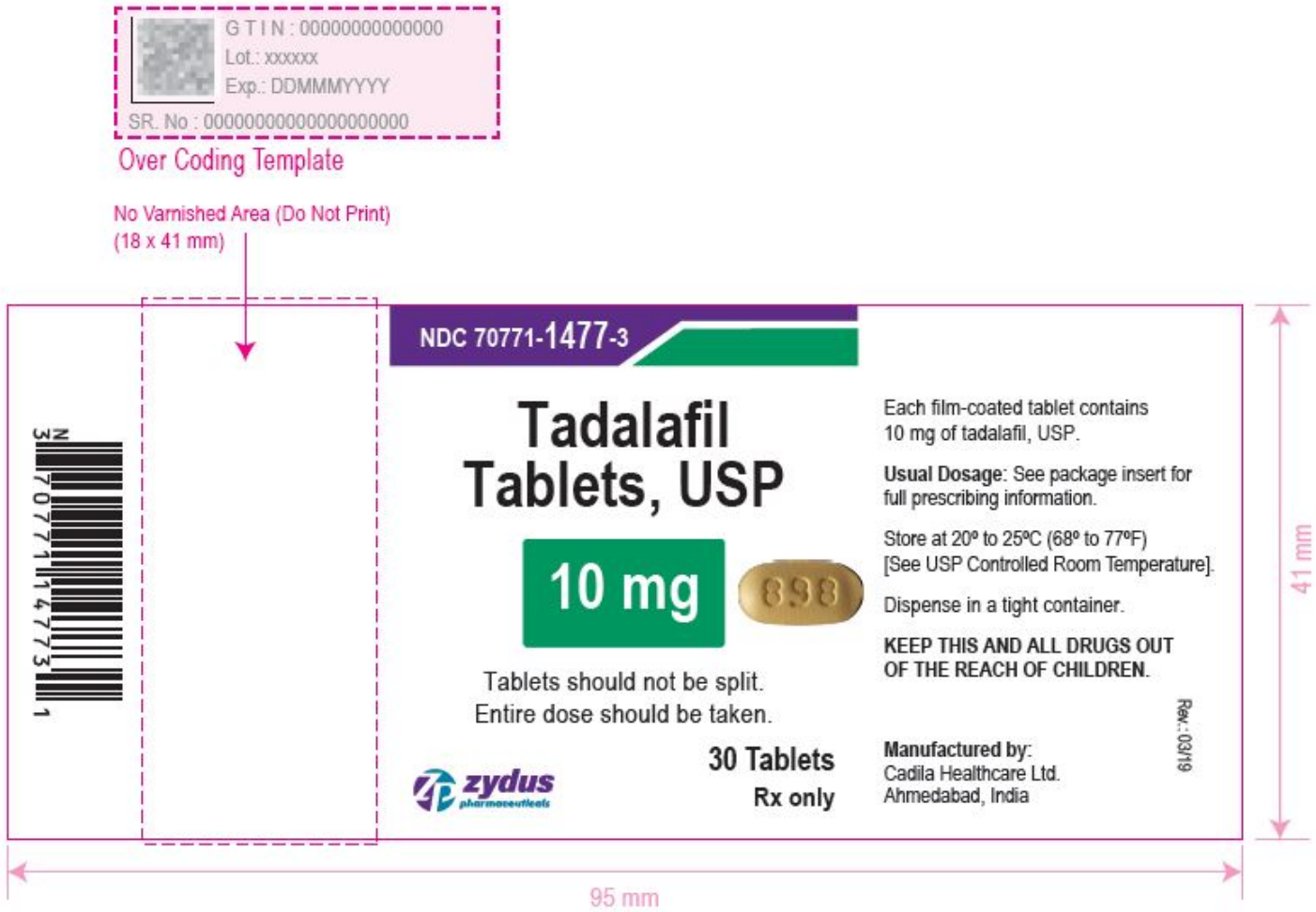


NDC 70771-1477-3 in bottle of 30 tablets

Tadalafil Tablets USP, 10 mg

Rx Only

30 tablets

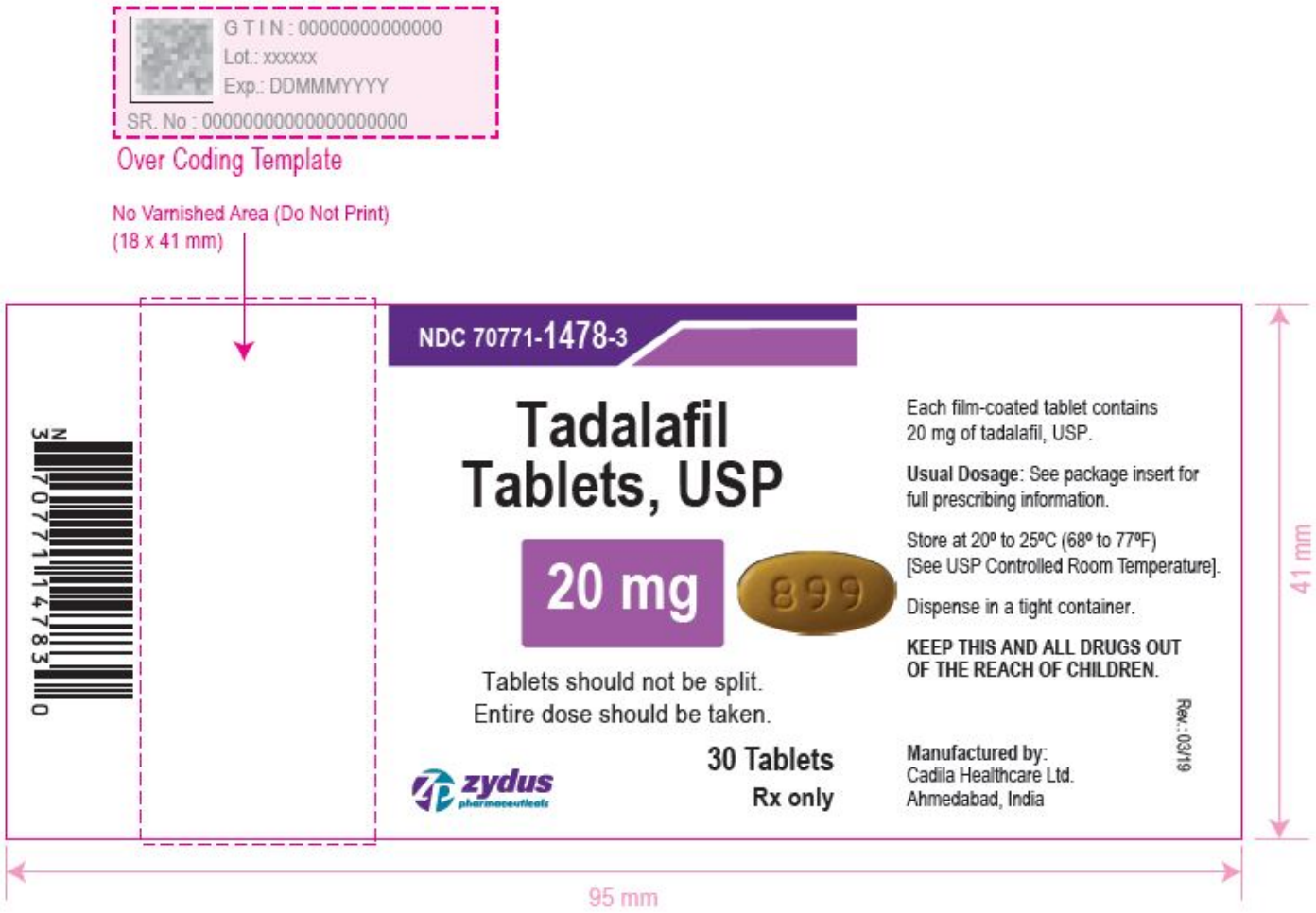


NDC 70771-1478-3 in bottle of 30 tablets

Tadalafil Tablets USP, 20 mg

Rx Only

30 tablets



TADALAFIL

tadalafil tablet, film coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1475
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
TADALAFIL (UNII: 742SXX0ICT) (TADALAFIL - UNII:742SXX0ICT)	TADALAFIL	2.5 mg

Inactive Ingredients	
Ingredient Name	**Strength**
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	

Product Characteristics			
Color	WHITE (WHITE)	**Score**	no score
Shape	CAPSULE (CAPSULE)	**Size**	6mm
Flavor		**Imprint Code**	T;1
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1475-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	03/27/2019	
2	NDC:70771-1475-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	03/27/2019	
3	NDC:70771-1475-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	03/27/2019	
4	NDC:70771-1475-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	03/27/2019	
5	NDC:70771-1475-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	03/27/2019	
6	NDC:70771-1475-4	2 in 1 CARTON	03/27/2019	
6		15 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	ANDA206693	03/27/2019	

TADALAFIL

tadalafil tablet, film coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1477
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TADALAFIL (UNII: 742SXX0ICT) (TADALAFIL - UNII:742SXX0ICT)	TADALAFIL	10 mg

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	

HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	

Product Characteristics			
Color	YELLOW (YELLOW)	**Score**	no score
Shape	CAPSULE (CAPSULE)	**Size**	10mm
Flavor		**Imprint Code**	898
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1477-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	03/27/2019	
2	NDC:70771-1477-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	03/27/2019	
3	NDC:70771-1477-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	03/27/2019	
4	NDC:70771-1477-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	03/27/2019	
5	NDC:70771-1477-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	03/27/2019	
6	NDC:70771-1477-4	2 in 1 CARTON	03/27/2019	
6		15 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	ANDA206693	03/27/2019	

TADALAFIL

tadalafil tablet, film coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1478
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TADALAFIL (UNII: 742SXX0ICT) (TADALAFIL - UNII:742SXX0ICT)	TADALAFIL	20 mg

Inactive Ingredients

Ingredient Name	Strength

CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	

Product Characteristics			
Color	YELLOW (YELLOW)	**Score**	no score
Shape	OVAL (OVAL)	**Size**	13mm
Flavor		**Imprint Code**	899
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1478-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	03/27/2019	
2	NDC:70771-1478-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	03/27/2019	
3	NDC:70771-1478-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	03/27/2019	
4	NDC:70771-1478-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	03/27/2019	
5	NDC:70771-1478-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	03/27/2019	
6	NDC:70771-1478-4	2 in 1 CARTON	03/27/2019	
6		15 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	ANDA206693	03/27/2019	

TADALAFIL

tadalafil tablet, film coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1476
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TADALAFIL (UNII: 742SXX0ICT) (TADALAFIL - UNII:742SXX0ICT)	TADALAFIL	5 mg

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	

Product Characteristics

Color	YELLOW (YELLOW)	**Score**	no score
Shape	OVAL (OVAL)	**Size**	8mm
Flavor		**Imprint Code**	897
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1476-7	10 in 1 BOTTLE; Type 0: Not a Combination Product	03/27/2019	
2	NDC:70771-1476-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	03/27/2019	
3	NDC:70771-1476-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	03/27/2019	
4	NDC:70771-1476-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	03/27/2019	
5	NDC:70771-1476-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	03/27/2019	
6	NDC:70771-1476-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	03/27/2019	
7	NDC:70771-1476-4	2 in 1 CARTON	03/27/2019	
7		15 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	ANDA206693	03/27/2019	

Labeler - Cadila Healthcare Limited (918596198)

Registrant - Cadila Healthcare Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Cadila Healthcare Limited		918596198	ANALYSIS(70771-1475, 70771-1476, 70771-1477, 70771-1478) , MANUFACTURE(70771-1475, 70771-1476, 70771-1477, 70771-1478)