

**TADALAFIL - tadalafil tablet, film coated**  
**Zydus Lifesciences Limited**

**TADALAFIL TABLETS**

**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

NDC 70771-1475-3 in bottle of 30 tablets

Tadalafil Tablets USP, 2.5 mg

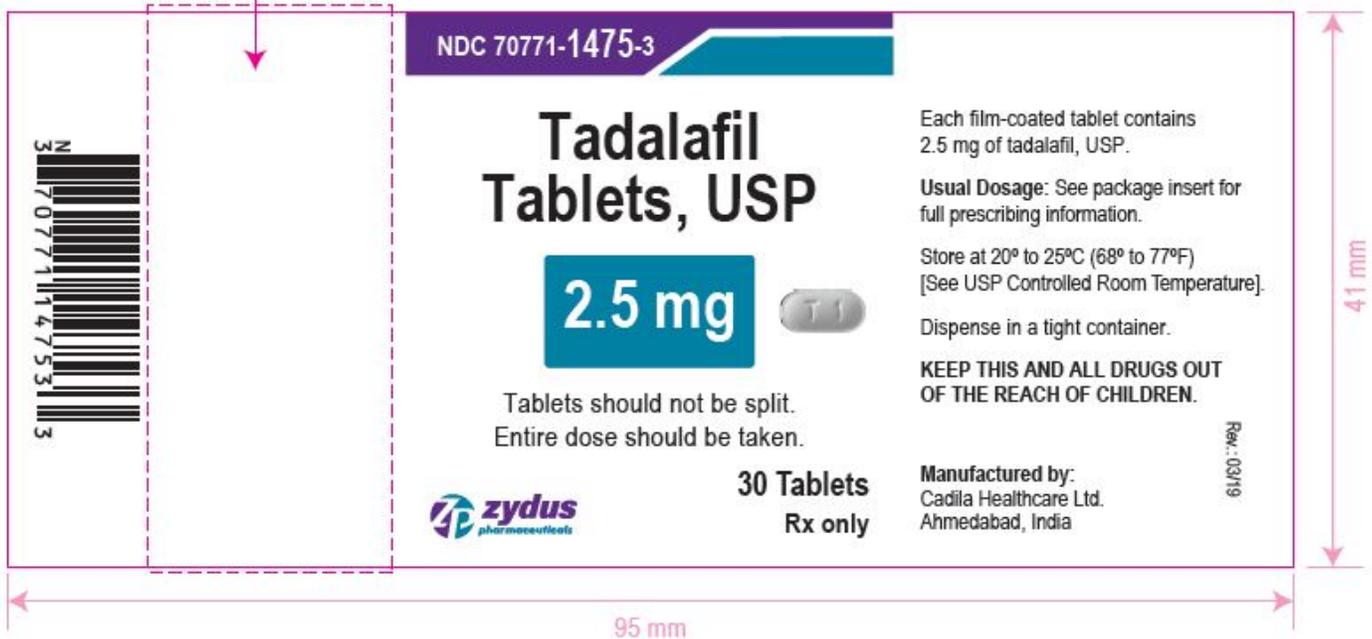
Rx Only

30 tablets



Over Coding Template

No Varnished Area (Do Not Print)  
(18 x 41 mm)



NDC 70771-1476-3 in bottle of 30 tablets

Tadalafil Tablets USP, 5 mg

Rx Only

30 tablets

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

Over Coding Template

No Varnished Area (Do Not Print)  
(18 x 41 mm)

NDC 70771-1476-3

**Tadalafil  
Tablets, USP**

**5 mg** 

Tablets should not be split.  
Entire dose should be taken.

**30 Tablets**  
Rx only

 **zydus**  
pharmaceutics

Each film-coated tablet contains  
5 mg of tadalafil, USP.

**Usual Dosage:** See package insert for  
full prescribing information.

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

Dispense in a tight container.

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

Rev.: 03/19

Manufactured by:  
Cadila Healthcare Ltd.  
Ahmedabad, India

3  
N  
7077114763  
2

95 mm

41 mm

NDC 70771-1477-3 in bottle of 30 tablets

Tadalafil Tablets USP, 10 mg

Rx Only

30 tablets



Over Coding Template

No Varnished Area (Do Not Print)  
(18 x 41 mm)

NDC 70771-1477-3

**Tadalafil  
Tablets, USP**

**10 mg**

898

Tablets should not be split.  
Entire dose should be taken.

**30 Tablets  
Rx only**

Each film-coated tablet contains 10 mg of tadalafil, USP.

**Usual Dosage:** See package insert for full prescribing information.

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

Dispense in a tight container.

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

Manufactured by:  
Cadila Healthcare Ltd.  
Ahmedabad, India

Reg.: 03/19

95 mm

41 mm

NDC 70771-1478-3 in bottle of 30 tablets

Tadalafil Tablets USP, 20 mg

Rx Only

30 tablets



Over Coding Template

No Varnished Area (Do Not Print)  
 (18 x 41 mm)

**NDC 70771-1478-3**

**Tadalafil Tablets, USP**

**20 mg**

Tablets should not be split.  
 Entire dose should be taken.

**30 Tablets**  
 Rx only

Each film-coated tablet contains 20 mg of tadalafil, USP.  
 Usual Dosage: See package insert for full prescribing information.  
 Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].  
 Dispense in a tight container.

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

Manufactured by:  
 Cadila Healthcare Ltd.  
 Ahmedabad, India

Rev: 03/19

Dimensions: 95 mm (width) x 41 mm (height)

**TADALAFIL**

tadalafil tablet, film coated

**Product Information**

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:70771-1475
<b>Route of Administration</b>	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

<b>Color</b>	WHITE (WHITE)	<b>Score</b>	no score
<b>Shape</b>	CAPSULE (CAPSULE)	<b>Size</b>	6mm
<b>Flavor</b>		<b>Imprint Code</b>	T;1
<b>Contains</b>			

### 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

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:70771-1477
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>TADALAFIL</b> (UNII: 742SXX0ICT) (TADALAFIL - UNII:742SXX0ICT)	TADALAFIL	10 mg

## Inactive Ingredients

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

## Product Characteristics

<b>Color</b>	YELLOW (YELLOW)	<b>Score</b>	no score
<b>Shape</b>	CAPSULE (CAPSULE)	<b>Size</b>	10mm
<b>Flavor</b>		<b>Imprint Code</b>	898
<b>Contains</b>			

## 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**

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:70771-1478
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
TADALAFIL (UNII: 742SXX0ICT) (TADALAFIL - UNII:742SXX0ICT)	TADALAFIL	20 mg

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ 8H6N6OH)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	

**Product Characteristics**

<b>Color</b>	YELLOW (YELLOW)	<b>Score</b>	no score
<b>Shape</b>	OVAL (OVAL)	<b>Size</b>	13mm
<b>Flavor</b>		<b>Imprint Code</b>	899
<b>Contains</b>			

**Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
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)	
CROSCARMELOSE 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)	
TRACETIN (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-	90 in 1 BOTTLE; Type 0: Not a Combination	03/27/2019	

3	1476-9	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** - Zydus Lifesciences Limited (918596198)

**Registrant** - Zydus Lifesciences Limited (918596198)

## Establishment

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

Revised: 10/2022

Zydus Lifesciences Limited