

VARDENAFIL - vardenafil tablet, film coated
Zydus Lifesciences Limited

VARDENAFIL HYDROCHLORIDE TABLETS

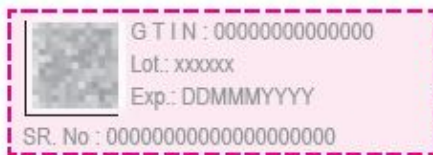
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1047-3

Vardenafil Tablets, 2.5 mg

30 Tablets

Rx only



Over Coding Template

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

NDC 70771-1047-3

**Vardenafil
Hydrochloride
Tablets**

2.5 mg*

30 Tablets
Rx only

zydus
pharmaceuticals

*Each film-coated tablet contains:
Vardenafil, USP.....2.5 mg
(equivalent to 2.963 mg Vardenafil Hydrochloride)

Dosage: Take one tablet as needed,
no more than once per day. See accompanying
complete prescribing information for dosage
and administration.

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

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

Manufactured by:
Cadila Healthcare Ltd.
Ahmedabad, India

Rev : 11/18

NDC 70771-1048-3

Vardenafil Tablets, 5 mg

30 Tablets

Rx only

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

Over Coding Template

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

NDC 70771-1048-3

**Vardenafil
Hydrochloride
Tablets**

5 mg*

**30 Tablets
Rx only**

zydus
pharmaceuticals

*Each film-coated tablet contains:
Vardenafil, USP.....5 mg
(equivalent to 5.926 mg Vardenafil Hydrochloride)

Dosage: Take one tablet as needed,
no more than once per day. See accompanying
complete prescribing information for dosage
and administration.

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

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

Manufactured by:
Cadila Healthcare Ltd.
Ahmedabad, India

Rev : 11/18

NDC 70771-1049-3

Vardenafil Tablets, 10 mg

30 Tablets

Rx only

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

Over Coding Template

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

NDC 70771-1049-3

Vardenafil Hydrochloride Tablets

10 mg*

30 Tablets
Rx only

Manufactured by:
Cadila Healthcare Ltd.
Ahmedabad, India

*Each film-coated tablet contains:
Vardenafil, USP.....10 mg
(equivalent to 11.852 mg Vardenafil Hydrochloride)

Dosage: Take one tablet as needed,
no more than once per day. See accompanying
complete prescribing information for dosage
and administration.

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

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

Rev: 1/18

NDC 70771-1050-3

Vardenafil Tablets, 20 mg

30 Tablets

Rx only

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

Over Coding Template

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



NDC 70771-1050-3

Vardenafil Hydrochloride Tablets

20 mg*



30 Tablets
Rx only

*Each film-coated tablet contains:
Vardenafil, USP20 mg
(equivalent to 23.705 mg Vardenafil Hydrochloride)

Dosage: Take one tablet as needed, no more than once per day. See accompanying complete prescribing information for dosage and administration.

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

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

Manufactured by:
Cadila Healthcare Ltd.
Ahmedabad, India

Rev: 1/18

VARDENAFIL

vardenafil tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1047
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
VARDENAFIL HYDROCHLORIDE TRIHYDRATE (UNII: 5M8S2CU0TS) (VARDENAFIL - UNII:UCE6F4125H)	VARDENAFIL	2.5 mg

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI)	

STARCH, CORN (UNII: O8232NY3SJ)

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE)	Score	no score
Shape	ROUND (ROUND)	Size	5mm
Flavor		Imprint Code	10;68
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1047-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	11/01/2018	
2	NDC:70771-1047-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	11/01/2018	
3	NDC:70771-1047-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	11/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA208960	11/01/2018	

VARDENAFIL

ildenafil tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1048
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
VARDENAFIL HYDROCHLORIDE TRIHYDRATE (UNII: 5M8S2CU0TS) (VARDENAFIL - UNII:UCE6F4125H)	VARDENAFIL	5 mg

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX43802MRT)	

HYPROMELLOSES (UNII: 3NXW29V3WO)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI)	
STARCH, CORN (UNII: O8232NY3SJ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	YELLOW (LIGHT YELLOW)	Score	no score
Shape	ROUND (ROUND)	Size	5mm
Flavor		Imprint Code	10;69
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1048-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	11/01/2018	
2	NDC:70771-1048-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	11/01/2018	
3	NDC:70771-1048-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	11/01/2018	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA208960	11/01/2018	

VARDENAFIL

varденаfil tablet, film coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1049
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
VARDENAFIL HYDROCHLORIDE TRIHYDRATE (UNII: 5M8S2CU0TS) (VARDENAFIL - UNII:UCE6F4125H)	VARDENAFIL	10 mg

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI)	
STARCH, CORN (UNII: O8232NY3SJ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	YELLOW (LIGHT YELLOW TO ORANGE)	Score	no score
Shape	ROUND (ROUND)	Size	7mm
Flavor		Imprint Code	10;70
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1049-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	11/01/2018	
2	NDC:70771-1049-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	11/01/2018	
3	NDC:70771-1049-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	11/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA208960	11/01/2018	

VARDENAFIL

vardenafil tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1050
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
VARDENAFIL HYDROCHLORIDE TRIHYDRATE (UNII: 5M8S2CU0TS) (VARDENAFIL - UNII:UCE6F4125H)	VARDENAFIL	20 mg

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI)	
STARCH, CORN (UNII: O8232NY3SJ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	YELLOW (LIGHT YELLOW TO ORANGE)	Score	no score
Shape	ROUND (ROUND)	Size	8mm
Flavor		Imprint Code	10;71
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1050-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	11/01/2018	
2	NDC:70771-1050-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	11/01/2018	
3	NDC:70771-1050-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	11/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA208960	11/01/2018	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (863362789)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		863362789	ANALYSIS(70771-1047, 70771-1048, 70771-1049, 70771-1050) , MANUFACTURE(70771-1047, 70771-1048, 70771-1049, 70771-1050)

