

**VARDENAFIL- vardenafil tablet, film coated**  
**Zydus Lifesciences Limited**

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**VARDENAFIL HYDROCHLORIDE TABLETS**

**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

NDC 70771-1047-3

Vardenafil Tablets, 2.5 mg

30 Tablets

Rx only



NDC 70771-1048-3

Vardenafil Tablets, 5 mg

30 Tablets

Rx only

3 N  
70710110693 5

Rev.: 08/24

# Vardenafil Hydrochloride Tablets

**5 mg\***

zydus

30 Tablets  
Rx only

\*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.  
This package is child-resistant.  
Store at 20°C to 25°C (68°F to 77°F) [See USP Controlled Room Temperature].  
**Keep this and all drugs out of the reach of children.**  
Product of Poland  
**Manufactured by:**  
Zydus Lifesciences Ltd.  
Ahmedabad, India

NDC 70771-1049-3

Vardenafil Tablets, 10 mg

30 Tablets

Rx only

3 N  
70710110703 1

Rev.: 08/24

# Vardenafil Hydrochloride Tablets

**10 mg\***

zydus

30 Tablets  
Rx only

\*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.  
This package is child-resistant.  
Store at 20°C to 25°C (68°F to 77°F) [See USP Controlled Room Temperature].  
**Keep this and all drugs out of the reach of children.**  
Product of Poland  
**Manufactured by:**  
Zydus Lifesciences Ltd.  
Ahmedabad, India

NDC 70771-1050-3

Vardenafil Tablets, 20 mg

30 Tablets

Rx only



Rev.: 08/24

# Vardenafil Hydrochloride Tablets

20 mg\*



\*Each film-coated tablet contains:  
Vardenafil, USP.....20 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.  
This package is child-resistant.  
Store at 20°C to 25°C (68°F to 77°F) [See  
USP Controlled Room Temperature].  
Keep this and all drugs out of the reach  
of children.  
Product of Poland  
Manufactured by:  
**Zydus Lifesciences Ltd.**  
Ahmedabad, India

**30 Tablets**  
Rx only

## VARDENAFIL

vardenafil tablet, film coated

### Product Information

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

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>SODIUM STEARYL FUMARATE</b> (UNII: 7CV7WJK4UI)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

### Product Characteristics

<b>Color</b>	WHITE (WHITE TO OFF-WHITE)	<b>Score</b>	no score
<b>Shape</b>	ROUND (ROUND)	<b>Size</b>	5mm
<b>Flavor</b>		<b>Imprint Code</b>	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**

vardenafil tablet, film coated

**Product Information**

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

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

Ingredient Name	Strength
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ05DW1A)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>SODIUM STEARYL FUMARATE</b> (UNII: 7CV7WJK4UI)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

## Product Characteristics

<b>Color</b>	YELLOW (LIGHT YELLOW)	<b>Score</b>	no score
<b>Shape</b>	ROUND (ROUND)	<b>Size</b>	5mm
<b>Flavor</b>		<b>Imprint Code</b>	10;69
<b>Contains</b>			

## 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

vardenafil tablet, film coated

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:70771-1049
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>VARDENAFIL HYDROCHLORIDE TRIHYDRATE</b> (UNII: 5M8S2CU0TS) (VARDENAFIL - UNII:UCE6F4125H)	VARDENAFIL	10 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>SODIUM STEARYL FUMARATE</b> (UNII: 7CV7WJK4UI)	

STARCH, CORN (UNII: O8232NY3SJ)

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

### Product Characteristics

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

### 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

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:70771-1050
<b>Route of Administration</b>	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: EX43802MRT)	

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

### Product Characteristics

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

### 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)

Revised: 8/2024

Zydus Lifesciences Limited