VARDENAFIL - vardenafil tablet, film coated
Zydus Lifesciences Limited

VARDENAFIL HYDROCHLORIDE TABLETS

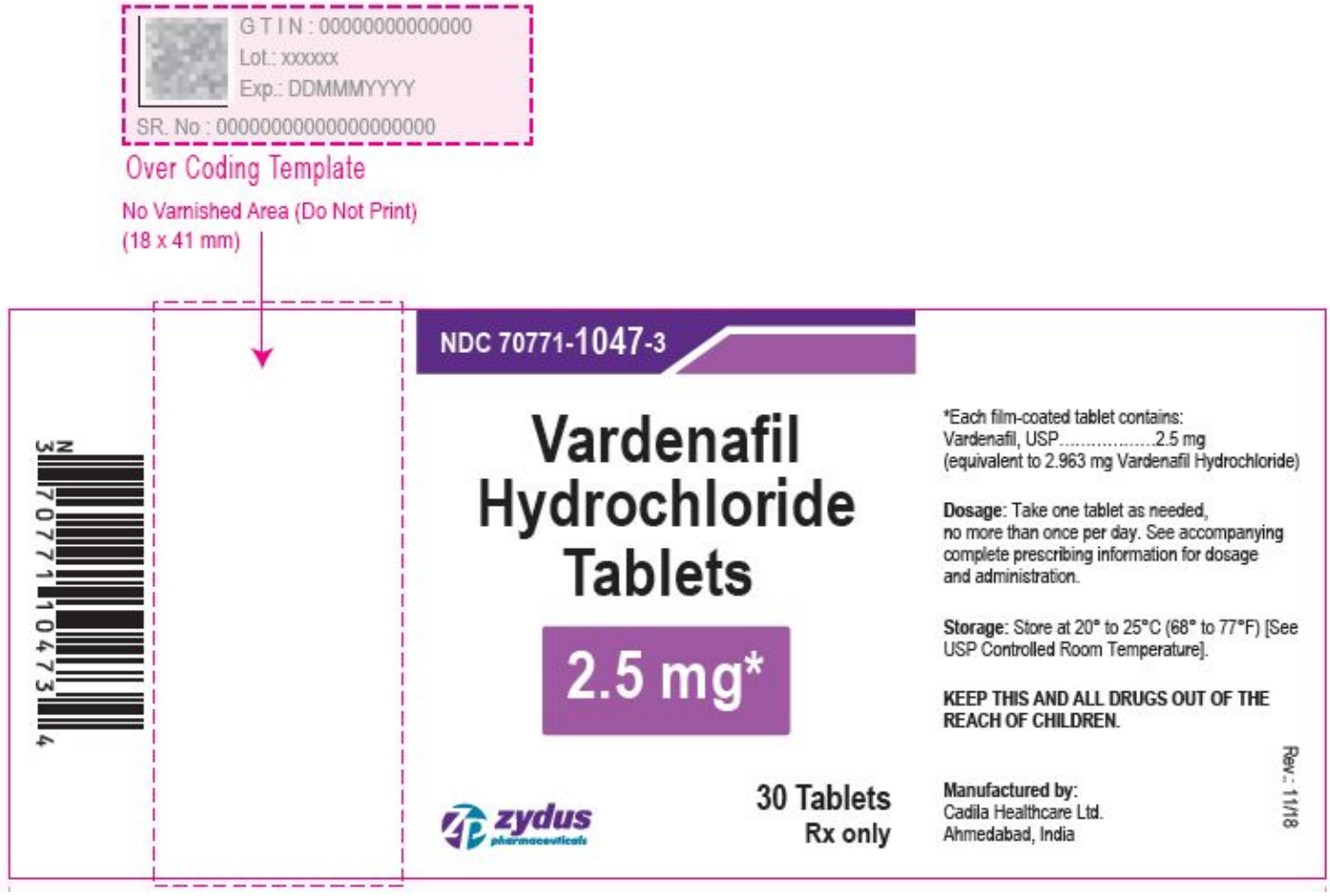
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1047-3

Vardenafil Tablets, 2.5 mg

30 Tablets

Rx only

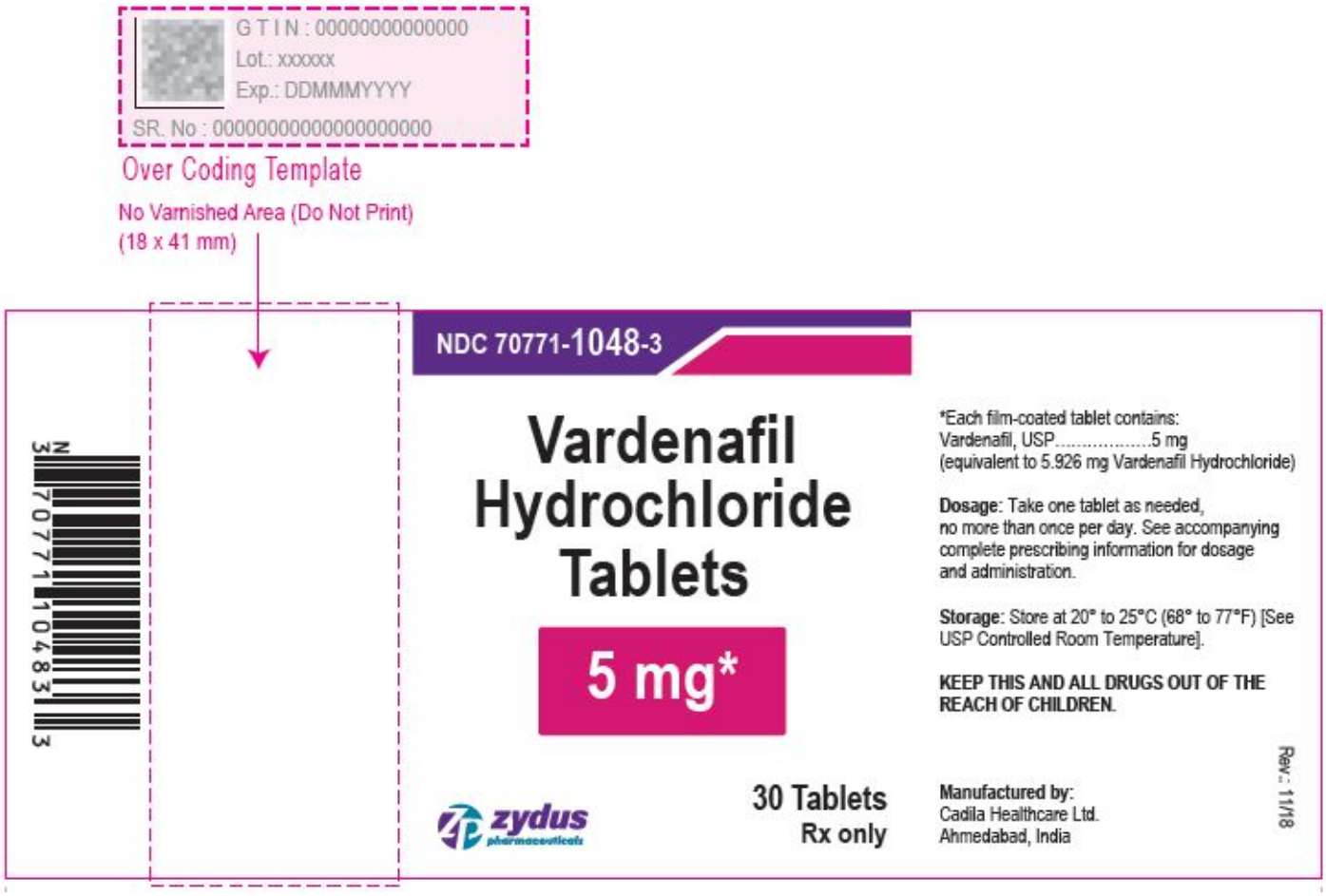


NDC 70771-1048-3

Vardenafil Tablets, 5 mg

30 Tablets

Rx only

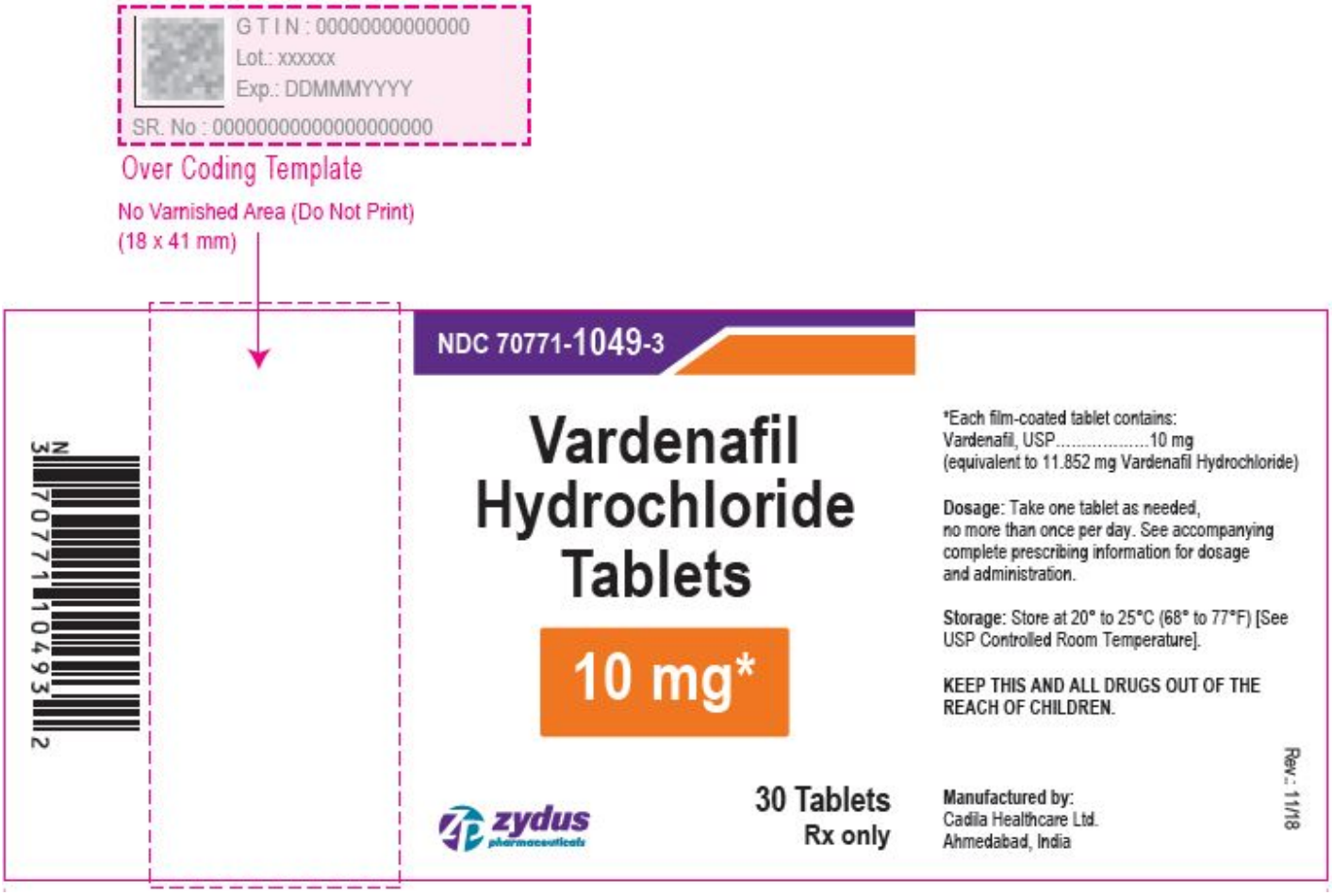


NDC 70771-1049-3

Vardenafil Tablets, 10 mg

30 Tablets

Rx only



NDC 70771-1050-3

Vardenafil Tablets, 20 mg

30 Tablets

Rx only

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: 3WQ0SDW1A)	
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

vardenafil 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: EX438O2MRT)	

HYPROMELLOSES (UNII: 3NXW29V3WO)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
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

vardenafil 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: 3WQ0SDW1A)	
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: 3WQ0SDW1A)	
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)