VENLAFAXINE HYDROCHLORIDE- venlafaxine hydrochloride capsule, extended release
Zydus Lifesciences Limited

VENLAFAXINE HYDROCHLORIDE EXTENDED-RELEASE CAPSULES

SPL MEDGUIDE

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 65841-751-10

Venlafaxine Hydrochloride Extended-release Capsules USP, 37.5 mg

1000 Capsules

Rx only

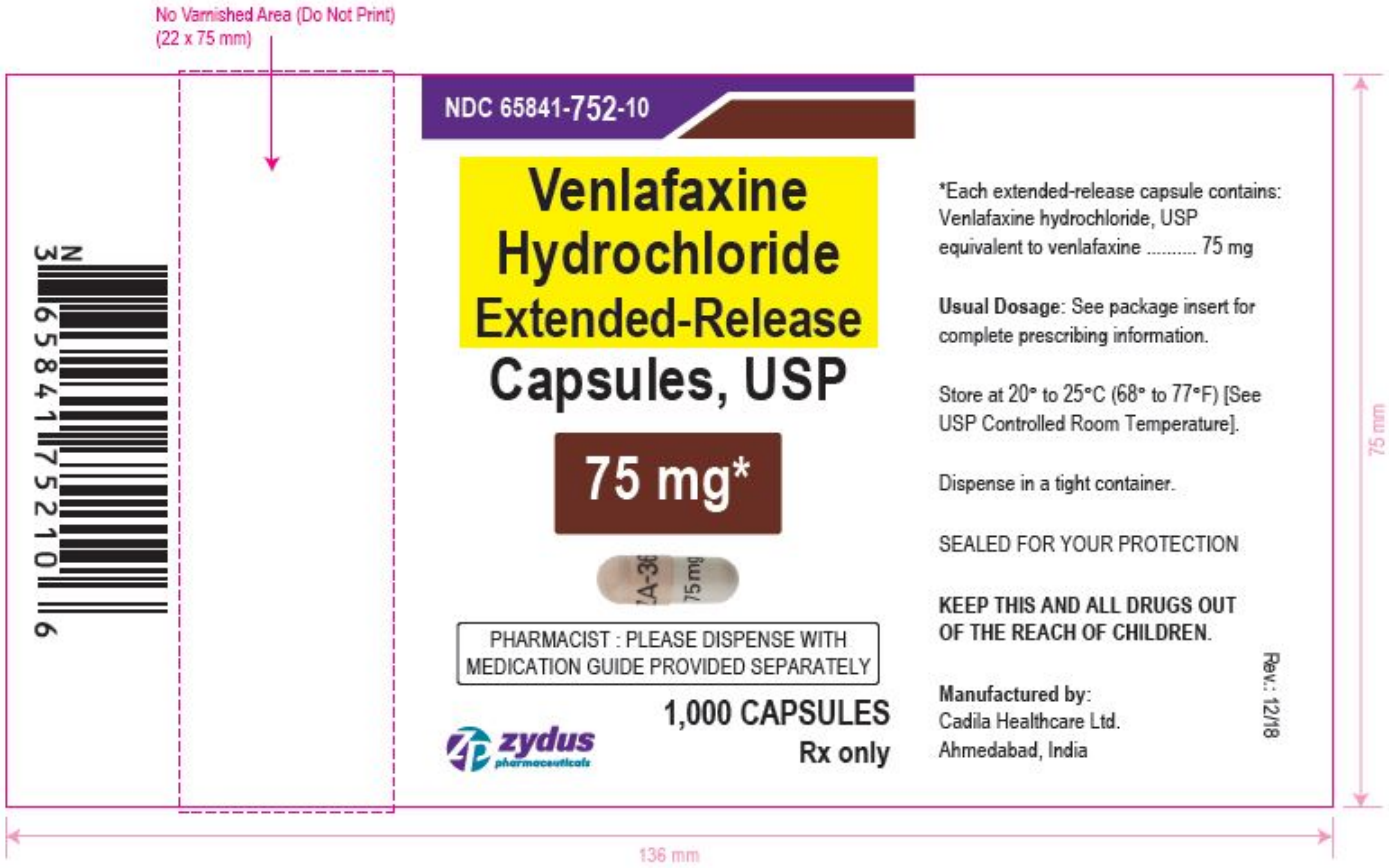
NDC 65841-752-10

Venlafaxine Hydrochloride Extended-release Capsules USP, 75 mg

1000 Capsules

.

Rx only

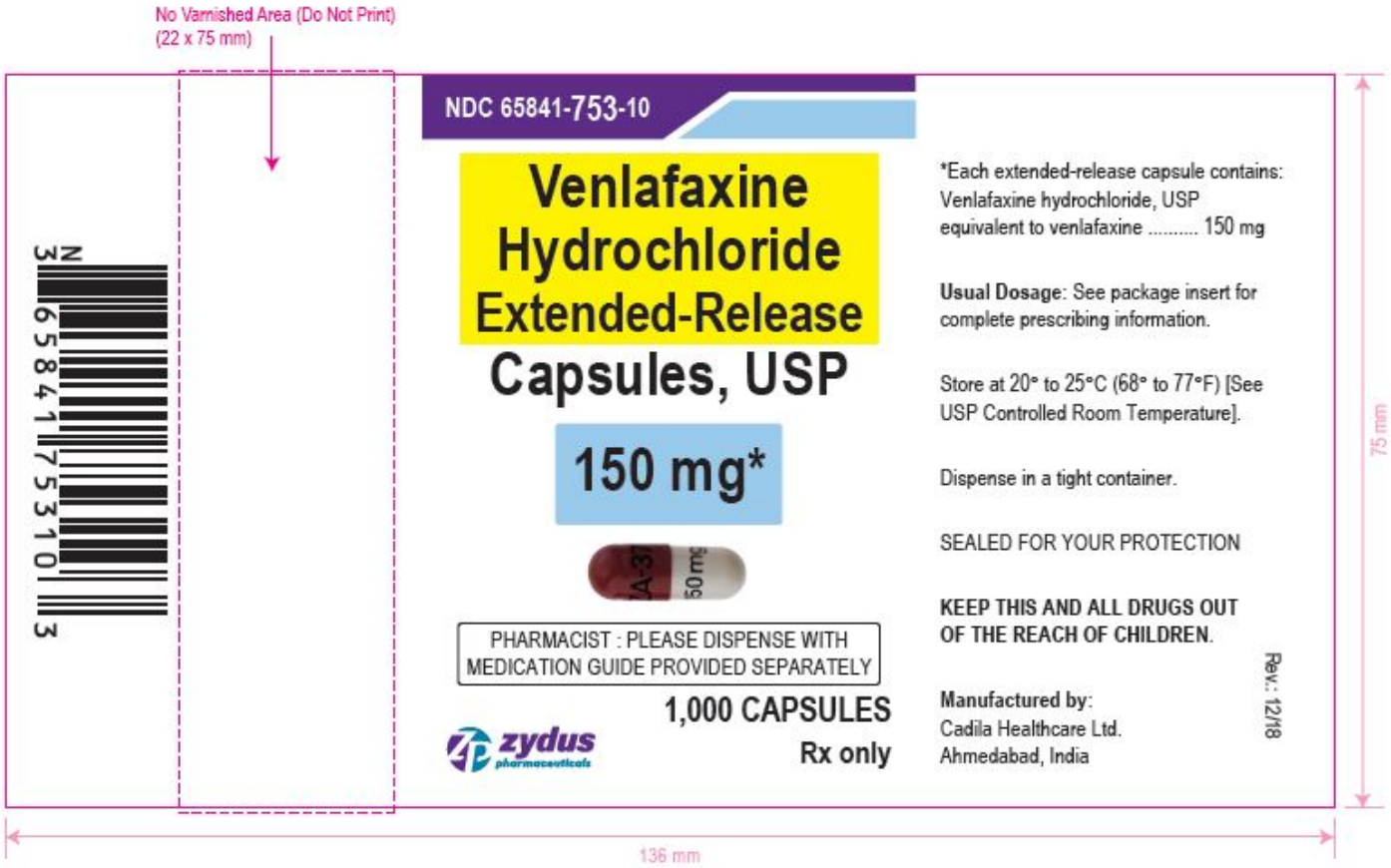


NDC 65841-753-10

Venlafaxine Hydrochloride Extended-release Capsules USP, 150 mg

1000 Capsules

Rx only



VENLAFAXINE HYDROCHLORIDE

venlafaxine hydrochloride capsule, extended release

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-751
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
VENLAFAXINE HYDROCHLORIDE (UNII: 7D7RX5A8MO) (VENLAFAXINE - UNII:GRZ5RCB1QG)	VENLAFAXINE	37.5 mg

Inactive Ingredients	
Ingredient Name	**Strength**
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
GELATIN (UNII: 2G86QN327L)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
ETHYL ACRYLATE AND METHYL METHACRYLATE COPOLYMER (2:1; 750000 MW) (UNII: P2OM2Q86BI)	

Product Characteristics			
Color	GRAY (GRAY) , WHITE (WHITE)	**Score**	no score
Shape	CAPSULE (CAPSULE)	**Size**	16mm
Flavor		**Imprint Code**	ZA;35;37;5;mg
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-751-06	30 in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2011	
2	NDC:65841-751-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2011	
3	NDC:65841-751-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2011	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090174	06/01/2011	

VENLAFAXINE HYDROCHLORIDE

venlafaxine hydrochloride capsule, extended release

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-752
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
VENLAFAXINE HYDROCHLORIDE (UNII: 7D7RX5A8MO) (VENLAFAXINE - UNII:GRZ5RCB1QG)	VENLAFAXINE	75 mg

Inactive Ingredients

Ingredient Name	Strength
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	

HYPROMELLOSES (UNII: 3NXW29V3WO)	
GELATIN (UNII: 2G86QN327L)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
ETHYL ACRYLATE AND METHYL METHACRYLATE COPOLYMER (2:1; 750000 MW) (UNII: P2OM2Q86BI)	

Product Characteristics

Color	ORANGE (PEACH) , WHITE (WHITE)	**Score**	no score
Shape	CAPSULE (CAPSULE)	**Size**	20mm
Flavor		**Imprint Code**	ZA;36;75;mg
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-752-06	30 in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2011	
2	NDC:65841-752-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2011	
3	NDC:65841-752-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2011	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090174	06/01/2011	

VENLAFAXINE HYDROCHLORIDE

venlafaxine hydrochloride capsule, extended release

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-753
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
VENLAFAXINE HYDROCHLORIDE (UNII: 7D7RX5A9MO) (VENLAFAXINE		

VENLAFAXINE HYDROCHLORIDE (UNII: 7D7RX5A8MO) (VENLAFAXINE - UNII:GRZ5RCB1QG)	VENLAFAXINE	150 mg

Inactive Ingredients

Ingredient Name	Strength
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
GELATIN (UNII: 2G86QN327L)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
ETHYL ACRYLATE AND METHYL METHACRYLATE COPOLYMER (2:1; 750000 MW) (UNII: P2OM2Q86BI)	

Product Characteristics

Color	ORANGE (DARK ORANGE) , WHITE (WHITE)	**Score**	no score
Shape	CAPSULE (CAPSULE)	**Size**	21mm
Flavor		**Imprint Code**	ZA;37;150;mg
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-753-06	30 in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2011	
2	NDC:65841-753-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2011	
3	NDC:65841-753-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2011	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090174	06/01/2011	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations

Zydus Lifesciences Limited		918596198	ANALYSIS(65841-751, 65841-752, 65841-753) , MANUFACTURE(65841-751, 65841-752, 65841-753)