

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

No Varnished Area (Do Not Print)
(22 x 75 mm)

NDC 65841-752-10

**Venlafaxine
Hydrochloride
Extended-Release
Capsules, USP**

75 mg*



PHARMACIST : PLEASE DISPENSE WITH
MEDICATION GUIDE PROVIDED SEPARATELY

1,000 CAPSULES
Rx only

zydus
pharmaceuticals

*Each extended-release capsule contains:
Venlafaxine hydrochloride, USP
equivalent to venlafaxine 75 mg

Usual Dosage: See package insert for
complete prescribing information.

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

Dispense in a tight container.

SEALED FOR YOUR PROTECTION

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

Manufactured by:
Cadila Healthcare Ltd.
Ahmedabad, India

Rev.: 12/18

136 mm

75 mm

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NDC 65841-753-10

Venlafaxine Hydrochloride Extended-release Capsules USP, 150 mg

1000 Capsules

Rx only

No Varnished Area (Do Not Print)
(22 x 75 mm)

NDC 65841-753-10

**Venlafaxine
Hydrochloride
Extended-Release
Capsules, USP**

150 mg*

PHARMACIST : PLEASE DISPENSE WITH
MEDICATION GUIDE PROVIDED SEPARATELY

1,000 CAPSULES
Rx only

*Each extended-release capsule contains:
Venlafaxine hydrochloride, USP
equivalent to venlafaxine 150 mg

Usual Dosage: See package insert for
complete prescribing information.

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

Dispense in a tight container.

SEALED FOR YOUR PROTECTION

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

Manufactured by:
Cadila Healthcare Ltd.
Ahmedabad, India

Rev: 12/18

136 mm

75 mm

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
FERROSO FERRIC 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
FERROSO FERRIC 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: 7D78V61M01) / VENLAFAXINE		

VENLAFAXINE HYDROCHLORIDE (UNII: 7D7R3D8MO) (VENLAFAXINE - UNII:GRZ5RCB1QG)	VENLAFAXINE	150 mg
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Inactive Ingredients

Ingredient Name	Strength
FERROSFERRIC 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
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Zydus Lifesciences Limited		918596198	ANALYSIS(65841-751, 65841-752, 65841-753) , MANUFACTURE(65841-751, 65841-752, 65841-753)
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Revised: 9/2023

Zydus Lifesciences Limited