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

VENLAFAXINE HYDROCHLORIDE EXTENDED-RELEASE CAPSULES

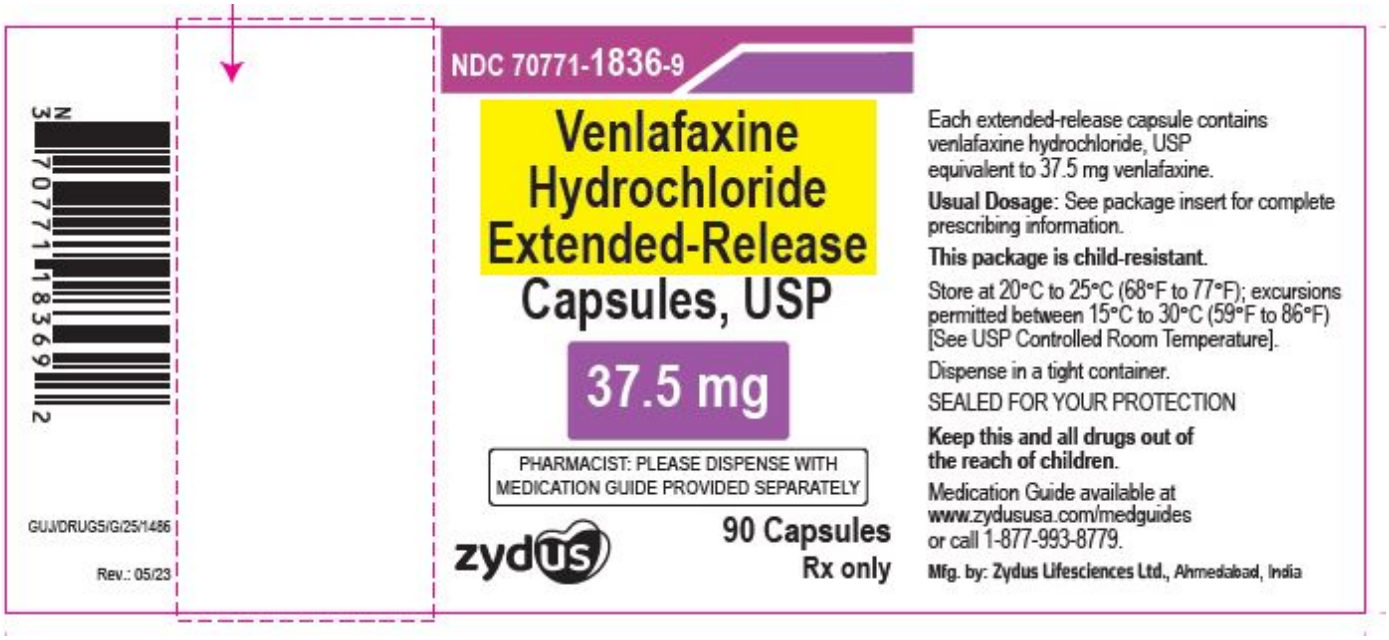
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1836-9

Venlafaxine Hydrochloride Extended-release Capsules USP, 37.5 mg

90 Capsules

Rx only

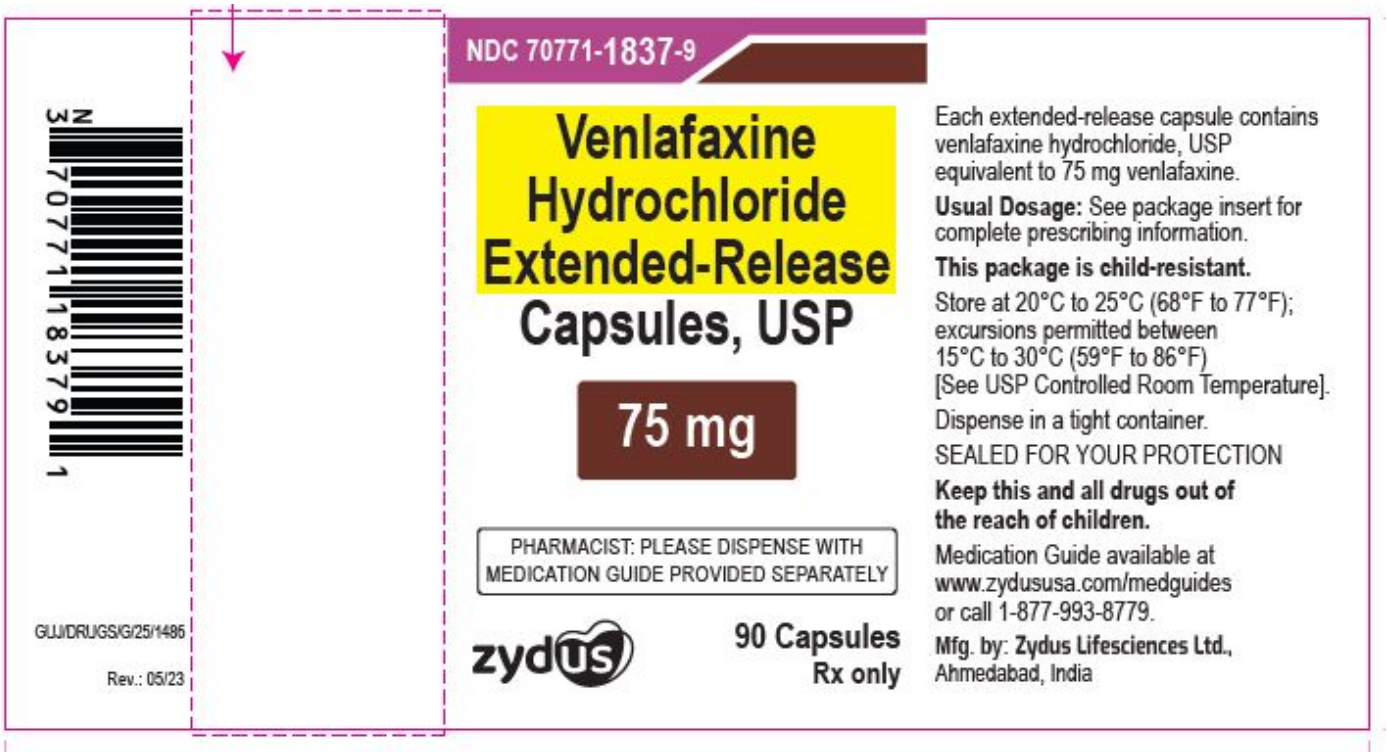


NDC 70771-1837-9

Venlafaxine Hydrochloride Extended-release Capsules USP, 75 mg

90 Capsules

Rx only

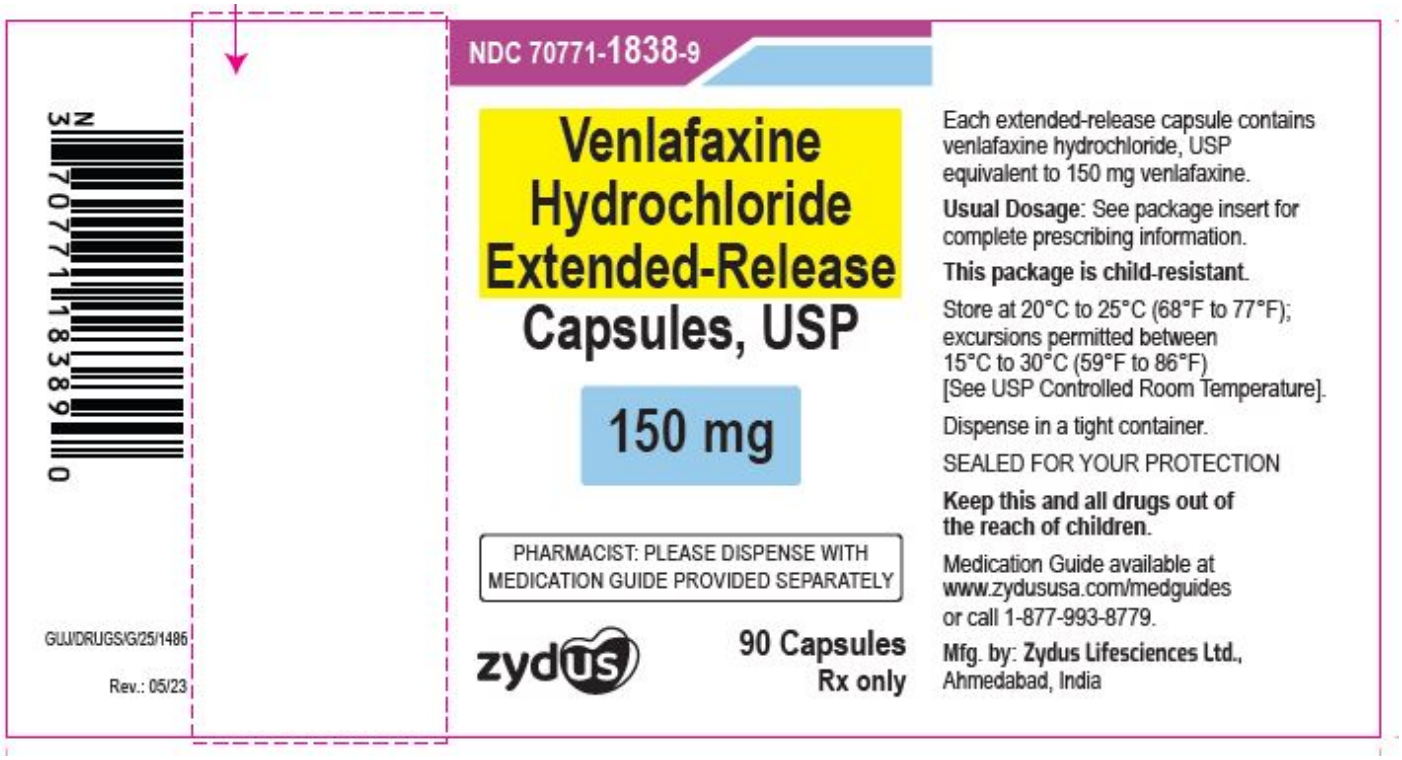


NDC 70771-1838-9

Venlafaxine Hydrochloride Extended-release Capsules USP, 150 mg

90 Capsules

Rx only



VENLAFAXINE HYDROCHLORIDE

venlafaxine hydrochloride capsule, extended release

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1836
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
ETHYLCELLULOSE (7 MPA.S) (UNII: H3UP11403C)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
GELATIN (UNII: 2G86QN327L)	
HYPROMELLOSE 2910 (15 MPA.S) (UNII: 36SFW2JZ0W)	
HYPROMELLOSE 2910 (5 MPA.S) (UNII: R75537T0T4)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 8000 (UNII: Q662QK8M3B)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	GRAY (grey opaque colored cap) , WHITE (white opaque colored body)	**Score**	no score
Shape	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:70771-1836-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	05/18/2023	
2	NDC:70771-1836-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	05/18/2023	
3	NDC:70771-1836-4	10 in 1 CARTON	05/18/2023	

3	NDC:70771-1836-2	10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
4	NDC:70771-1836-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	05/18/2023	
5	NDC:70771-1836-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	05/18/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090174	05/18/2023	

VENLAFAXINE HYDROCHLORIDE

venlafaxine hydrochloride capsule, extended release

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1837
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
ETHYLCELLULOSE (7 MPA.S) (UNII: H3UP11403C)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
GELATIN (UNII: 2G86QN327L)	
HYPROMELLOSE 2910 (15 MPA.S) (UNII: 36SFW2JZ0W)	
HYPROMELLOSE 2910 (5 MPA.S) (UNII: R75537T0T4)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 8000 (UNII: Q662QK8M3B)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	PINK (peach opaque colored cap) , WHITE (white opaque colored body)	**Score**	no score
Shape	CAPSULE	**Size**	19mm
Flavor		**Imprint Code**	ZA;36;75;mg
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1837-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	05/18/2023	
2	NDC:70771-1837-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	05/18/2023	
3	NDC:70771-1837-4	10 in 1 CARTON	05/18/2023	
3	NDC:70771-1837-2	10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
4	NDC:70771-1837-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	05/18/2023	
5	NDC:70771-1837-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	05/18/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090174	05/18/2023	

VENLAFAXINE HYDROCHLORIDE

venlafaxine hydrochloride capsule, extended release

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1838
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
VENLAFAXINE HYDROCHLORIDE (UNII: 7D7RX5A8MO) (VENLAFAXINE - UNII:GRZ5RCB1QG)	VENLAFAXINE	150 mg

Inactive Ingredients

Ingredient Name	Strength
ETHYLCELLULOSE (7 MPA.S) (UNII: H3UP11403C)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	

GELATIN (UNII: 2G86QN327L)	
HYPROMELLOSE 2910 (15 MPA.S) (UNII: 36SFW2JZ0W)	
HYPROMELLOSE 2910 (5 MPA.S) (UNII: R75537T0T4)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 8000 (UNII: Q662QK8M3B)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	ORANGE (dark orange opaque colored cap) , WHITE (white opaque colored body)	**Score**	no score
Shape	CAPSULE	**Size**	23mm
Flavor		**Imprint Code**	ZA;37;150;mg
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1838-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	05/18/2023	
2	NDC:70771-1838-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	05/18/2023	
3	NDC:70771-1838-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	05/18/2023	
4	NDC:70771-1838-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	05/18/2023	
5	NDC:70771-1838-4	10 in 1 CARTON	05/18/2023	
5	NDC:70771-1838-2	10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090174	05/18/2023	

Labeler - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences		918596198	ANALYSIS(70771-1836, 70771-1837, 70771-1838) , MANUFACTURE(70771-

Limited		918596198	1836, 70771-1837, 70771-1838)