

DESVENLAFAXINE- desvenlafaxine tablet, extended release
Zydus Lifesciences Limited

DESVENLAFAXINE EXTENDED-RELEASE TABLETS

SPL MEDGUIDE

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Desvenlafaxine Extended-release Tablets, 25 mg

NDC 70771-1661-3

30 tablets

Rx only



NDC 68382-469-67 in bottle of 14 tablets in unit-of-use package

Desvenlafaxine Extended-release Tablets, 50 mg

14 tablets

R_x only

Zydus

NDC 70771-1311-7

**Desvenlafaxine
Extended-release
Tablets**

50 mg

PHARMACIST: Dispense the medication guide provided separately to each patient.

zydus pharmaceuticals

Unit of Use 14 TABLETS
Rx only

Each film-coated, extended-release tablet contains 72.42 mg of desvenlafaxine succinate equivalent to 50 mg desvenlafaxine.

Usual Dosage: See package insert for complete prescribing information. Swallow tablets whole. Do not crush, cut, chew, or dissolve the tablets. Sealed for your protection.

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

Package intended to be dispensed as a unit.

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

Manufactured by:
Cadila Healthcare Ltd. Ahmedabad, India

Rev.:02/18

NDC 68382-741-67 in bottle of 14 tablets in unit-of-use package

Desvenlafaxine Extended-release Tablets, 100 mg

14 tablets

R_x only

Zydus

NDC 70771-1312-7

**Desvenlafaxine
Extended-release
Tablets**

100 mg

PHARMACIST: Dispense the medication guide provided separately to each patient.

zydus pharmaceuticals

Unit of Use 14 TABLETS
Rx only

Each film-coated, extended-release tablet contains 144.84 mg of desvenlafaxine succinate equivalent to 100 mg desvenlafaxine.

Usual Dosage: See package insert for complete prescribing information. Swallow tablets whole. Do not crush, cut, chew, or dissolve the tablets. Sealed for your protection.

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

Package intended to be dispensed as a unit.

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

Manufactured by:
Cadila Healthcare Ltd. Ahmedabad, India

Rev.:02/18

DESVENLAFAXINE

desvenlafaxine tablet, extended release

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1311
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DESVENLAFAXINE (UNII: NG99554ANW) (DESVENLAFAXINE - UNII:NG99554ANW)	DESVENLAFAXINE	50 mg

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I3O)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE)	Score	no score
Shape	SQUARE (SQUARE)	Size	9mm
Flavor		Imprint Code	469
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1311-7	14 in 1 BOTTLE; Type 0: Not a Combination Product	05/08/2018	
2	NDC:70771-1311-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	05/08/2018	
3	NDC:70771-1311-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	05/08/2018	
4	NDC:70771-1311-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/08/2018	
5	NDC:70771-1311-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	05/08/2018	
6	NDC:70771-1311-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	05/08/2018	
7	NDC:70771-1311-4	10 in 1 CARTON	05/08/2018	
7	NDC:70771-1311-2	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	ANDA204020	05/08/2018	

DESVENLAFAXINE

desvenlafaxine tablet, extended release

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1312
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DESVENLAFAXINE (UNII: NG99554ANW) (DESVENLAFAXINE - UNII:NG99554ANW)	DESVENLAFAXINE	100 mg

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	ORANGE (ORANGE)	Score	no score
Shape	SQUARE (SQUARE)	Size	9mm
Flavor		Imprint Code	741
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1312-7	14 in 1 BOTTLE; Type 0: Not a Combination Product	05/08/2018	
2	NDC:70771-1312-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	05/08/2018	
3	NDC:70771-1312-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	05/08/2018	
4	NDC:70771-1312-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/08/2018	
5	NDC:70771-1312-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	05/08/2018	
6	NDC:70771-1312-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	05/08/2018	
7	NDC:70771-1312-4	10 in 1 CARTON	05/08/2018	
7	NDC:70771-1312-2	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	ANDA204020	05/08/2018	

DESVENLAFAXINE

desvenlafaxine tablet, extended release

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1661
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DESVENLAFAXINE (UNII: NG99554ANW) (DESVENLAFAXINE - UNII:NG99554ANW)	DESVENLAFAXINE	25 mg

Inactive Ingredients

Ingredient Name	Strength
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
HYPROMELLOSE 2208 (100 MPA.S) (UNII: B1QE5P712K)	
HYPROMELLOSE 2208 (15000 MPA.S) (UNII: Z78RG6M2N2)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
MAGNESIUM STEARATE (UNII: 70097M6130)	
MICROCRYSTALLINE CELLULOSE 102 (UNII: PNR0YF693Y)	
POLYETHYLENE GLYCOL 4000 (UNII: 4R4HFI6D95)	
POLYETHYLENE GLYCOL 6000 (UNII: 30IQX730WE)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	YELLOW (Light Yellow to Yellow)	Score	no score
Shape	SQUARE (Square)	Size	9mm
Flavor		Imprint Code	1257
Contains			

Packaging

#	Item Code	Package Description	Marketing Start	Marketing End
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#	Item Code	Package Description	Date	Date
1	NDC:70771-1661-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	11/30/2022	
2	NDC:70771-1661-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	11/30/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA204020	11/30/2022	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		918596198	ANALYSIS(70771-1311, 70771-1312, 70771-1661) , MANUFACTURE(70771-1311, 70771-1312, 70771-1661)

Revised: 9/2023

Zydus Lifesciences Limited