DULOXETINE- duloxetine capsule, delayed release
Zydus Lifesciences Limited

DULOXETINE DELAYED-RELEASE CAPSULES

Manufactured by:

Cadila Healthcare Ltd.

India.

SPL MEDGUIDE

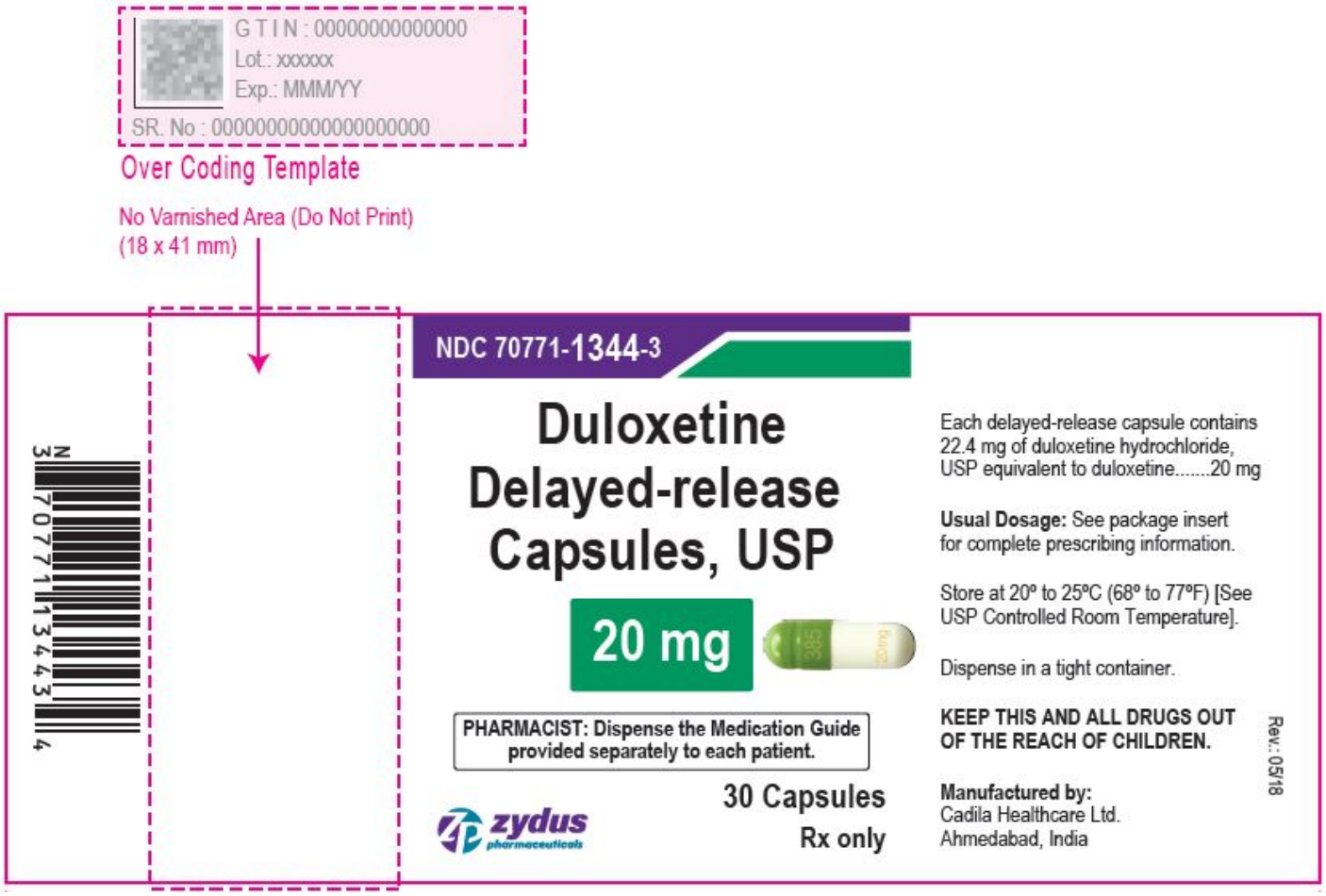
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1344-3

Duloxetine Delayed-release Capsules, 20mg

30 Capsules

Rx only

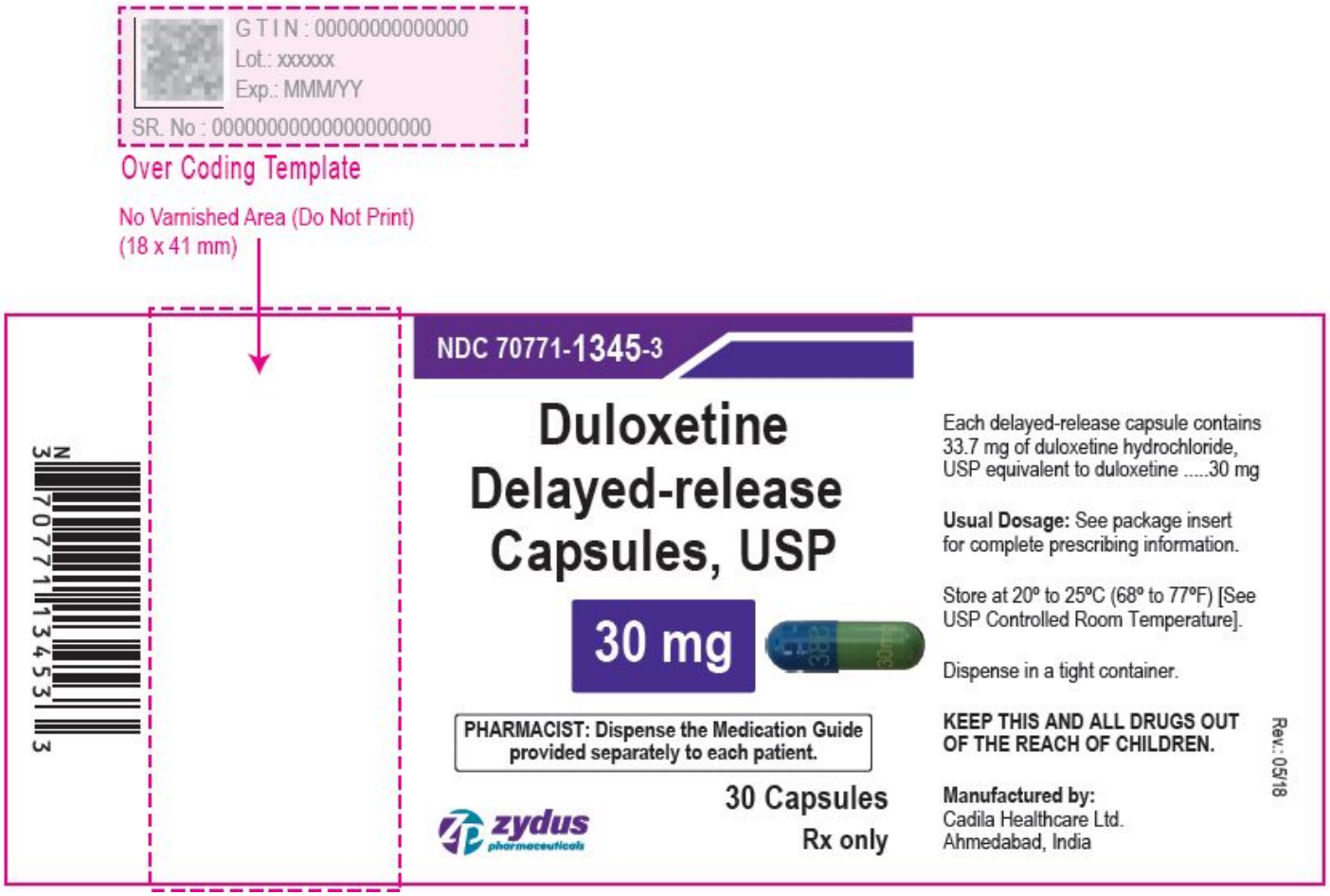


NDC 70771-1345-3

Duloxetine Delayed-release Capsules, 30mg

30 Capsules

Rx only

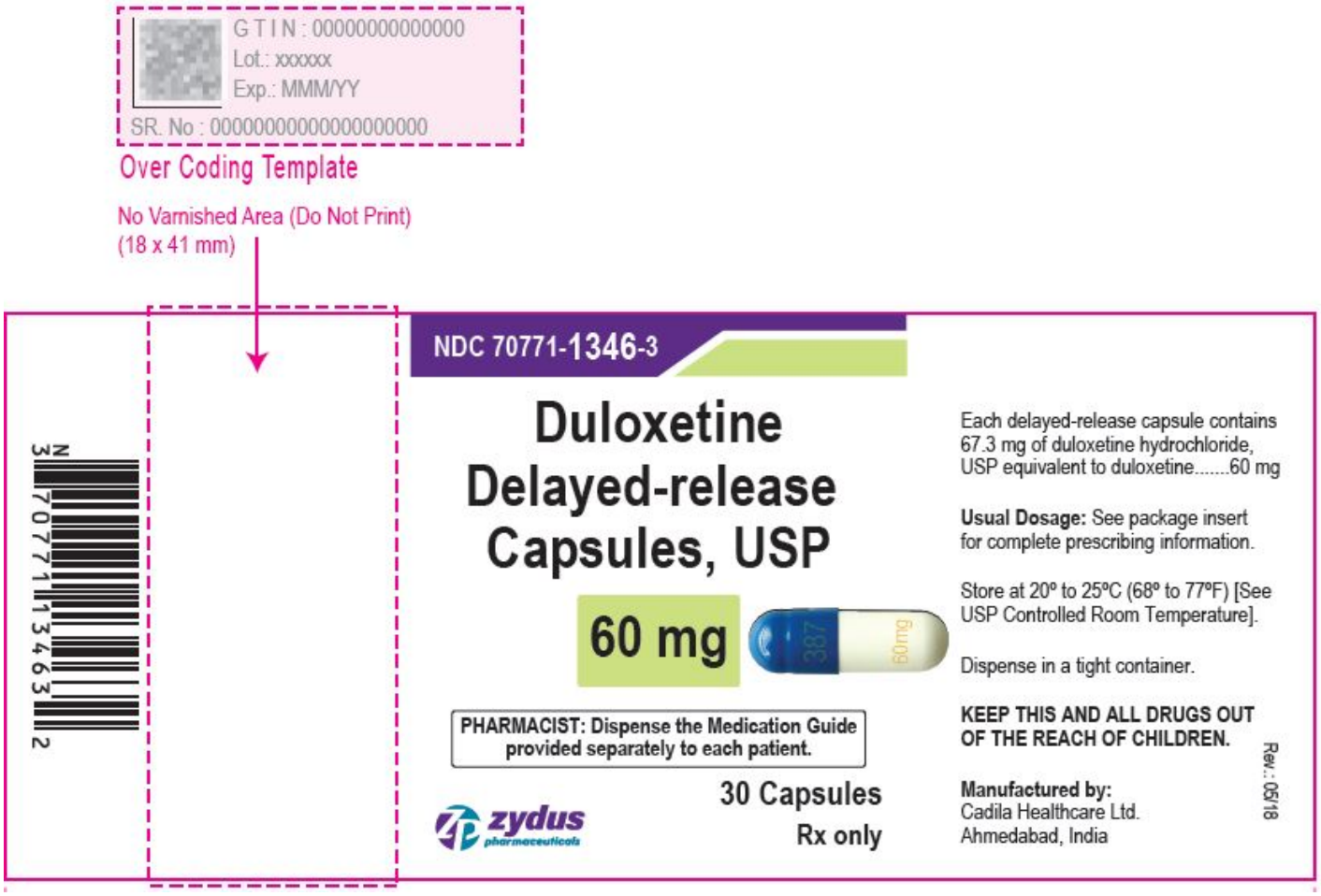


NDC 70771-1346-3

Duloxetine Delayed-release Capsules, 60mg

30 Capsules

Rx only



DULOXETINE

duloxetine capsule, delayed release

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1344
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DULOXETINE HYDROCHLORIDE (UNII: 9044SC542W) (DULOXETINE - UNII:O5TNM5N07U)	DULOXETINE	20 mg

Inactive Ingredients	
Ingredient Name	**Strength**
ALCOHOL (UNII: 3K9958V90M)	
AMMONIA (UNII: 5138Q19F1X)	
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
GELATIN (UNII: 2G86QN327L)	
HYPROMELLOSE PHTHALATE (31% PHTHALATE, 40 CST) (UNII: G4U024CQK6)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STARCH, CORN (UNII: O8232NY3SJ)	
SUCROSE (UNII: C151H8M554)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

Product Characteristics

Color	GREEN (GREEN) , WHITE (WHITE)	**Score**	no score
Shape	CAPSULE (CAPSULE)	**Size**	14mm
Flavor		**Imprint Code**	385;20;mg
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1344-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	05/27/2014	
2	NDC:70771-1344-6	60 in 1 BOTTLE; Type 0: Not a Combination Product	05/27/2014	
3	NDC:70771-1344-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	05/27/2014	
4	NDC:70771-1344-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	04/06/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090728	05/27/2014	

DULOXETINE

duloxetine capsule, delayed release

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1345
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DULOXETINE HYDROCHLORIDE (UNII: 9044SC542W) (DULOXETINE - UNII:O5TNM5N07U)	DULOXETINE	30 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
HYPROMELLOSE PHTHALATE (31% PHTHALATE, 40 CST) (UNII: G4U024CQK6)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SUCROSE (UNII: C151H8M554)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)	
ALCOHOL (UNII: 3K9958V90M)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
AMMONIA (UNII: 5138Q19F1X)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	BLUE (BLUE) , GREEN (GREEN)	**Score**	no score
Shape	CAPSULE (CAPSULE)	**Size**	16mm
Flavor		**Imprint Code**	386;30;mg
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1345-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	05/27/2014	
2	NDC:70771-1345-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	05/27/2014	
3	NDC:70771-1345-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	04/06/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090728	05/27/2014	

DULOXETINE

duloxetine capsule, delayed release

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1346
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DULOXETINE HYDROCHLORIDE (UNII: 9044SC542W) (DULOXETINE - UNII:O5TNM5N07U)	DULOXETINE	60 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
HYPROMELLOSE PHTHALATE (31% PHTHALATE, 40 CST) (UNII: G4U024CQK6)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SUCROSE (UNII: C151H8M554)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)	
ALCOHOL (UNII: 3K9958V90M)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
AMMONIA (UNII: 5138Q19F1X)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	BLUE (BLUE) , WHITE (WHITE)	**Score**	no score
Shape	CAPSULE (CAPSULE)	**Size**	19mm
Flavor		**Imprint Code**	387;60;mg
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1346-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	05/27/2014	
2	NDC:70771-1346-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	05/27/2014	
3	NDC:70771-1346-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	04/06/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090728	05/27/2014	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		918596198	ANALYSIS(70771-1344, 70771-1345, 70771-1346) , MANUFACTURE(70771-1344, 70771-1345, 70771-1346)

Revised: 9/2023 Zydus Lifesciences Limited