MIRTAZAPINE- mirtazapine tablet, orally disintegrating
SQUARE PHARMACEUTICALS LIMITED

MIRTAZAPINE ORALLY DISINTEGRATING TABLETS

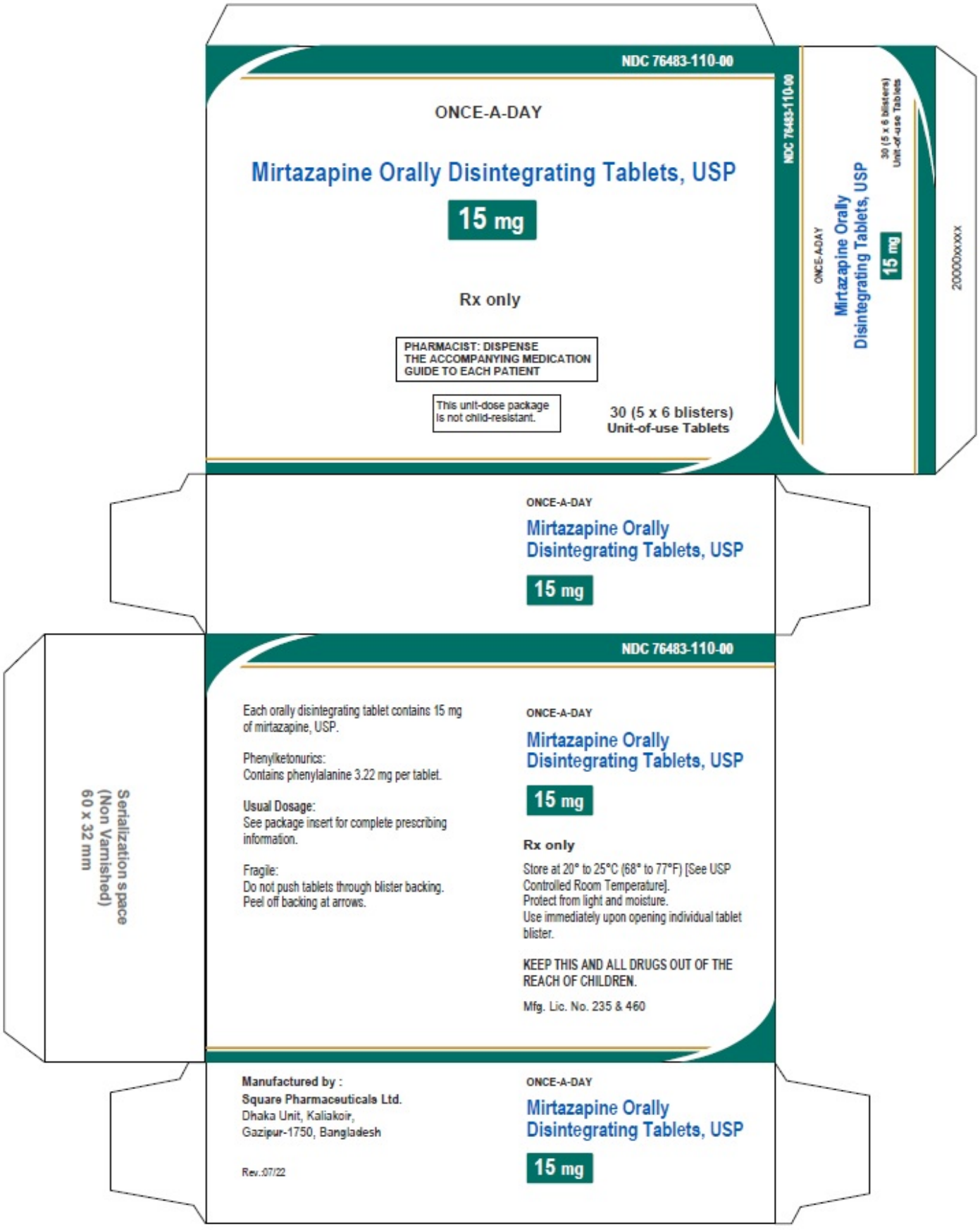
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 76483-110-00 in unit-dose blister cartons of 30 (5 x 6 blisters) Unit-of-use Tablets

Mirtazapine Orally Disintegrating Tablets USP, 15 mg

Rx only

30 Tablets

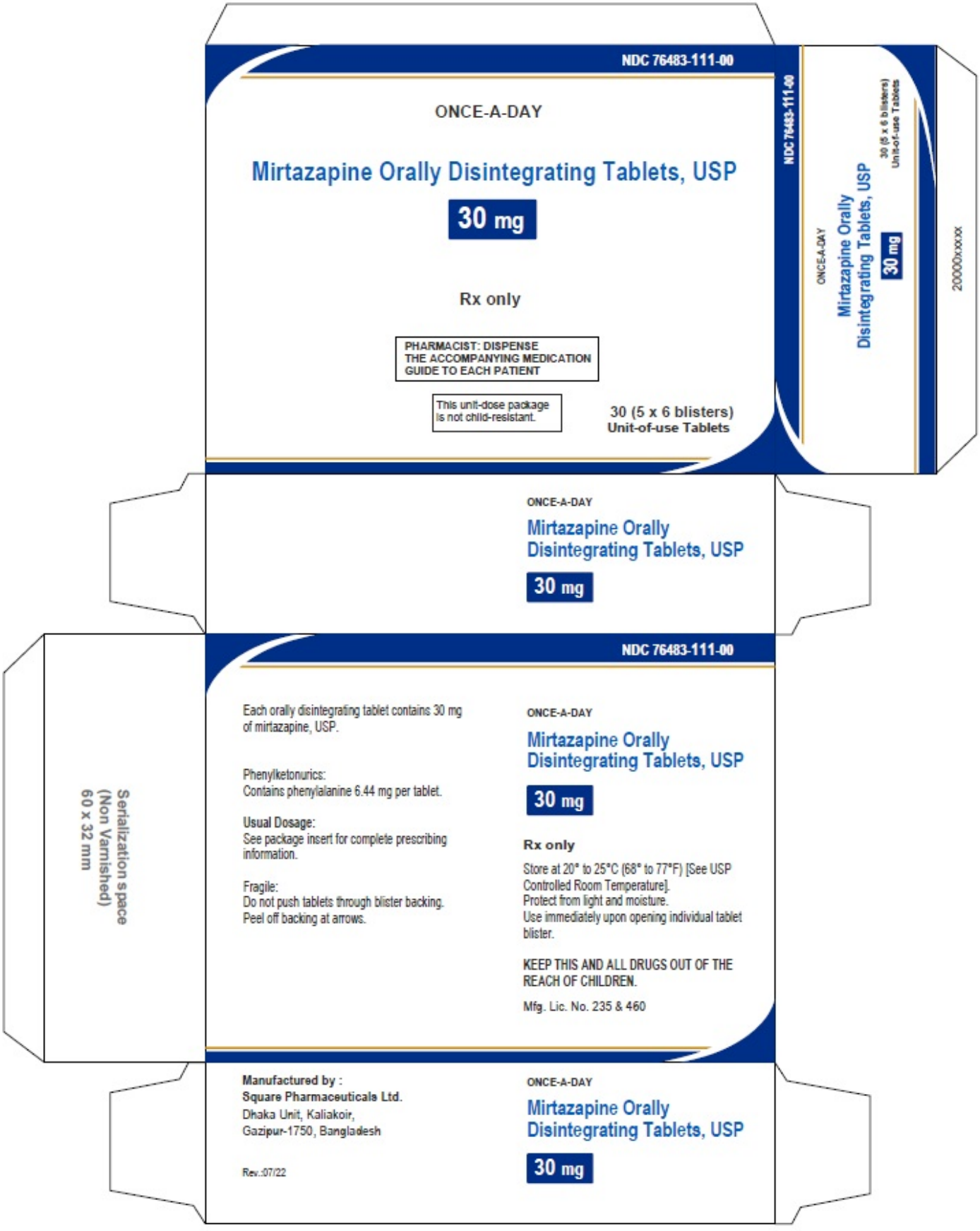


NDC 76483-111-00 in unit-dose blister cartons of 30 (5 x 6 blisters) Unit-of-use Tablets

Mirtazapine Orally Disintegrating Tablets USP, 30 mg

Rx only

30 Tablets

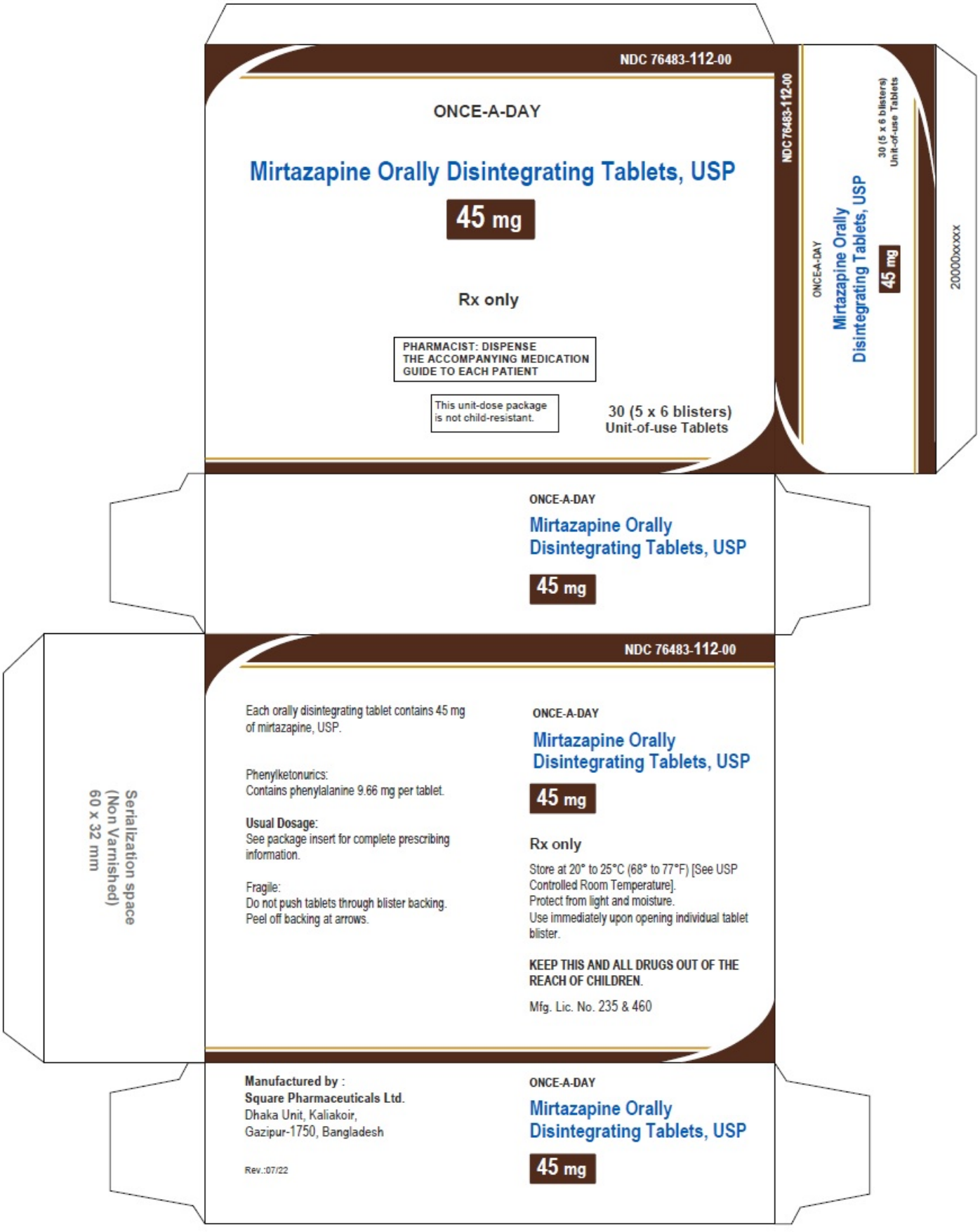


NDC 76483-112-00 in unit-dose blister cartons of 30 (5 x 6 blisters) Unit-of-use Tablets

Mirtazapine Orally Disintegrating Tablets USP, 45 mg

Rx only

30 Tablets



MIRTAZAPINE

mirtazapine tablet, orally disintegrating

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:76483-110
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MIRTAZAPINE (UNII: A051Q2099Q) (MIRTAZAPINE - UNII:A051Q2099Q)	MIRTAZAPINE	15 mg

Inactive Ingredients	
Ingredient Name	**Strength**
MANNITOL (UNII: 3OWL53L36A)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
CROSPOVIDONE (UNII: 2S7830E561)	
POVIDONE K30 (UNII: U725QWY32X)	
ASPARTAME (UNII: Z0H242BBR1)	
ALPHA-TOCOPHEROL (UNII: H4N855PNZ1)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI)	

Product Characteristics			
Color	WHITE (white to off-white)	**Score**	no score
Shape	ROUND	**Size**	7mm
Flavor		**Imprint Code**	677
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:76483-110-00	30 in 1 CARTON; Type 0: Not a Combination Product	11/15/2022	

Marketing Information			
Marketing Category	**Application Number or Monograph Citation**	**Marketing Start Date**	**Marketing End Date**
ANDA	ANDA205798	11/15/2022	

MIRTAZAPINE

mirtazapine tablet, orally disintegrating

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:76483-111
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MIRTAZAPINE (UNII: A051Q2099Q) (MIRTAZAPINE - UNII:A051Q2099Q)	MIRTAZAPINE	30 mg

Inactive Ingredients

Ingredient Name	Strength
MANNITOL (UNII: 3OWL53L36A)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
CROSPOVIDONE (UNII: 2S7830E561)	
POVIDONE K30 (UNII: U725QWY32X)	
ASPARTAME (UNII: Z0H242BBR1)	
ALPHA-TOCOPHEROL (UNII: H4N855PNZ1)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI)	

Product Characteristics

Color	WHITE (white to off-white)	**Score**	no score
Shape	ROUND	**Size**	9mm
Flavor		**Imprint Code**	676
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76483-111-00	30 in 1 CARTON; Type 0: Not a Combination Product	11/15/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA205798	11/15/2022	

MIRTAZAPINE

mirtazapine tablet, orally disintegrating

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:76483-112
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MIRTAZAPINE (UNII: A051Q2099Q) (MIRTAZAPINE - UNII:A051Q2099Q)	MIRTAZAPINE	45 mg

Inactive Ingredients	
Ingredient Name	**Strength**
MANNITOL (UNII: 3OWL53L36A)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
CROSPOVIDONE (UNII: 2S7830E561)	
POVIDONE K30 (UNII: U725QWY32X)	
ASPARTAME (UNII: Z0H242BBR1)	
ALPHA-TOCOPHEROL (UNII: H4N855PNZ1)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI)	

Product Characteristics			
Color	WHITE (white to off-white)	**Score**	no score
Shape	ROUND	**Size**	10mm
Flavor		**Imprint Code**	679
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:76483-112-00	30 in 1 CARTON; Type 0: Not a Combination Product	11/15/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA205798	11/15/2022	

Labeler - SQUARE PHARMACEUTICALS LIMITED (731487153)

Registrant - SQUARE PHARMACEUTICALS LIMITED (731487153)

Establishment

Name	Address	ID/FEI	Business Operations
SQUARE PHARMACEUTICALS LIMITED, Dhaka unit		850366520	ANALYSIS(76483-110, 76483-111, 76483-112) , LABEL(76483-110, 76483-111, 76483-112) , MANUFACTURE(76483-110, 76483-111, 76483-112) , PACK(76483-110, 76483-111, 76483-112)

Revised: 7/2023 SQUARE PHARMACEUTICALS LIMITED