

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 76483-110-00

ONCE-A-DAY

Mirtazapine Orally Disintegrating Tablets, USP

15 mg

Rx only

PHARMACIST: DISPENSE
THE ACCOMPANYING MEDICATION
GUIDE TO EACH PATIENT

This unit-dose package
is not child-resistant.

30 (5 x 6 blisters)
Unit-of-use Tablets

NDC 76483-110-00

ONCE-A-DAY

Mirtazapine Orally
Disintegrating Tablets, USP

30 (5 x 6 blisters)
Unit-of-use Tablets

15 mg

20000xxxxx

ONCE-A-DAY

Mirtazapine Orally Disintegrating Tablets, USP

15 mg

NDC 76483-110-00

Each orally disintegrating tablet contains 15 mg
of mirtazapine, USP.

Phenylethanolamines:
Contains phenylalanine 3.22 mg per tablet.

Usual Dosage:
See package insert for complete prescribing
information.

Fragile:
Do not push tablets through blister backing.
Peel off backing at arrows.

ONCE-A-DAY

Mirtazapine Orally Disintegrating Tablets, USP

15 mg

Rx only

Store at 20° to 25°C (68° to 77°F) [See USP
Controlled Room Temperature].
Protect from light and moisture.
Use immediately upon opening individual tablet
blister.

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

Mfg. Lic. No. 235 & 460

Serialization space
(Non Varnished)
60 x 32 mm

Manufactured by :
Square Pharmaceuticals Ltd.
Dhaka Unit, Kaliakoir,
Gazipur-1750, Bangladesh

Rev.:07/22

ONCE-A-DAY

Mirtazapine Orally Disintegrating Tablets, USP

15 mg

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

NDC 76483-112-00

ONCE-A-DAY

Mirtazapine Orally Disintegrating Tablets, USP

45 mg

Rx only

PHARMACIST: DISPENSE
THE ACCOMPANYING MEDICATION
GUIDE TO EACH PATIENT

This unit-dose package
is not child-resistant.

30 (5 x 6 blisters)
Unit-of-use Tablets

NDC 76483-112-00

ONCE-A-DAY

Mirtazapine Orally Disintegrating Tablets, USP

30 (5 x 6 blisters)
Unit-of-use Tablets

45 mg

20000xxxxx

ONCE-A-DAY

Mirtazapine Orally Disintegrating Tablets, USP

45 mg

NDC 76483-112-00

Each orally disintegrating tablet contains 45 mg
of mirtazapine, USP.

Phenylketonurics:
Contains phenylalanine 9.66 mg per tablet.

Usual Dosage:
See package insert for complete prescribing
information.

Fragile:
Do not push tablets through blister backing.
Peel off backing at arrows.

ONCE-A-DAY

Mirtazapine Orally Disintegrating Tablets, USP

45 mg

Rx only

Store at 20° to 25°C (68° to 77°F) [See USP
Controlled Room Temperature].
Protect from light and moisture.
Use immediately upon opening individual tablet
blister.

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

Mfg. Lic. No. 235 & 460

Serialization space
(Non Varnished)
60 x 32 mm

Manufactured by :
Square Pharmaceuticals Ltd.
Dhaka Unit, Kaliakoir,
Gazipur-1750, Bangladesh

Rev.:07/22

ONCE-A-DAY

Mirtazapine Orally Disintegrating Tablets, USP

45 mg

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)	
CROSPVIDONE (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)	
CROSPVIDONE (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)	
CROSPVIDONE (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