

PAROXETINE- paroxetine hydrochloride tablet, film coated
Zydus Lifesciences Limited

Paroxetine Tablets, USP

SPL MEDGUIDE

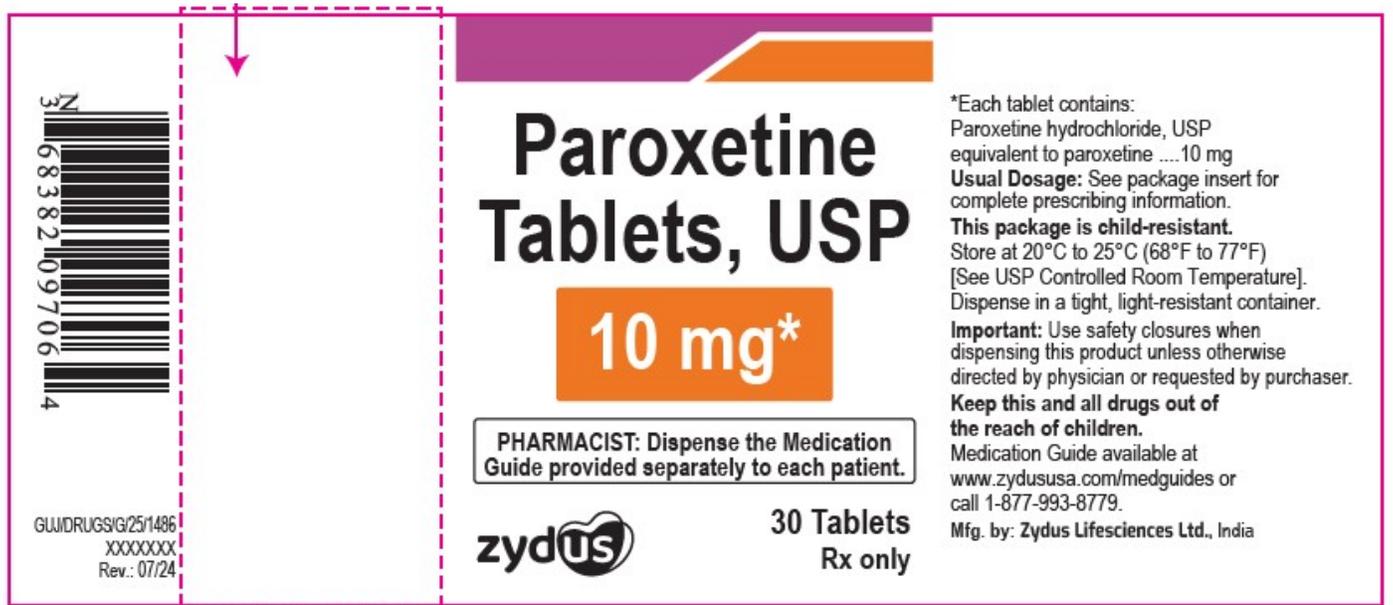
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 65841-097-06 in pack count of 30 tablets

Paroxetine Tablets USP, 10 mg

R_x only

30 tablets



NDC 65841-098-06 in pack count of 30 tablets

Paroxetine Tablets USP, 20 mg

R_x only

30 tablets

NDC 68382-109806-1
 GUJDRUGS/G/25/1486
 XXXXXXX
 Rev.: 07/24

Paroxetine Tablets, USP

20 mg*

PHARMACIST: Dispense the Medication Guide provided separately to each patient.

zydUS

30 Tablets
Rx only

*Each tablet contains: Paroxetine hydrochloride, USP equivalent to paroxetine 20 mg
Usual Dosage: See package insert for complete prescribing information.
This package is child-resistant.
 Store at 20°C to 25°C (68°F to 77°F) [See USP Controlled Room Temperature].
 Dispense in a tight, light-resistant container.
Important: Use safety closures when dispensing this product unless otherwise directed by physician or requested by purchaser.
Keep this and all drugs out of the reach of children.
 Medication Guide available at www.zydususa.com/medguides or call 1-877-993-8779.
 Mfg. by: Zydus Lifesciences Ltd., India

NDC 65841-099-06 in pack count of 30 tablets

Paroxetine Tablets USP, 30 mg

R_x only

30 tablets

NDC 68382-109906-8
 GUJDRUGS/G/25/1486
 XXXXXXX
 Rev.: 07/24

Paroxetine Tablets, USP

30 mg*

PHARMACIST: Dispense the Medication Guide provided separately to each patient.

zydUS

30 Tablets
Rx only

*Each tablet contains: Paroxetine hydrochloride, USP equivalent to paroxetine 30 mg
Usual Dosage: See package insert for complete prescribing information.
This package is child-resistant.
 Store at 20°C to 25°C (68°F to 77°F) [See USP Controlled Room Temperature].
 Dispense in a tight, light-resistant container.
Important: Use safety closures when dispensing this product unless otherwise directed by physician or requested by purchaser.
Keep this and all drugs out of the reach of children.
 Medication Guide available at www.zydususa.com/medguides or call 1-877-993-8779.
 Mfg. by: Zydus Lifesciences Ltd., India

NDC 65841-601-06 in pack count of 30 tablets

Paroxetine Tablets USP, 40 mg

R_x only

30 tablets



GUJDRUGS/G/25/1486
XXXXXXX
Rev.: 07/24



Paroxetine Tablets, USP

40 mg*

PHARMACIST: Dispense the Medication Guide provided separately to each patient.



30 Tablets
Rx only

*Each tablet contains:
Paroxetine hydrochloride, USP
equivalent to paroxetine 40 mg
Usual Dosage: See package insert for
complete prescribing information.
This package is child-resistant.
Store at 20°C to 25°C (68°F to 77°F)
[See USP Controlled Room Temperature].
Dispense in a tight, light-resistant container.
Important: Use safety closures when
dispensing this product unless otherwise
directed by physician or requested by purchaser.
**Keep this and all drugs out of
the reach of children.**
Medication Guide available at
www.zydususa.com/medguides or
call 1-877-993-8779.
Mfg. by: Zydus Lifesciences Ltd., India

PAROXETINE

paroxetine hydrochloride tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:65841-097
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PAROXETINE HYDROCHLORIDE ANHYDROUS (UNII: 3I3T11UD2S) (PAROXETINE - UNII:41VRH5220H, PAROXETINE - UNII:41VRH5220H)	PAROXETINE	10 mg

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL 6000 (UNII: 30IQX730WE)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
POVIDONE (UNII: FZ989GH94E)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE)	Score	2 pieces
Shape	ROUND (ROUND)	Size	6mm
Flavor		Imprint Code	ZC;15
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-097-06	30 in 1 BOTTLE; Type 0: Not a Combination Product	04/13/2007	
2	NDC:65841-097-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	04/13/2007	
3	NDC:65841-097-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	04/13/2007	
4	NDC:65841-097-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	04/13/2007	
5	NDC:65841-097-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	04/13/2007	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077584	04/13/2007	

PAROXETINE

paroxetine hydrochloride tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:65841-098
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PAROXETINE HYDROCHLORIDE ANHYDROUS (UNII: 3I3T11UD2S) (PAROXETINE - UNII:41VRH5220H, PAROXETINE - UNII:41VRH5220H)	PAROXETINE	20 mg

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL 6000 (UNII: 30IQX730WE)	

SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)

POVIDONE (UNII: FZ989GH94E)

TALC (UNII: 7SEV7J4R1U)

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE)	Score	2 pieces
Shape	ROUND (ROUND)	Size	8mm
Flavor		Imprint Code	ZC;16
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-098-06	30 in 1 BOTTLE; Type 0: Not a Combination Product	04/13/2007	
2	NDC:65841-098-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	04/13/2007	
3	NDC:65841-098-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	04/13/2007	
4	NDC:65841-098-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	04/13/2007	
5	NDC:65841-098-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	04/13/2007	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077584	04/13/2007	

PAROXETINE

paroxetine hydrochloride tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:65841-099
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PAROXETINE HYDROCHLORIDE ANHYDROUS (UNII: 3I3T11UD2S) (PAROXETINE - UNII:41VRH5220H, PAROXETINE - UNII:41VRH5220H)	PAROXETINE	30 mg

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I3O)	
POLYETHYLENE GLYCOL 6000 (UNII: 30IQX730WE)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
POVIDONE (UNII: FZ989GH94E)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE)	Score	no score
Shape	ROUND (ROUND)	Size	10mm
Flavor		Imprint Code	ZC17
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-099-06	30 in 1 BOTTLE; Type 0: Not a Combination Product	04/13/2007	
2	NDC:65841-099-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	04/13/2007	
3	NDC:65841-099-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	04/13/2007	
4	NDC:65841-099-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	04/13/2007	
5	NDC:65841-099-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	04/13/2007	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077584	04/13/2007	

PAROXETINE

paroxetine hydrochloride tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:65841-601
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PAROXETINE HYDROCHLORIDE ANHYDROUS (UNII: 3I3T11UD2S) (PAROXETINE - UNII:41VRH5220H, PAROXETINE - UNII:41VRH5220H)	PAROXETINE	40 mg

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL 6000 (UNII: 3OIQX730WE)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
POVIDONE (UNII: FZ989GH94E)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE)	Score	no score
Shape	ROUND (ROUND)	Size	11mm
Flavor		Imprint Code	ZC18
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-601-06	30 in 1 BOTTLE; Type 0: Not a Combination Product	04/13/2007	
2	NDC:65841-601-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	04/13/2007	
3	NDC:65841-601-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	04/13/2007	
4	NDC:65841-601-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	04/13/2007	
5	NDC:65841-601-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	04/13/2007	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077584	04/13/2007	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		918596198	ANALYSIS(65841-097, 65841-098, 65841-099, 65841-601) , MANUFACTURE(65841-097, 65841-098, 65841-099, 65841-601)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		677605858	MANUFACTURE(65841-097, 65841-098, 65841-099, 65841-601)

Revised: 12/2024

Zydus Lifesciences Limited