PAROXETINE - paroxetine hydrochloride tablet, film coated
Zydus Lifesciences Limited

Paroxetine Tablets, USP

SPL MEDGUIDE

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 65841-097-05 in pack count of 500 tablets

Paroxetine Tablets USP, 10 mg

R_x only

500 tablets

NDC 65841-098-16 in pack count of 90 tablets

Paroxetine Tablets USP, 20 mg

R_x only

90 tablets

NDC 65841-099-10 in pack count of 1000 tablets

Paroxetine Tablets USP, 30 mg

R_x only

1000 tablets

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

Paroxetine Tablets USP, 40 mg

R_x only

30 tablets

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: 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**	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: 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**	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)