SERTRALINE HYDROCHLORIDE- sertraline hydrochloride tablet, film coated
Zydus Lifesciences Limited

SERTRALINE HYDROCHLORIDE TABLETS

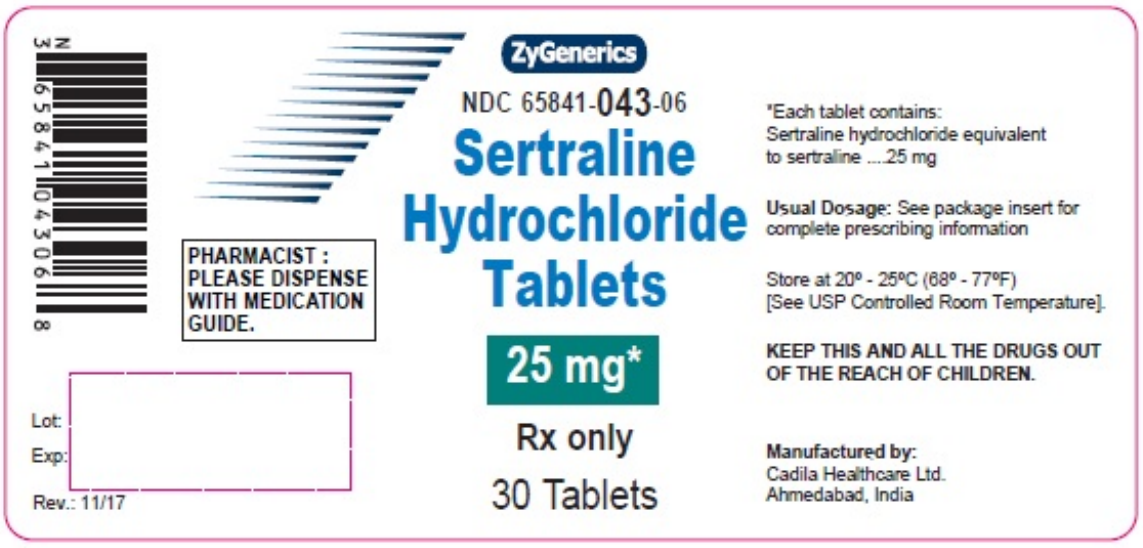
SPL MEDGUIDE

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 65841-043-06 in bottles of 30 tablets

Sertraline Hydrochloride Tablets, 25 mg

30 Tablets



NDC 65841-044-06 in bottles of 30 tablets

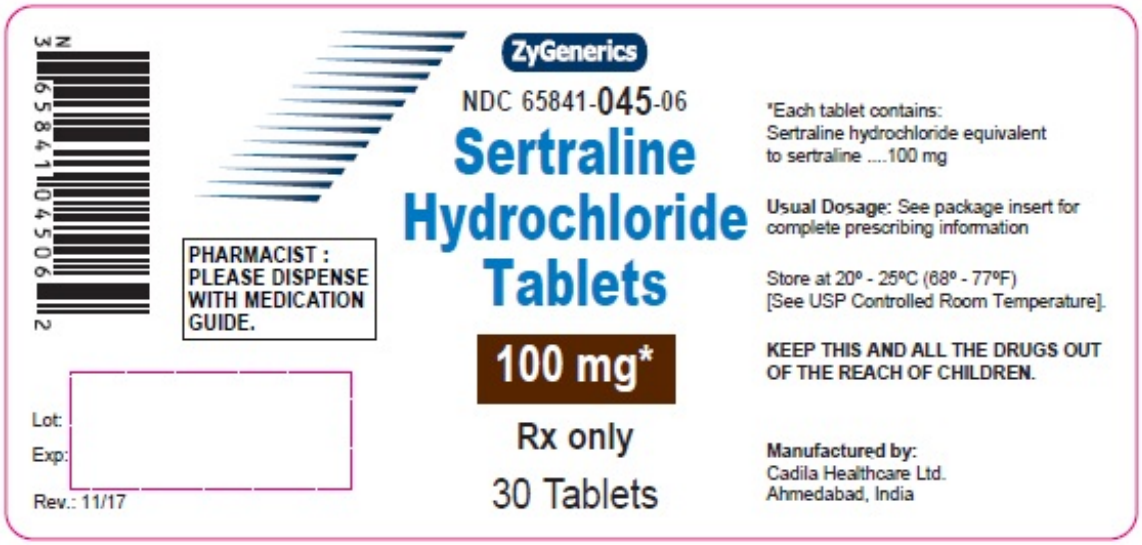
Sertraline Hydrochloride Tablets, 50 mg

30 Tablets

NDC 65841-045-06 in bottles of 30 tablets

Sertraline Hydrochloride Tablets, 100 mg

30 Tablets



SERTRALINE HYDROCHLORIDE

sertraline hydrochloride tablet, film coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-043
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SERTRALINE HYDROCHLORIDE (UNII: UTI8907Y6X) (SERTRALINE - UNII:QUC7NX6WMB)	SERTRALINE	25 mg

Inactive Ingredients

Ingredient Name	Strength
ALUMINUM OXIDE (UNII: LMI26O6933)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POVIDONE (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	

Product Characteristics

Color	GREEN (LIGHT GREEN)	**Score**	2 pieces
Shape	ROUND (ROUND)	**Size**	6mm
Flavor		**Imprint Code**	Z;82
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-043-06	30 in 1 BOTTLE; Type 0: Not a Combination Product	12/02/2017	
2	NDC:65841-043-18	50 in 1 BOTTLE; Type 0: Not a Combination Product	12/02/2017	
3	NDC:65841-043-14	60 in 1 BOTTLE; Type 0: Not a Combination Product	12/02/2017	
4	NDC:65841-043-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	12/02/2017	
5	NDC:65841-043-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	12/02/2017	
6	NDC:65841-043-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	12/02/2017	
7	NDC:65841-043-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	12/02/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077106	12/02/2017	

SERTRALINE HYDROCHLORIDE

sertraline hydrochloride tablet, film coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-044
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SERTRALINE HYDROCHLORIDE (UNII: UTI8907Y6X) (SERTRALINE - UNII:QUC7NX6WMB)	SERTRALINE	50 mg

Inactive Ingredients	
Ingredient Name	**Strength**
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POVIDONE (UNII: FZ989GH94E)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	

Product Characteristics			
Color	BLUE (LIGHT BLUE)	**Score**	2 pieces
Shape	ROUND (ROUND)	**Size**	8mm
Flavor		**Imprint Code**	Z;81
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:65841-044-06	30 in 1 BOTTLE; Type 0: Not a Combination Product	12/02/2017	
2	NDC:65841-044-14	60 in 1 BOTTLE; Type 0: Not a Combination Product	12/02/2017	
3	NDC:65841-044-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	12/02/2017	
4	NDC:65841-044-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	12/02/2017	

5	NDC:65841-044-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	12/02/2017	
6	NDC:65841-044-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	12/02/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077106	12/02/2017	

SERTRALINE HYDROCHLORIDE

sertraline hydrochloride tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-045
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SERTRALINE HYDROCHLORIDE (UNII: UTI8907Y6X) (SERTRALINE - UNII:QUC7NX6WMB)	SERTRALINE	100 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POVIDONE (UNII: FZ989GH94E)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	

Product Characteristics

Color	YELLOW (YELLOW)	**Score**	2 pieces
Shape	ROUND (ROUND)	**Size**	10mm
Flavor		**Imprint Code**	Z;80
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-045-06	30 in 1 BOTTLE; Type 0: Not a Combination Product	12/02/2017	
2	NDC:65841-045-14	60 in 1 BOTTLE; Type 0: Not a Combination Product	12/02/2017	
3	NDC:65841-045-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	12/02/2017	
4	NDC:65841-045-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	12/02/2017	
5	NDC:65841-045-40	5000 in 1 BOTTLE; Type 0: Not a Combination Product	12/02/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077106	12/02/2017	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		918596198	ANALYSIS(65841-043, 65841-044, 65841-045) , MANUFACTURE(65841-043, 65841-044, 65841-045)

Revised: 9/2023 Zydus Lifesciences Limited