

SERTRALINE HYDROCHLORIDE- sertraline hydrochloride tablet, film coated
Cadila Healthcare Limited

SERTRALINE HYDROCHLORIDE TABLETS

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 65841-043-06 in bottles of 30 tablets

Sertraline Hydrochloride Tablets, 25 mg

30 Tablets

ZyGenerics
NDC 65841-043-06
Sertraline Hydrochloride Tablets
25 mg*
Rx only
30 Tablets

PHARMACIST :
PLEASE DISPENSE
WITH MEDICATION
GUIDE.

*Each tablet contains:
Sertraline hydrochloride equivalent
to sertraline25 mg

Usual Dosage: See package insert for
complete prescribing information

Store at 20° - 25°C (68° - 77°F)
[See USP Controlled Room Temperature].

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

Manufactured by:
Cadila Healthcare Ltd.
Ahmedabad, India

Lot:
Exp:
Rev.: 11/17

NDC 65841-044-06 in bottles of 30 tablets

Sertraline Hydrochloride Tablets, 50 mg

30 Tablets

ZyGenerics
NDC 65841-044-06
Sertraline Hydrochloride Tablets
50 mg*
Rx only
30 Tablets

*Each tablet contains:
Sertraline hydrochloride equivalent to sertraline50 mg

Usual Dosage: See package insert for complete prescribing information

Store at 20° - 25°C (68° - 77°F)
[See USP Controlled Room Temperature].

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

Manufactured by:
Cadila Healthcare Ltd.
Ahmedabad, India

PHARMACIST : PLEASE DISPENSE WITH MEDICATION GUIDE.

Lot:
Exp:
Rev.: 11/17

NDC 65841-045-06 in bottles of 30 tablets
Sertraline Hydrochloride Tablets, 100 mg
30 Tablets

ZyGenerics
NDC 65841-045-06
Sertraline Hydrochloride Tablets
100 mg*
Rx only
30 Tablets

*Each tablet contains:
Sertraline hydrochloride equivalent to sertraline100 mg

Usual Dosage: See package insert for complete prescribing information

Store at 20° - 25°C (68° - 77°F)
[See USP Controlled Room Temperature].

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

Manufactured by:
Cadila Healthcare Ltd.
Ahmedabad, India

PHARMACIST : PLEASE DISPENSE WITH MEDICATION GUIDE.

Lot:
Exp:
Rev.: 11/17

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: UTI8907Y6 X) (SERTRALINE - UNII:QUC7NX6WMB)	SERTRALINE	25 mg

Inactive Ingredients

Ingredient Name	Strength
ALUMINUM OXIDE (UNII: LM26O6933)	
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)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
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	8 mm
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)	
CROSCARMELOSE 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 - Cadila Healthcare Limited (918596198)

Registrant - Cadila Healthcare Limited (918596198)

Establishment

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

Revised: 9/2020

Cadila Healthcare Limited