DONEPEZIL HYDROCHLORIDE - donepezil hydrochloride tablet, film coated
Zydus Lifesciences Limited

DONEPEZIL HYDROCHLORIDE TABLETS

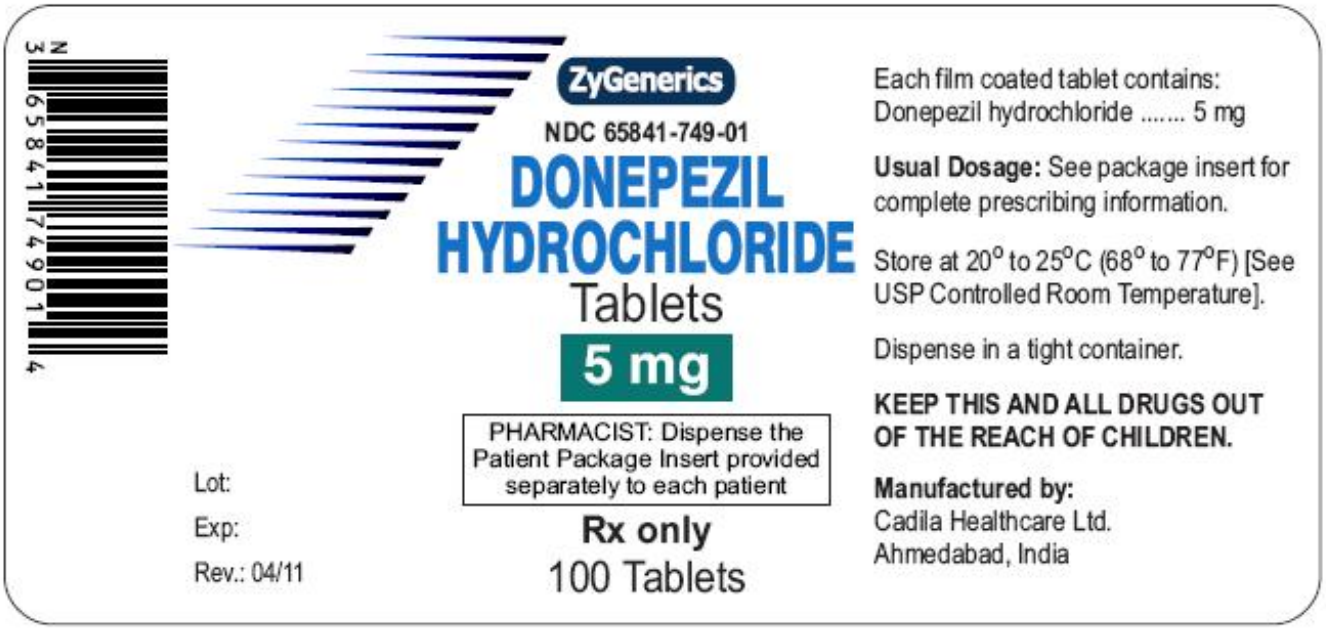
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 65841-749-01 in bottle of 100 tablets

Donepezil Hydrochloride Tablets USP, 5 mg

R_x only

100 tablets

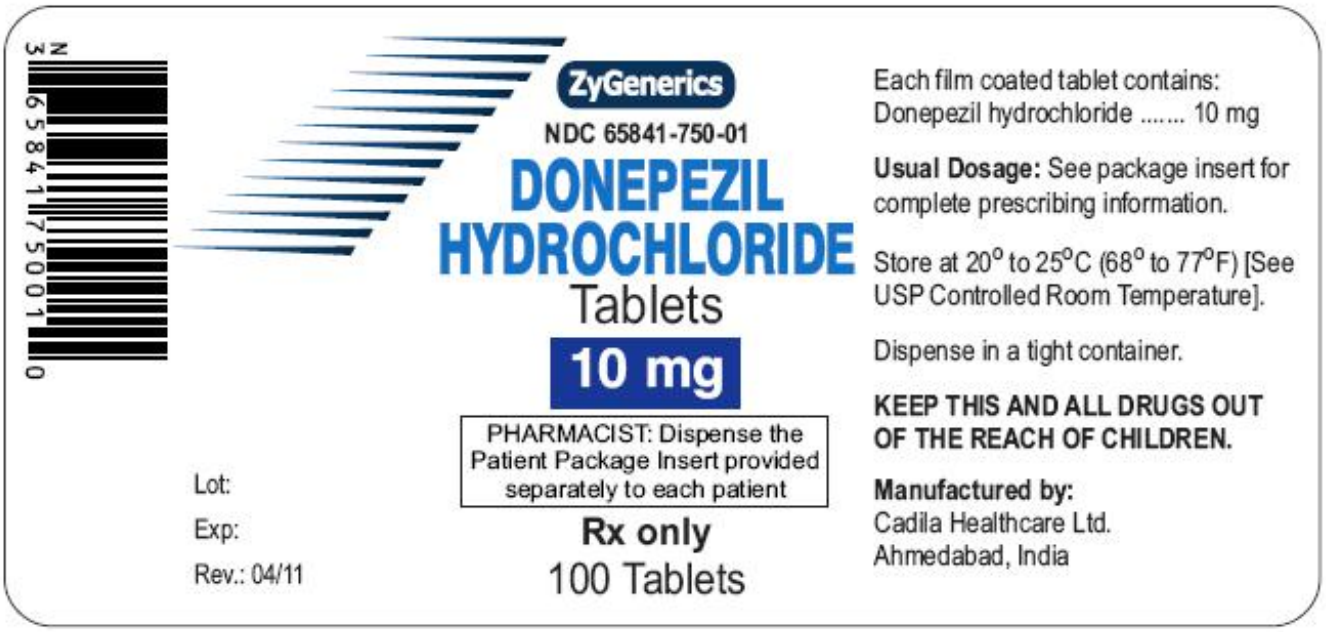


NDC 65841-750-01 in bottle of 100 tablets

Donepezil Hydrochloride Tablets USP, 10 mg

R_x only

100 tablets



DONEPEZIL HYDROCHLORIDE

donepezil hydrochloride tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-749
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DONEPEZIL HYDROCHLORIDE (UNII: 3O2T2PJ89D) (DONEPEZIL - UNII:8SSC91326P)	DONEPEZIL HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
HYDROXYPROPYL CELLULOSE (1600000 WAMW) (UNII: RFW2ET671P)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE)	**Score**	no score

Shape	ROUND (ROUND)	**Size**	7mm
Flavor		**Imprint Code**	ZF9
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-749-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	05/25/2011	
2	NDC:65841-749-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	05/25/2011	
3	NDC:65841-749-06	30 in 1 BOTTLE; Type 0: Not a Combination Product	05/25/2011	
4	NDC:65841-749-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	05/25/2011	
5	NDC:65841-749-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/25/2011	
6	NDC:65841-749-30	10 in 1 CARTON	05/25/2011	
6		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090100	05/25/2011	

DONEPEZIL HYDROCHLORIDE

donepezil hydrochloride tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-750
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DONEPEZIL HYDROCHLORIDE (UNII: 3O2T2PJ89D) (DONEPEZIL - UNII:8SSC91326P)	DONEPEZIL HYDROCHLORIDE	10 mg

Inactive Ingredients

Ingredient Name	Strength
HYDROXYPROPYL CELLULOSE (1600000 WAMW) (UNII: RFW2ET671P)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE)	**Score**	no score
Shape	ROUND (ROUND)	**Size**	9mm
Flavor		**Imprint Code**	ZF10
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-750-06	30 in 1 BOTTLE; Type 0: Not a Combination Product	05/25/2011	
2	NDC:65841-750-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	05/25/2011	
3	NDC:65841-750-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/25/2011	
4	NDC:65841-750-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	05/25/2011	
5	NDC:65841-750-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	05/25/2011	
6	NDC:65841-750-30	10 in 1 CARTON	05/25/2011	
6		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090100	05/25/2011	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		918596198	ANALYSIS(65841-749, 65841-750) , MANUFACTURE(65841-749, 65841-750)