DONEPEZIL HYDROCHLORIDE- donepezil hydrochloride tablet, orally disintegrating
Zydus Lifesciences Limited

DONEPEZIL HYDROCHLORIDE ORALLY DISINTEGRATING TABLETS

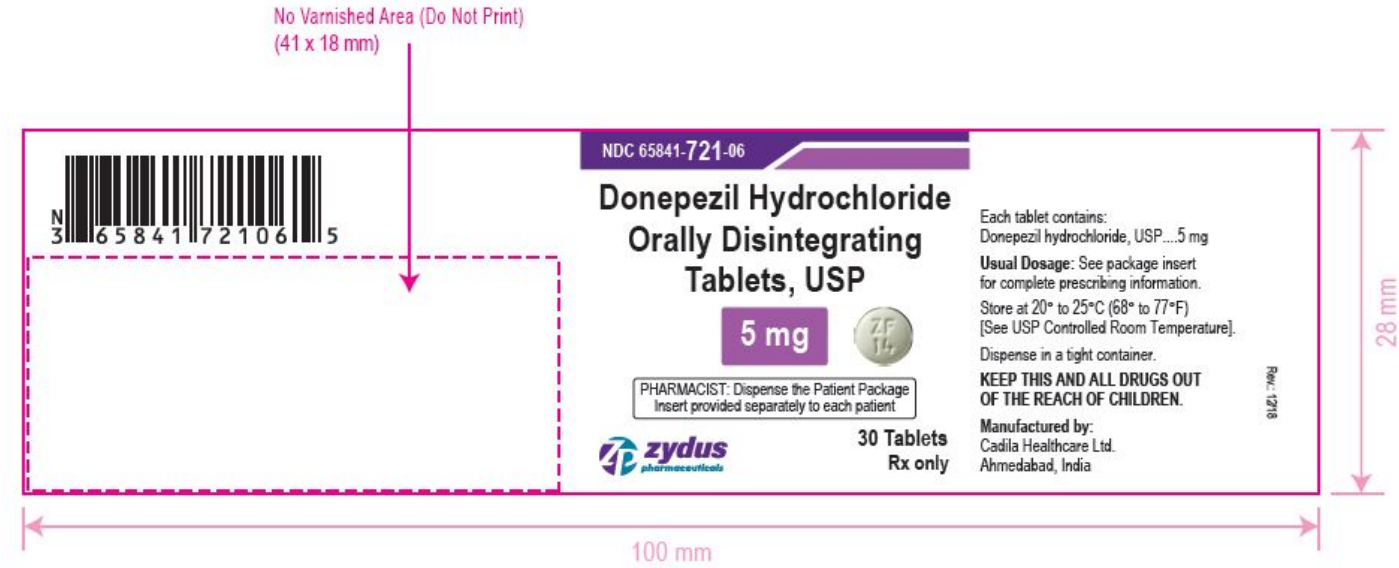
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 65841-721-06 in bottle of 30 tablets

Donepezil Hydrochloride Orally Disintegrating Tablets USP, 5 mg

R_x only

30 tablets

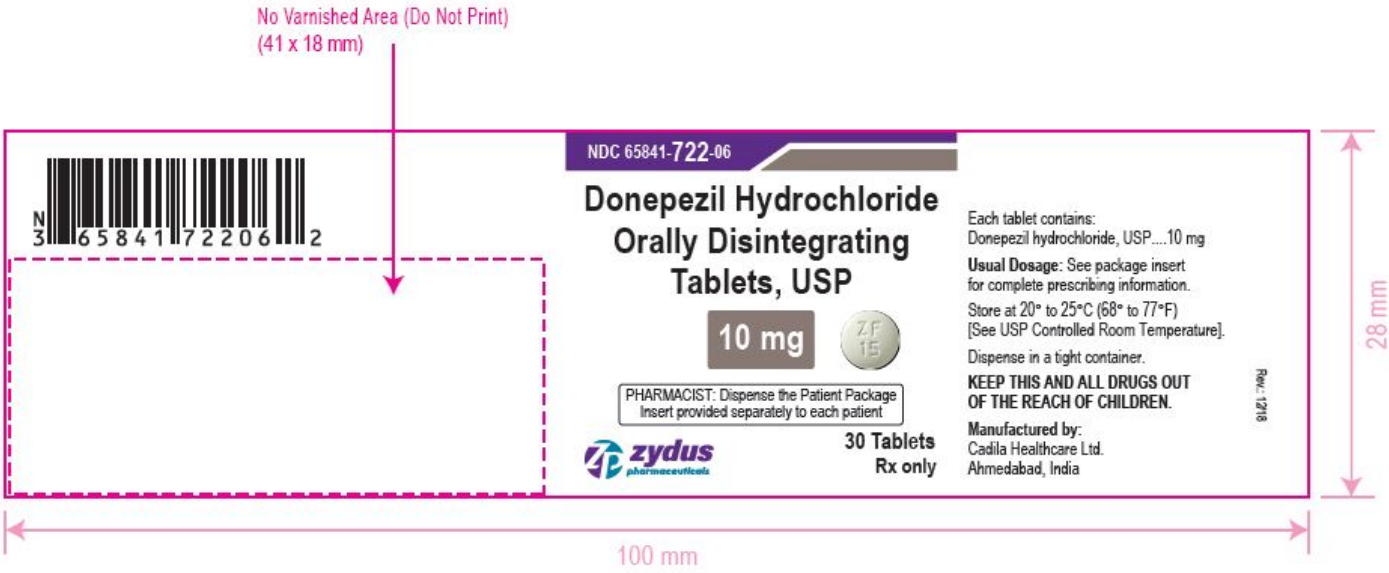


NDC 65841-722-06 in bottle of 30 tablets

Donepezil Hydrochloride Orally Disintegrating Tablets USP, 10 mg

R_x only

30 tablets



DONEPEZIL HYDROCHLORIDE

donepezil hydrochloride tablet, orally disintegrating

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-721
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
CROSPOVIDONE (UNII: 2S7830E561)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
PEPPERMINT (UNII: V95R5KMY2B)	
STRAWBERRY (UNII: 4J2TY8Y81V)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Product Characteristics

Color	WHITE (WHITE TO OFF WHITE)	**Score**	no score
Shape	ROUND (ROUND)	**Size**	7mm
Flavor	PEPPERMINT (flavor firmenich powder peppermint) , STRAWBERRY (flavor strawberry)	**Imprint Code**	ZF;14

Contains	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-721-06	30 in 1 BOTTLE; Type 0: Not a Combination Product	05/11/2011	
2	NDC:65841-721-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	05/11/2011	
3	NDC:65841-721-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/11/2011	
4	NDC:65841-721-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	05/11/2011	
5	NDC:65841-721-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	05/11/2011	
6	NDC:65841-721-30	10 in 1 CARTON	05/11/2011	
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	ANDA090175	05/11/2011	

DONEPEZIL HYDROCHLORIDE

donepezil hydrochloride tablet, orally disintegrating

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-722
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
CROSPOVIDONE (UNII: 2S7830E561)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
PEPPERMINT (UNII: V95R5KMY2B)	
STRAWBERRY (UNII: 4J2TY8Y81V)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Product Characteristics

Color	WHITE (WHITE TO OFF WHITE)	**Score**	no score
Shape	ROUND (ROUND)	**Size**	10mm
Flavor	PEPPERMINT (flavor firmenich powder peppermint) , STRAWBERRY (flavor strawberry)	**Imprint Code**	ZF;15
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-722-06	30 in 1 BOTTLE; Type 0: Not a Combination Product	05/11/2011	
2	NDC:65841-722-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	05/11/2011	
3	NDC:65841-722-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/11/2011	
4	NDC:65841-722-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	05/11/2011	
5	NDC:65841-722-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	05/11/2011	
6	NDC:65841-722-30	10 in 1 CARTON	05/11/2011	
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	ANDA090175	05/11/2011	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		918596198	ANALYSIS(65841-721, 65841-722) , MANUFACTURE(65841-721, 65841-722)