

# DONEPEZIL HYDROCHLORIDE - donepezil hydrochloride tablet, orally disintegrating

Zydus Lifesciences Limited

## DONEPEZIL HYDROCHLORIDE ORALLY DISINTEGRATING TABLETS

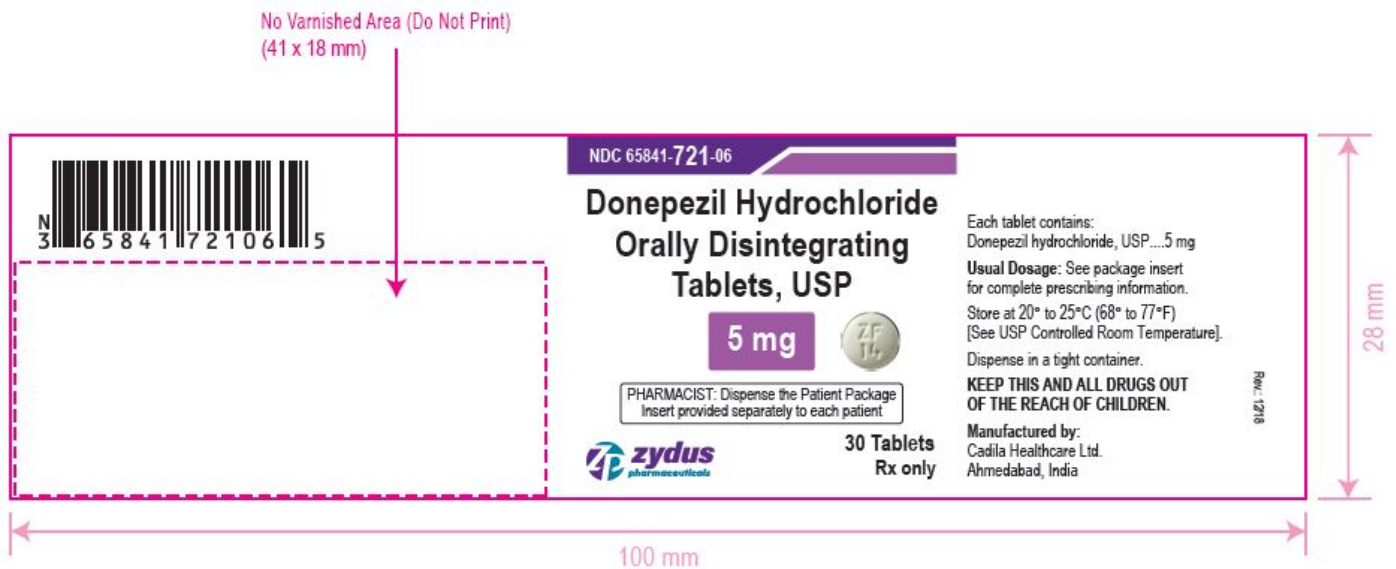
### PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 65841-721-06 in bottle of 30 tablets

Donepezil Hydrochloride Orally Disintegrating Tablets USP, 5 mg

R<sub>x</sub> only

30 tablets

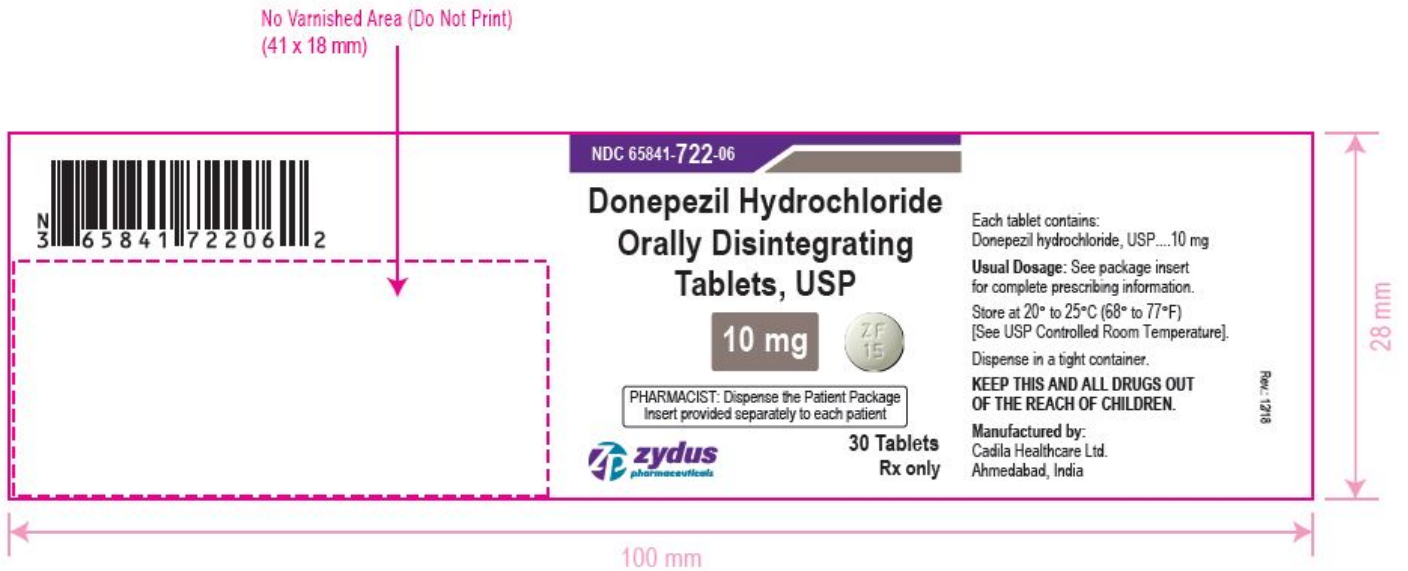


NDC 65841-722-06 in bottle of 30 tablets

Donepezil Hydrochloride Orally Disintegrating Tablets USP, 10 mg

R<sub>x</sub> only

30 tablets



## DONEPEZIL HYDROCHLORIDE

donepezil hydrochloride tablet, orally disintegrating

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:65841-721
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
<b>CROSPROVIDONE</b> (UNII: 2S7830E561)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MANNITOL</b> (UNII: 3OWL53L36A)	
<b>PEPPERMINT</b> (UNII: V95R5KMY2B)	
<b>STRAWBERRY</b> (UNII: 4J2TY8Y81V)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	

### Product Characteristics

<b>Color</b>	WHITE (WHITE TO OFF WHITE)	<b>Score</b>	no score
<b>Shape</b>	ROUND (ROUND)	<b>Size</b>	7mm
<b>Flavor</b>	PEPPERMINT (flavor firmenich powder peppermint) , STRAWBERRY (flavor strawberry)	<b>Imprint Code</b>	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**

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:65841-722
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

Ingredient Name	Strength
<b>CROSPVIDONE</b> (UNII: 2S7830E561)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6130)	
<b>MANNITOL</b> (UNII: 3OWL53L36A)	
<b>PEPPERMINT</b> (UNII: V95R5KMY2B)	
<b>STRAWBERRY</b> (UNII: 4J2TY8Y81V)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	

**SILICON DIOXIDE** (UNII: ETJ7Z6XBU4)

### Product Characteristics

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

### 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)

Revised: 10/2022

Zydus Lifesciences Limited