

**DONEPEZIL HYDROCHLORIDE - donepezil hydrochloride tablet, film coated**  
**Zyclus Lifesciences Limited**

**DONEPEZIL HYDROCHLORIDE TABLETS**

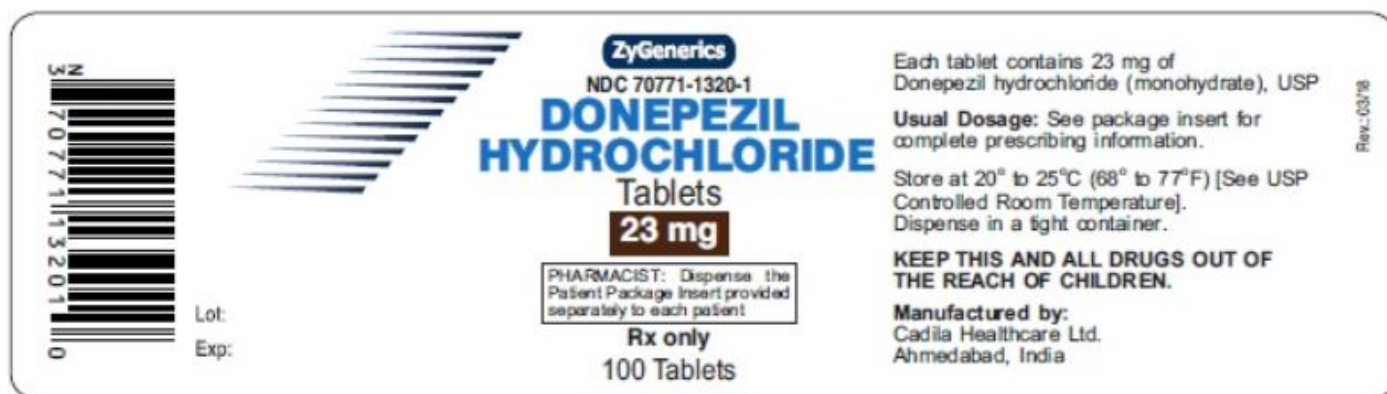
**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

NDC 70771-1320-1 in bottle of 100 tablets

Donepezil Hydrochloride Tablets, 23 mg

R<sub>x</sub> only

100 tablets



**DONEPEZIL HYDROCHLORIDE**

donepezil hydrochloride tablet, film coated

**Product Information**

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:70771-1320
<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	23 mg

**Inactive Ingredients**

Ingredient Name	Strength
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	

<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	

### Product Characteristics

<b>Color</b>	RED (red-brown)	<b>Score</b>	no score
<b>Shape</b>	ROUND (round)	<b>Size</b>	8mm
<b>Flavor</b>		<b>Imprint Code</b>	521
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1320-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	03/07/2018	
2	NDC:70771-1320-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	03/07/2018	
3	NDC:70771-1320-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	03/07/2018	
4	NDC:70771-1320-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	03/07/2018	
5	NDC:70771-1320-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	03/07/2018	
6	NDC:70771-1320-4	10 in 1 CARTON	03/07/2018	
6	NDC:70771-1320-2	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	ANDA203162	03/07/2018	

**Labeler** - Zydus Lifesciences Limited (918596198)

**Registrant** - Zydus Lifesciences Limited (918596198)

### Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		918596198	ANALYSIS(70771-1320) , MANUFACTURE(70771-1320)

