

**MEMANTINE HYDROCHLORIDE- memantine hydrochloride tablet, film coated**  
**Zydus Lifesciences Limited**

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**MEMANTINE HYDROCHLORIDE TABLETS**

**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

NDC 70771-1119-5 in bottle of 500 tablets

Memantine Hydrochloride Tablets USP, 5 mg

Rx only

500 tablets



NDC 70771-1120-5 in bottle of 500 tablets

Memantine Hydrochloride Tablets USP, 10 mg

Rx only

500 tablets

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7

Rev.: 08/24

# Memantine Hydrochloride Tablets, USP

## 10 mg

500 Tablets  
Rx only

VIONA

Each tablet contains:  
Memantine hydrochloride, USP 10 mg

**Usual Dosage:** See package insert for complete prescribing information.

Store at 20° to 25°C (68° to 77°F)  
[See USP Controlled Room Temperature].  
Dispense in a tight container.

**Keep this and all drugs out of the reach of children.**

Product of Italy

Mfd. by: Zydus Lifesciences Ltd.  
Ahmedabad, India

## MEMANTINE HYDROCHLORIDE

memantine hydrochloride tablet, film coated

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:70771-1119
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>MEMANTINE HYDROCHLORIDE</b> (UNII: JY0WD0UA60) (MEMANTINE - UNII:W8O17SJF3T)	MEMANTINE HYDROCHLORIDE	5 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>CROSCARMELLOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>DIBASIC CALCIUM PHOSPHATE DIHYDRATE</b> (UNII: O7TSZ97GEP)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	

## Product Characteristics

<b>Color</b>	WHITE (WHITE TO OFF-WHITE)	<b>Score</b>	no score
<b>Shape</b>	CAPSULE (CAPSULE)	<b>Size</b>	9mm
<b>Flavor</b>		<b>Imprint Code</b>	ZF;41
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1119-4	100 in 1 CARTON	09/28/2017	
1	NDC:70771-1119-2	1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:70771-1119-6	60 in 1 BOTTLE; Type 0: Not a Combination Product	09/28/2017	
3	NDC:70771-1119-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	09/28/2017	
4	NDC:70771-1119-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	09/28/2017	
5	NDC:70771-1119-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	09/28/2017	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090961	09/28/2017	

## MEMANTINE HYDROCHLORIDE

memantine hydrochloride tablet, film coated

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:70771-1120
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>MEMANTINE HYDROCHLORIDE</b> (UNII: JY0WD0UA60) (MEMANTINE - UNII:W8O17SJF3T)	MEMANTINE HYDROCHLORIDE	10 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>CROSCARMELOSE SODIUM</b> (UNII: M28OL1HH48)	

<b>DIBASIC CALCIUM PHOSPHATE DIHYDRATE</b> (UNII: O7TSZ97GEP)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	

### Product Characteristics

<b>Color</b>	WHITE (WHITE TO OFF-WHITE)	<b>Score</b>	no score
<b>Shape</b>	CAPSULE (CAPSULE)	<b>Size</b>	11mm
<b>Flavor</b>		<b>Imprint Code</b>	ZF;40
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1120-6	60 in 1 BOTTLE; Type 0: Not a Combination Product	09/28/2017	
2	NDC:70771-1120-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	09/28/2017	
3	NDC:70771-1120-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	09/28/2017	
4	NDC:70771-1120-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	09/28/2017	
5	NDC:70771-1120-4	1000 in 1 CARTON	09/28/2017	
5	NDC:70771-1120-2	1 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	ANDA090961	09/28/2017	

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

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

### Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		918596198	ANALYSIS(70771-1119, 70771-1120) , MANUFACTURE(70771-1119, 70771-1120)