

# MEMANTINE HYDROCHLORIDE- memantine hydrochloride capsule, extended release Cadila Healthcare Limited

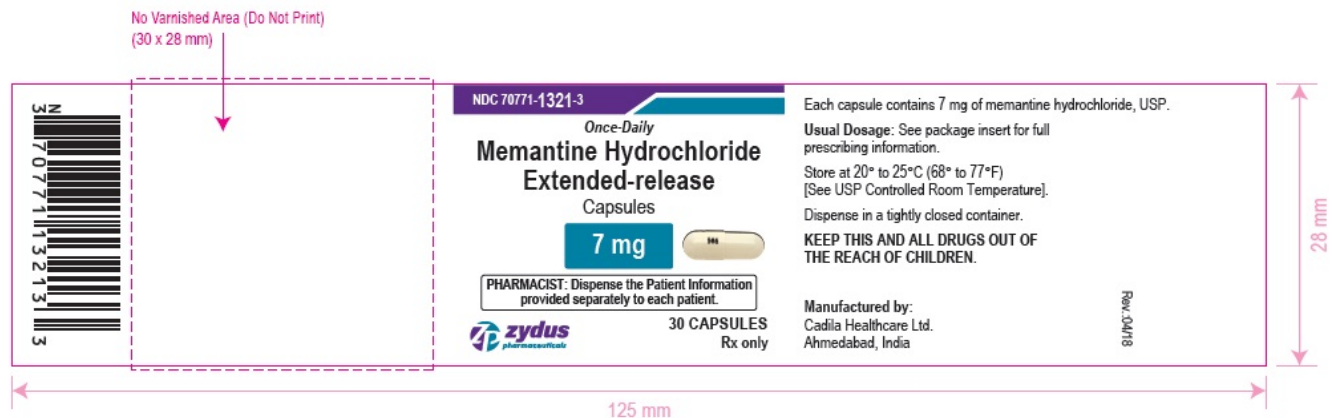
## MEMANTINE HYDROCHLORIDE EXTENDED-RELEASE CAPSULES

### PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Memantine Hydrochloride Extended-release Capsules, 7 mg

NDC 70771-1321-3

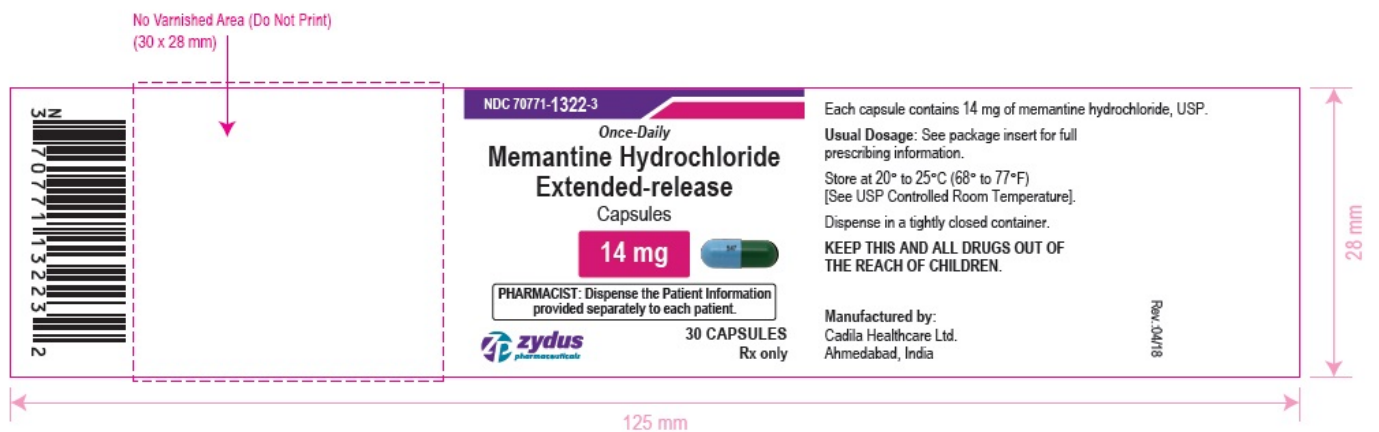
30 Counts



Memantine Hydrochloride Extended-release Capsules, 14 mg

70771-1322-3

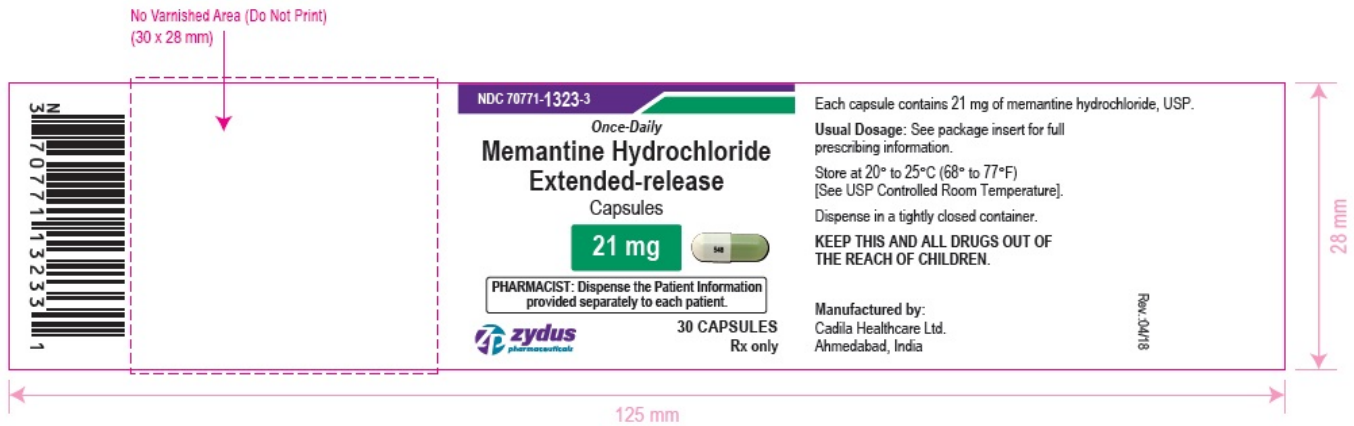
30 Counts



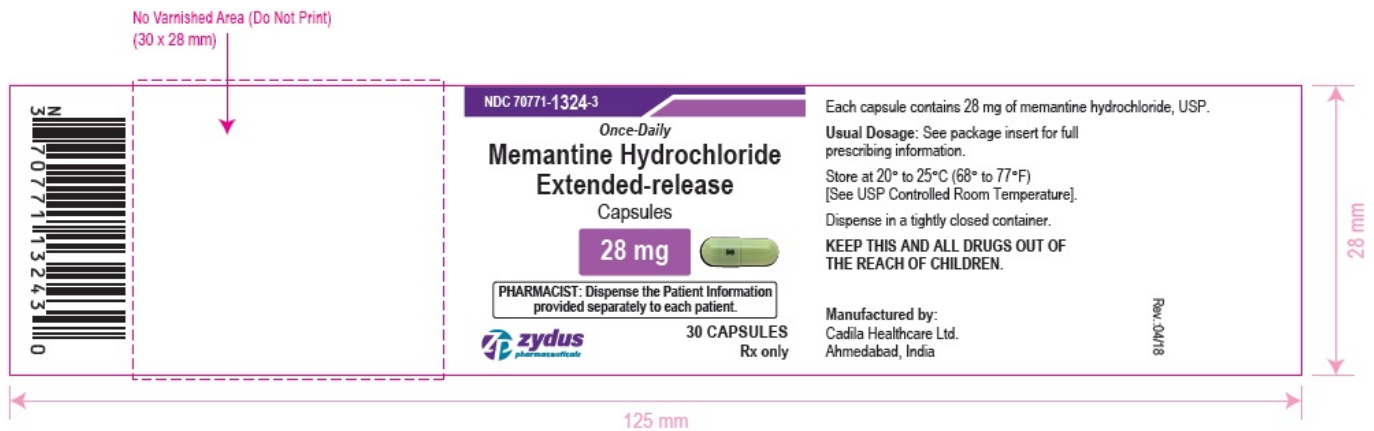
Memantine Hydrochloride Extended-release Capsules, 21 mg

NDC 70771-1323-3

30 Counts



Memantine Hydrochloride Extended-release Capsules, 28 mg  
 NDC 70771-1324-3  
 30 Counts



<b>MEMANTINE HYDROCHLORIDE</b>			
memantine hydrochloride capsule, extended release			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:70771-1321
<b>Route of Administration</b>	ORAL		
<b>Active Ingredient/Active Moiety</b>			
<b>Ingredient Name</b>		<b>Basis of Strength</b>	<b>Strength</b>
MEMANTINE HYDROCHLORIDE (UNII: JY0WD0UA60) (MEMANTINE - UNII:W8O17SJF3T)		MEMANTINE HYDROCHLORIDE	7 mg
<b>Inactive Ingredients</b>			
<b>Ingredient Name</b>			<b>Strength</b>

AMMONIA (UNII: 5138Q19F1X)	
ALCOHOL (UNII: 3K9958V90M)	
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)	
ETHYLCELLULOSE (7 MPA.S) (UNII: HBUP11403C)	
GELATIN (UNII: 2G86QN327L)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SUCROSE (UNII: C151H8M554)	
TALC (UNII: 7SEV7J4R1U)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	

### Product Characteristics

Color	WHITE (WHITE) , WHITE (WHITE)	Score	no score
Shape	CAPSULE (CAPSULE)	Size	14mm
Flavor		Imprint Code	546
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1321-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	04/08/2018	
2	NDC:70771-1321-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	04/08/2018	
3	NDC:70771-1321-4	10 in 1 CARTON	04/08/2018	
3	NDC:70771-1321-2	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	ANDA203293	04/08/2018	

## MEMANTINE HYDROCHLORIDE

memantine hydrochloride capsule, extended release

### Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1322
Route of Administration	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
MEMANTINE HYDROCHLORIDE (UNII: JY0WD0UA60) (MEMANTINE - UNII:W8O17SJF3T)	MEMANTINE HYDROCHLORIDE	14 mg

**Inactive Ingredients**

Ingredient Name	Strength
AMMONIA (UNII: 5138Q19F1X)	
ALCOHOL (UNII: 3K9958V90M)	
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)	
ETHYLCELLULOSE (7 MPA.S) (UNII: H3UP11403C)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 3 (UNII: PN2ZH5LOQY)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
GELATIN (UNII: 2G86QN327L)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SUCROSE (UNII: C151H8M554)	
TALC (UNII: 7SEV7J4R1U)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	

**Product Characteristics**

Color	BLUE (LIGHT-BLUE) , GREEN (GREEN)	Score	no score
Shape	CAPSULE (CAPSULE)	Size	14mm
Flavor		Imprint Code	547
Contains			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1322-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	04/08/2018	
2	NDC:70771-1322-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	04/08/2018	
3	NDC:70771-1322-4	10 in 1 CARTON	04/08/2018	
3	NDC:70771-1322-2	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	ANDA203293	04/08/2018	

# MEMANTINE HYDROCHLORIDE

memantine hydrochloride capsule, extended release

## Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:70771-1323
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MEMANTINE HYDROCHLORIDE (UNII: JY0WD0UA60) (MEMANTINE - UNII:W8O17SJF3T)	MEMANTINE HYDROCHLORIDE	21 mg

## Inactive Ingredients

Ingredient Name	Strength
AMMONIA (UNII: 5138Q19F1X)	
ALCOHOL (UNII: 3K9958V90M)	
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)	
ETHYLCELLULOSE (7 MPA.S) (UNII: H3UP11403C)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
GELATIN (UNII: 2G86QN327L)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SUCROSE (UNII: C151H8M554)	
TALC (UNII: 7SEV7J4R1U)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	

## Product Characteristics

<b>Color</b>	WHITE (WHITE) , GREEN (GREEN)	<b>Score</b>	no score
<b>Shape</b>	CAPSULE (CAPSULE)	<b>Size</b>	14mm
<b>Flavor</b>		<b>Imprint Code</b>	548
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1323-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	04/08/2018	
2	NDC:70771-1323-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	04/08/2018	
3	NDC:70771-1323-4	10 in 1 CARTON	04/08/2018	
3	NDC:70771-1323-2	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	ANDA203293	04/08/2018	

## MEMANTINE HYDROCHLORIDE

memantine hydrochloride capsule, extended release

### Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1324
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MEMANTINE HYDROCHLORIDE (UNII: JY0WD0UA60) (MEMANTINE - UNII:W8O17SJF3T)	MEMANTINE HYDROCHLORIDE	28 mg

### Inactive Ingredients

Ingredient Name	Strength
AMMONIA (UNII: 5138Q19F1X)	
ALCOHOL (UNII: 3K9958V90M)	
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)	
ETHYLCELLULOSE (7 MPA.S) (UNII: H3UP11403C)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
GELATIN (UNII: 2G86QN327L)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SUCROSE (UNII: C151H8M554)	
TALC (UNII: 7SEV7J4R1U)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0K00R)	

## Product Characteristics

<b>Color</b>	GREEN (LIGHT-GREEN) , GREEN (LIGHT-GREEN)	<b>Score</b>	no score
<b>Shape</b>	CAPSULE (CAPSULE)	<b>Size</b>	16mm
<b>Flavor</b>		<b>Imprint Code</b>	549
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1324-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	04/08/2018	
2	NDC:70771-1324-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	04/08/2018	
3	NDC:70771-1324-4	10 in 1 CARTON	04/08/2018	
3	NDC:70771-1324-2	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	ANDA203293	04/08/2018	

**Labeler** - Cadila Healthcare Limited (918596198)

**Registrant** - Cadila Healthcare Limited (918596198)

## Establishment

Name	Address	ID/FEI	Business Operations
Cadila Healthcare Limited		918596198	ANALYSIS(70771-1321, 70771-1322, 70771-1323, 70771-1324) , MANUFACTURE(70771-1321, 70771-1322, 70771-1323, 70771-1324)

Revised: 9/2020

Cadila Healthcare Limited