MEMANTINE HYDROCHLORIDE- memantine hydrochloride capsule, extended release
Zydus Lifesciences 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

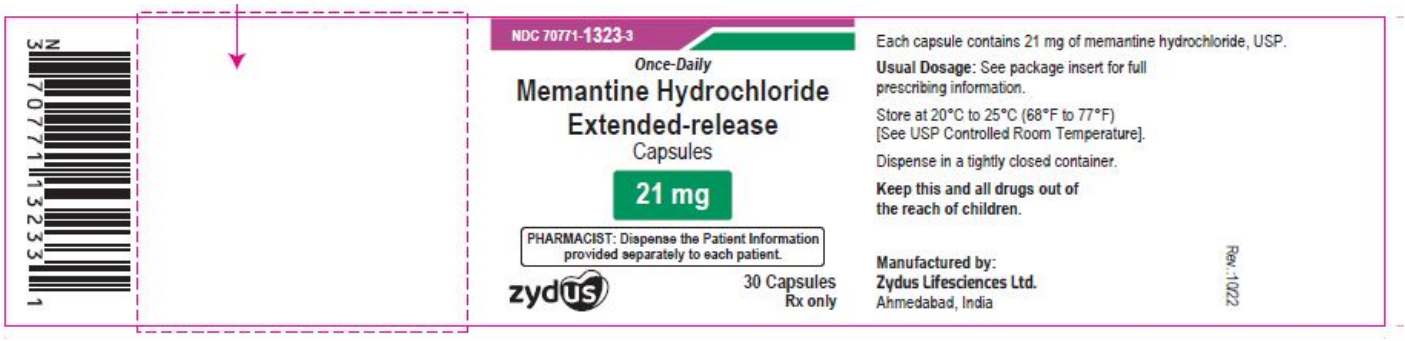
70771-1322-3

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

MEMANTINE HYDROCHLORIDE

memantine hydrochloride capsule, extended release

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1321
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MEMANTINE HYDROCHLORIDE (UNII: JY0WD0UA60) (MEMANTINE - UNII:W8O17SJF3T)	MEMANTINE HYDROCHLORIDE	7 mg

Inactive Ingredients	
Ingredient Name	**Strength**
AMMONIA (UNII: 5138Q19F1X)	
ALCOHOL (UNII: 3K9958V90M)	
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)	
ETHYLCELLULOSE (7 MPA.S) (UNII: H3UP11403C)	
GELATIN (UNII: 2G86QN327L)	

HYPROMELLOSES (UNII: 3NXW29V3WO)	
FERROSOFERRIC 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)	
FERROSOFERRIC 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

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1323
Route of Administration	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)	
FERROSOFERRIC 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

Color	WHITE (WHITE) , GREEN (GREEN)	**Score**	no score
Shape	CAPSULE (CAPSULE)	**Size**	14mm
Flavor		**Imprint Code**	548
Contains			

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)	
FERROSOFERRIC 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

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

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 - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

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