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

MEMANTINE HYDROCHLORIDE TABLETS

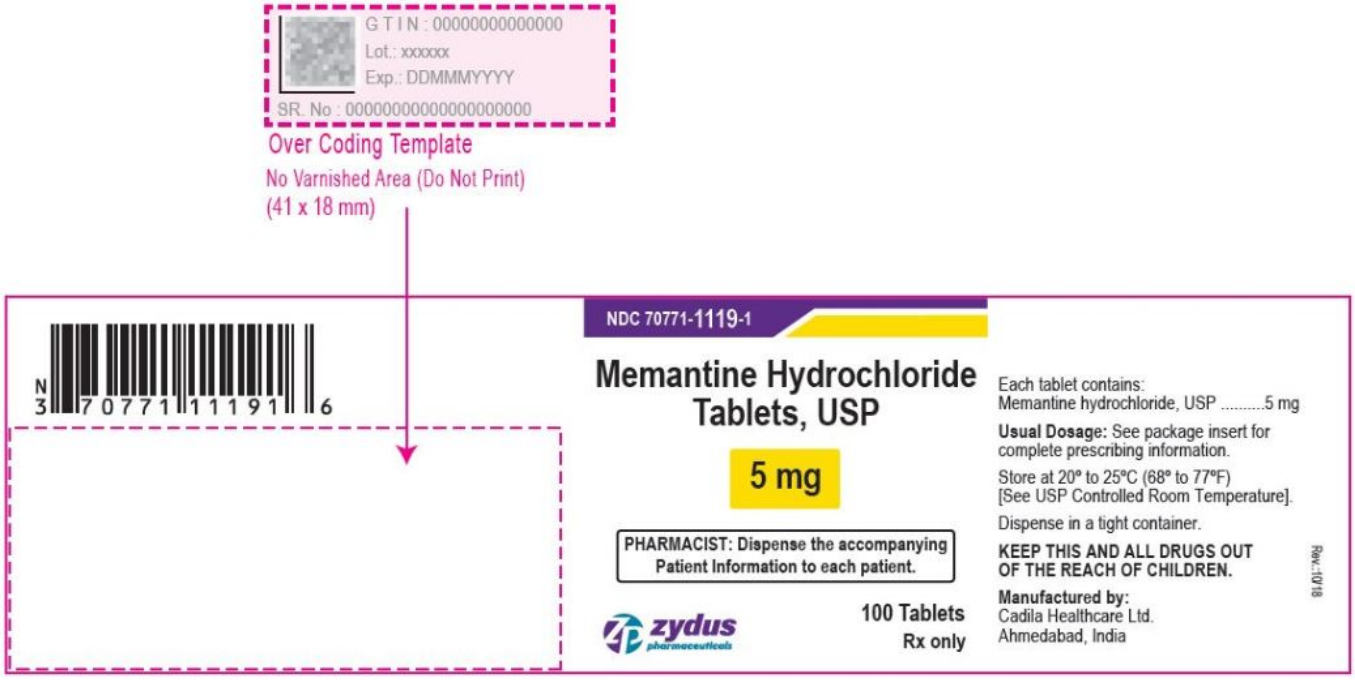
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1119-1 in bottle of 100 tablets

Memantine Hydrochloride Tablets USP, 5 mg

Rx only

100 tablets

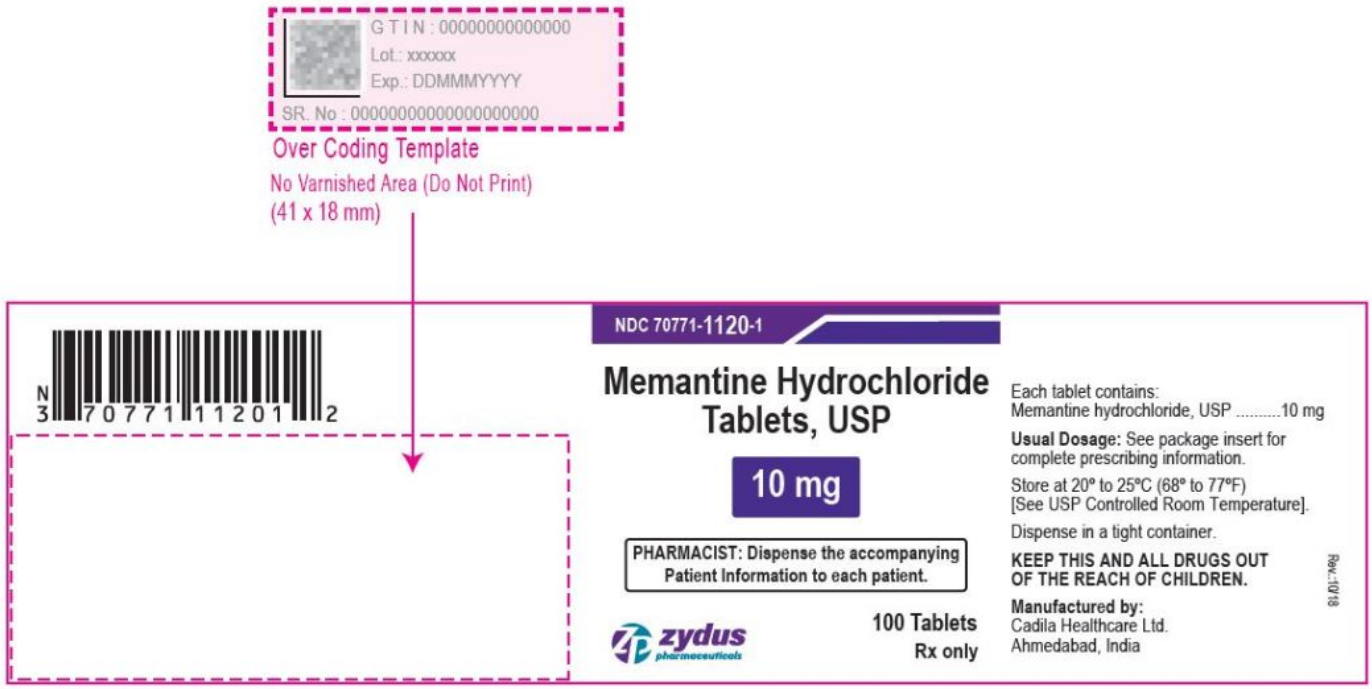


NDC 70771-1120-1 in bottle of 100 tablets

Memantine Hydrochloride Tablets USP, 10 mg

Rx only

100 tablets



MEMANTINE HYDROCHLORIDE

memantine hydrochloride tablet, film coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1119
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MEMANTINE HYDROCHLORIDE (UNII: JY0WD0UA60) (MEMANTINE - UNII:W8O17SJF3T)	MEMANTINE HYDROCHLORIDE	5 mg

Inactive Ingredients	
Ingredient Name	**Strength**
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POVIDONE (UNII: FZ989GH94E)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	

Product Characteristics			
Color	WHITE (WHITE TO OFF-WHITE)	**Score**	no score
Shape	CAPSULE (CAPSULE)	**Size**	9mm
Flavor		**Imprint Code**	ZF;41
Contains			

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

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1120
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	

HYPROMELLOSES (UNII: 3NXW29V3WO)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POVIDONE (UNII: FZ989GH94E)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	

Product Characteristics

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

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)