

MEMANTINE HYDROCHLORIDE- memantine hydrochloride tablet, film coated
Cadila Healthcare Limited

MEMANTINE HYDROCHLORIDE TABLETS

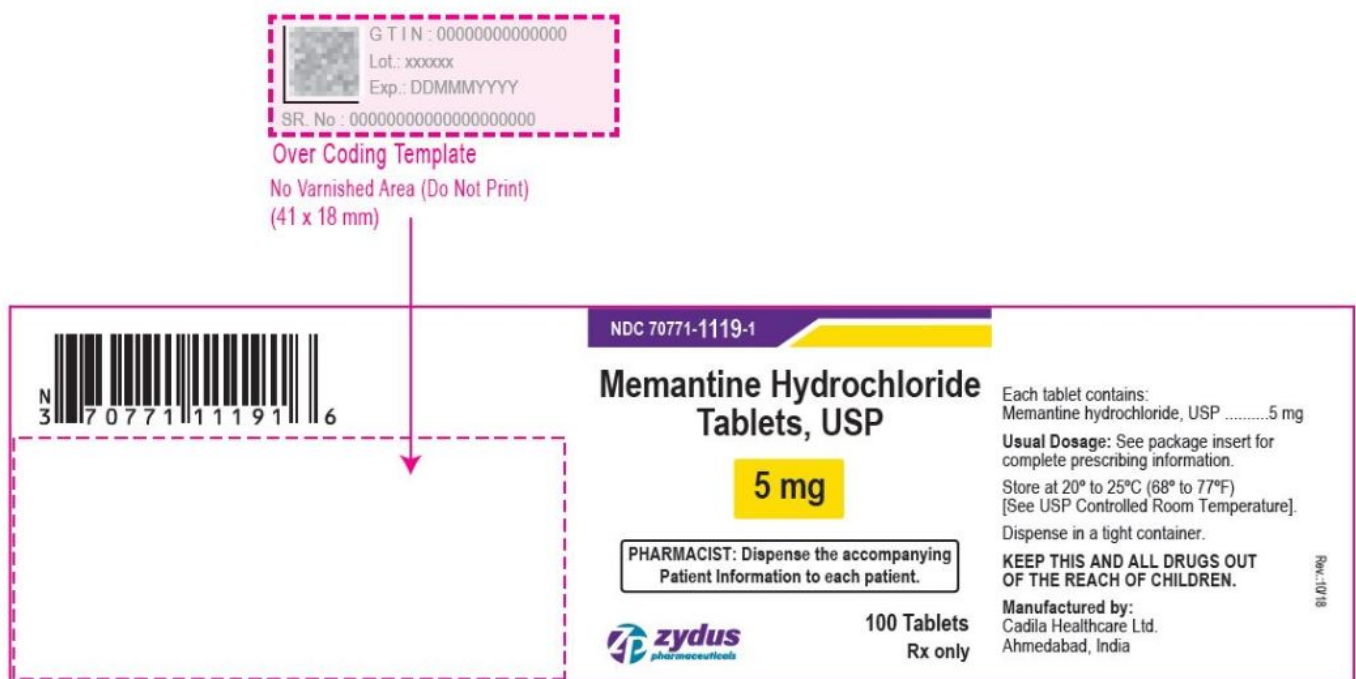
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

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



Over Coding Template
 No Varnished Area (Do Not Print)
 (41 x 18 mm)



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NDC 70771-1120-1

Memantine Hydrochloride Tablets, USP

10 mg

Each tablet contains:
 Memantine hydrochloride, USP10 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.

Manufactured by:
 Cadila Healthcare Ltd.
 Ahmedabad, India

PHARMACIST: Dispense the accompanying Patient Information to each patient.



100 Tablets
Rx only

Rev:10/18

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: 3WJQ0SDW1A)	

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)	
CROSCARMELOSE 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: 3WJQ0SDW1A)

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 - Cadila Healthcare Limited (918596198)

Registrant - Cadila Healthcare Limited (918596198)

Establishment

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

Revised: 9/2020

Cadila Healthcare Limited