

AMITRIPTYLINE HYDROCHLORIDE- amitriptyline hydrochloride tablet, film coated
Cadila Healthcare Limited

Amitriptyline Hydrochloride Tablets, USP

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1173-1 in bottle of 100 Tablets

Amitriptyline Hydrochloride Tablets USP, 10 mg

Rx only

100 Tablets



NDC 70771-1174-1 in bottle of 100 Tablets

Amitriptyline Hydrochloride Tablets USP, 25 mg

Rx only

100 Tablets



NDC 70771-1175-1 in bottle of 100 Tablets
 Amitriptyline Hydrochloride Tablets USP, 50 mg
 Rx only
 100 Tablets



NDC 70771-1176-1 in bottle of 100 Tablets
 Amitriptyline Hydrochloride Tablets USP, 75 mg
 Rx only
 100 Tablets



NDC 70771-1177-1 in bottle of 100 Tablets
 Amitriptyline Hydrochloride Tablets USP, 100 mg
 Rx only
 100 Tablets



NDC 70771-1178-1 in bottle of 100 Tablets
 Amitriptyline Hydrochloride Tablets USP, 150 mg
 Rx only
 100 Tablets



AMITRIPTYLINE HYDROCHLORIDE

amitriptyline hydrochloride tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1173
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AMITRIPTYLINE HYDROCHLORIDE (UNII: 26LUD4JO9K) (AMITRIPTYLINE - UNII:1806D8D52K)	AMITRIPTYLINE HYDROCHLORIDE	10 mg

Inactive Ingredients

Ingredient Name	Strength
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
POLYETHYLENE GLYCOL 8000 (UNII: Q662QK8M3B)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics

Color	WHITE (OFF-WHITE)	Score	no score
Shape	ROUND (ROUND)	Size	5mm
Flavor		Imprint Code	ZA;1
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1173-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	12/26/2017	
2	NDC:70771-1173-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	12/26/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA210086	12/26/2017	

AMITRIPTYLINE HYDROCHLORIDE

amitriptyline hydrochloride tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1174
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AMITRIPTYLINE HYDROCHLORIDE (UNII: 26LUD4JO9K) (AMITRIPTYLINE - UNII:1806D8D52K)	AMITRIPTYLINE HYDROCHLORIDE	25 mg

Inactive Ingredients

Ingredient Name	Strength
LACTOSE MONOHYDRATE (UNII: EWQ57Q815X)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
HYPROMELLOSE 2910 (6 MPAS) (UNII: 0WZ8WG20P6)	
POLYETHYLENE GLYCOL 8000 (UNII: Q662QK8M3B)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
ALUMINUM OXIDE (UNII: LM26O6933)	

Product Characteristics

Color	GREEN (LIGHT GREEN)	Score	no score
Shape	ROUND (ROUND)	Size	6mm
Flavor		Imprint Code	ZA;2
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1174-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	12/26/2017	
2	NDC:70771-1174-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	12/26/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA210086	12/26/2017	

AMITRIPTYLINE HYDROCHLORIDE

amitriptyline hydrochloride tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1175
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AMITRIPTYLINE HYDROCHLORIDE (UNII: 26LUD4JO9K) (AMITRIPTYLINE - UNII:1806D8D52K)	AMITRIPTYLINE HYDROCHLORIDE	50 mg

Inactive Ingredients

Ingredient Name	Strength
ALUMINUM OXIDE (UNII: LM26O6933)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
HYPROMELLOSE 2910 (6 MPAS) (UNII: 0WZ8WG20P6)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL 8000 (UNII: Q662QK8M3B)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	

TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	BROWN (BROWN)	Score	no score
Shape	ROUND (ROUND)	Size	8mm
Flavor		Imprint Code	ZA;3
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1175-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	12/26/2017	
2	NDC:70771-1175-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	12/26/2017	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA210086	12/26/2017	

AMITRIPTYLINE HYDROCHLORIDE

amitriptyline hydrochloride tablet, film coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1176
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
AMITRIPTYLINE HYDROCHLORIDE (UNII: 26LUD4JO9K) (AMITRIPTYLINE - UNII:1806D8D52K)	AMITRIPTYLINE HYDROCHLORIDE	75 mg

Inactive Ingredients	
Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
HYPROMELLOSE 2910 (6 MPAS) (UNII: 0WZ8WG20P6)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL 8000 (UNII: Q662QK8M3B)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

STARCH, CORN (UNII: O8232NY3SJ)

TALC (UNII: 7SEV7J4R1U)

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

Product Characteristics

Color	BLUE (LIGHT BLUE)	Score	no score
Shape	ROUND (ROUND)	Size	11mm
Flavor		Imprint Code	12;28
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1176-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	12/26/2017	
2	NDC:70771-1176-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	12/26/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA210086	12/26/2017	

AMITRIPTYLINE HYDROCHLORIDE

amitriptyline hydrochloride tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1177
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AMITRIPTYLINE HYDROCHLORIDE (UNII: 26LUD4JO9K) (AMITRIPTYLINE - UNII:1806D8D52K)	AMITRIPTYLINE HYDROCHLORIDE	100 mg

Inactive Ingredients

Ingredient Name	Strength
ALUMINUM OXIDE (UNII: LM26O6933)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
HYPROMELLOSE 2910 (6 MPAS) (UNII: 0WZ8WG20P6)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

POLYETHYLENE GLYCOL 8000 (UNII: Q662QK8M3B)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	ORANGE (ORANGE)	Score	no score
Shape	ROUND (ROUND)	Size	11mm
Flavor		Imprint Code	12;29
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1177-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	12/26/2017	
2	NDC:70771-1177-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	12/26/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA210086	12/26/2017	

AMITRIPTYLINE HYDROCHLORIDE

amitriptyline hydrochloride tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1178
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AMITRIPTYLINE HYDROCHLORIDE (UNII: 26LUD4JO9K) (AMITRIPTYLINE - UNII:1806D8D52K)	AMITRIPTYLINE HYDROCHLORIDE	150 mg

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	

MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL 8000 (UNII: Q662QK8M3B)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	WHITE (CREAM TO BEIGE)	Score	no score
Shape	CAPSULE (MODIFIED CAPSULE)	Size	17mm
Flavor		Imprint Code	1230
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1178-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	12/26/2017	
2	NDC:70771-1178-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	12/26/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA210086	12/26/2017	

Labeler - Cadila Healthcare Limited (918596198)

Registrant - Cadila Healthcare Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Cadila Healthcare Limited		863362789	ANALYSIS(70771-1173, 70771-1174, 70771-1175, 70771-1176, 70771-1177, 70771-1178) , MANUFACTURE(70771-1173, 70771-1174, 70771-1175, 70771-1176, 70771-1177, 70771-1178)

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Cadila Healthcare Limited