ROPINIROLE HYDROCHLORIDE- ropinirole hydrochloride tablet, film coated
Cadila Healthcare Limited

ROPINIROLE TABELTS

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 65841-712-01 in bottle of 100 tablets

Ropinirole Hydrochloride Tablets, 0.25 mg

100 tablets

NDC 65841-713-01 in bottle of 100 tablets

Ropinirole Hydrochloride Tablets, 0.5 mg

100 tablets

NDC 65841-714-01 in bottle of 100 tablets

Ropinirole Hydrochloride Tablets, 1 mg

100 tablets

NDC 65841-715-01in bottle of 100 tablets

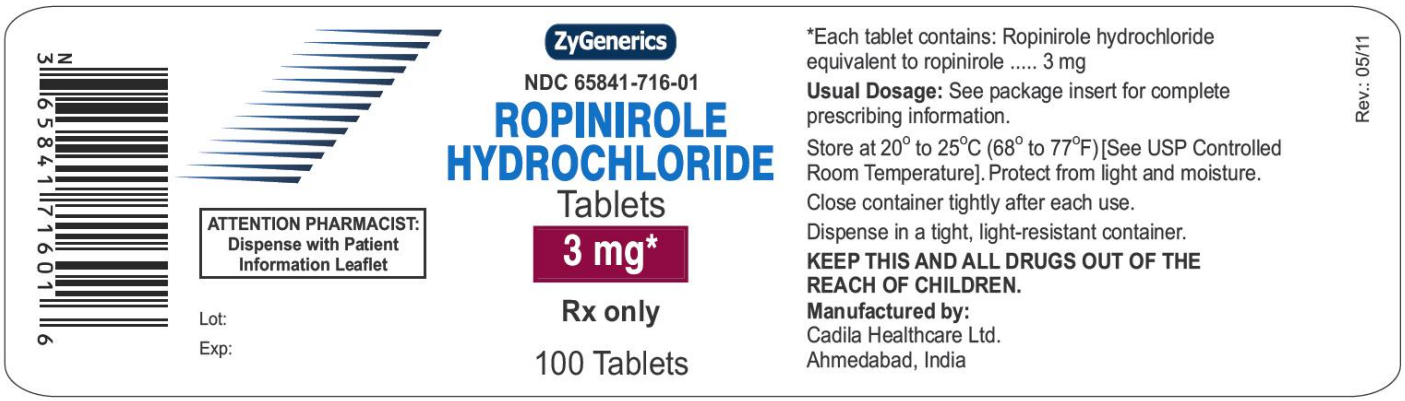
Ropinirole Hydrochloride Tablets, 2 mg

100 tablets

NDC 65841-716-01 in bottle of 100 tablets

Ropinirole Hydrochloride Tablets, 3 mg

100 tablets



NDC 65841-717-01 in bottle of 100 tablets

Ropinirole Hydrochloride Tablets, 4 mg

100 tablets

NDC 65841-718-01 in bottle of 100 tablets

Ropinirole Hydrochloride Tablets, 5 mg

100 tablets

ROPINIROLE HYDROCHLORIDE

ropinirole hydrochloride tablet, film coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-712
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ROPINIROLE HYDROCHLORIDE (UNII: D7ZD41RZI9) (ROPINIROLE - UNII:030PYR8953)	ROPINIROLE	0.25 mg

Inactive Ingredients	
Ingredient Name	**Strength**
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	

HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	

Product Characteristics

Color	WHITE (WHITE)	**Score**	no score
Shape	ROUND (ROUND)	**Size**	7mm
Flavor		**Imprint Code**	ZF22
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-712-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	09/23/2009	
2	NDC:65841-712-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	09/23/2009	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090411	09/23/2009	

ROPINIROLE HYDROCHLORIDE

ropinirole hydrochloride tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-713
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ROPINIROLE HYDROCHLORIDE (UNII: D7ZD41RZI9) (ROPINIROLE - UNII:030PYR8953)	ROPINIROLE	0.5 mg

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	

Product Characteristics			
Color	YELLOW (YELLOW)	**Score**	no score
Shape	ROUND (ROUND)	**Size**	7mm
Flavor		**Imprint Code**	ZF23
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-713-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	09/23/2009	
2	NDC:65841-713-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	09/23/2009	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090411	09/23/2009	

ROPINIROLE HYDROCHLORIDE

ropinirole hydrochloride tablet, film coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-714
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ROPINIROLE HYDROCHLORIDE (UNII: D7ZD41RZI9) (ROPINIROLE - UNII:030PYR8953)	ROPINIROLE	1 mg

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	

Product Characteristics			
Color	GREEN (GREEN)	**Score**	no score
Shape	ROUND (ROUND)	**Size**	7mm
Flavor		**Imprint Code**	ZF24
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-714-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	09/23/2009	
2	NDC:65841-714-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	09/23/2009	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090411	09/23/2009	

ROPINIROLE HYDROCHLORIDE

ropinirole hydrochloride tablet, film coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-715
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ROPINIROLE HYDROCHLORIDE (UNII: D7ZD41RZI9) (ROPINIROLE - UNII:030PYR8953)	ROPINIROLE	2 mg

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	

Product Characteristics			
Color	PINK (PINK)	**Score**	no score
Shape	ROUND (ROUND)	**Size**	7mm
Flavor		**Imprint Code**	ZF25
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:65841-715-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	09/23/2009	
2	NDC:65841-715-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	09/23/2009	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090411	09/23/2009	

ROPINIROLE HYDROCHLORIDE

ropinirole hydrochloride tablet, film coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-716
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ROPINIROLE HYDROCHLORIDE (UNII: D7ZD41RZI9) (ROPINIROLE - UNII:030PYR8953)	ROPINIROLE	3 mg

Inactive Ingredients	
Ingredient Name	**Strength**
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CARMINIC ACID (UNII: CID8Z8N95N)	

Product Characteristics			
Color	PURPLE (PURPLE)	**Score**	no score
Shape	ROUND (ROUND)	**Size**	7mm
Flavor		**Imprint Code**	ZF42
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:65841-716-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	09/23/2009	
2	NDC:65841-716-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	09/23/2009	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090411	09/23/2009	

ROPINIROLE HYDROCHLORIDE

ropinirole hydrochloride tablet, film coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-717
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ROPINIROLE HYDROCHLORIDE (UNII: D7ZD41RZI9) (ROPINIROLE - UNII:030PYR8953)	ROPINIROLE	4 mg

Inactive Ingredients	
Ingredient Name	**Strength**
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	

Product Characteristics

Color	BROWN (BROWN)	**Score**	no score
Shape	ROUND (ROUND)	**Size**	7mm
Flavor		**Imprint Code**	ZF43
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-717-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	09/23/2009	
2	NDC:65841-717-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	09/23/2009	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090411	09/23/2009	

ROPINIROLE HYDROCHLORIDE

ropinirole hydrochloride tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-718
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ROPINIROLE HYDROCHLORIDE (UNII: D7ZD41RZI9) (ROPINIROLE - UNII:030PYR8953)	ROPINIROLE	5 mg

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	

Product Characteristics

Color	BLUE (BLUE)	**Score**	no score
Shape	ROUND (ROUND)	**Size**	7mm
Flavor		**Imprint Code**	ZF26

Contains	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-718-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	09/23/2009	
2	NDC:65841-718-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	09/23/2009	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090411	09/23/2009	

Labeler - Cadila Healthcare Limited (918596198)

Registrant - Cadila Healthcare Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Cadila Healthcare Limited		918596198	ANALYSIS(65841-712, 65841-713, 65841-714, 65841-715, 65841-716, 65841-717, 65841-718) , MANUFACTURE(65841-712, 65841-713, 65841-714, 65841-715, 65841-716, 65841-717, 65841-718)

Revised: 9/2020 Cadila Healthcare Limited