

ROPINIROLE HYDROCHLORIDE - ropinirole hydrochloride tablet, film coated
Zydus Lifesciences Limited

ROPINIROLE TABLETS

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 65841-712-01 in bottle of 100 tablets

Ropinirole Hydrochloride Tablets, 0.25 mg

100 tablets

ZyGenerics
NDC 65841-712-01
**ROPINIROLE
HYDROCHLORIDE**
Tablets
0.25 mg*
Rx only
100 Tablets

ATTENTION PHARMACIST:
Dispense with Patient
Information Leaflet

Lot:
Exp:

*Each tablet contains: Ropinirole hydrochloride equivalent to ropinirole 0.25 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]. Protect from light and moisture. Close container tightly after each use. Dispense in a tight, light-resistant container.
KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.
Manufactured by:
Cadila Healthcare Ltd.
Ahmedabad, India

Rev.: 05/11

NDC 65841-713-01 in bottle of 100 tablets

Ropinirole Hydrochloride Tablets, 0.5 mg

100 tablets

ZyGenerics
NDC 65841-713-01
**ROPINIROLE
HYDROCHLORIDE**
Tablets
0.5 mg*
Rx only
100 Tablets

ATTENTION PHARMACIST:
Dispense with Patient
Information Leaflet

Lot:
Exp:

*Each tablet contains: Ropinirole hydrochloride equivalent to ropinirole 0.5 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]. Protect from light and moisture. Close container tightly after each use. Dispense in a tight, light-resistant container.
KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.
Manufactured by:
Cadila Healthcare Ltd.
Ahmedabad, India

Rev.: 05/11

NDC 65841-714-01 in bottle of 100 tablets

Ropinirole Hydrochloride Tablets, 1 mg

100 tablets

The label features a barcode on the left with the number 31658411714012 printed vertically. To the right of the barcode is a box with the text "ATTENTION PHARMACIST: Dispense with Patient Information Leaflet". Below this box are the fields "Lot:" and "Exp:". The central part of the label displays the ZyGenerics logo, the NDC number 65841-714-01, and the product name "ROPINIROLE HYDROCHLORIDE Tablets" in large blue letters. Below the name is a dark blue box containing "1 mg*" in white, followed by "Rx only" and "100 Tablets". On the right side, there is a vertical line of text "Rev.: 05/11".

ZyGenerics
NDC 65841-714-01
**ROPINIROLE
HYDROCHLORIDE**
Tablets
1 mg*
Rx only
100 Tablets

*Each tablet contains: Ropinirole hydrochloride equivalent to ropinirole 1 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]. Protect from light and moisture.
Close container tightly after each use.
Dispense in a tight, light-resistant container.
KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.
Manufactured by:
Cadila Healthcare Ltd.
Ahmedabad, India

Rev.: 05/11

NDC 65841-715-01 in bottle of 100 tablets

Ropinirole Hydrochloride Tablets, 2 mg

100 tablets

The label features a barcode on the left with the number 31658411715019 printed vertically. To the right of the barcode is a box with the text "ATTENTION PHARMACIST: Dispense with Patient Information Leaflet". Below this box are the fields "Lot:" and "Exp:". The central part of the label displays the ZyGenerics logo, the NDC number 65841-715-01, and the product name "ROPINIROLE HYDROCHLORIDE Tablets" in large blue letters. Below the name is a purple box containing "2 mg*" in white, followed by "Rx only" and "100 Tablets". On the right side, there is a vertical line of text "Rev.: 05/11".

ZyGenerics
NDC 65841-715-01
**ROPINIROLE
HYDROCHLORIDE**
Tablets
2 mg*
Rx only
100 Tablets

*Each tablet contains: Ropinirole hydrochloride equivalent to ropinirole 2 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]. Protect from light and moisture.
Close container tightly after each use.
Dispense in a tight, light-resistant container.
KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.
Manufactured by:
Cadila Healthcare Ltd.
Ahmedabad, India

Rev.: 05/11

NDC 65841-716-01 in bottle of 100 tablets

Ropinirole Hydrochloride Tablets, 3 mg

100 tablets




NDC 65841-716-01

**ROPINIROLE
HYDROCHLORIDE**
Tablets

3 mg*

Rx only

100 Tablets

ATENTION PHARMACIST:
Dispense with Patient
Information Leaflet

Lot:
Exp:

*Each tablet contains: Ropinirole hydrochloride equivalent to ropinirole 3 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]. Protect from light and moisture.
Close container tightly after each use.
Dispense in a tight, light-resistant container.
KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.
Manufactured by:
Cadila Healthcare Ltd.
Ahmedabad, India

Rev.: 05/11

NDC 65841-717-01 in bottle of 100 tablets
Ropinirole Hydrochloride Tablets, 4 mg
100 tablets




NDC 65841-717-01

**ROPINIROLE
HYDROCHLORIDE**
Tablets

4 mg*

Rx only

100 Tablets

ATENTION PHARMACIST:
Dispense with Patient
Information Leaflet

Lot:
Exp:

*Each tablet contains: Ropinirole hydrochloride equivalent to ropinirole 4 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]. Protect from light and moisture.
Close container tightly after each use.
Dispense in a tight, light-resistant container.
KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.
Manufactured by:
Cadila Healthcare Ltd.
Ahmedabad, India

Rev.: 05/11

NDC 65841-718-01 in bottle of 100 tablets
Ropinirole Hydrochloride Tablets, 5 mg
100 tablets




NDC 65841-718-01

**ROPINIROLE
HYDROCHLORIDE**
Tablets

5 mg*

Rx only

100 Tablets

ATENTION PHARMACIST:
Dispense with Patient
Information Leaflet

Lot:
Exp:

*Each tablet contains: Ropinirole hydrochloride equivalent to ropinirole 5 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]. Protect from light and moisture.
Close container tightly after each use.
Dispense in a tight, light-resistant container.
KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.
Manufactured by:
Cadila Healthcare Ltd.
Ahmedabad, India

Rev.: 05/11

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: D7ZD41RZ19) (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: D7ZD41RZ19) (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
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ANDA	ANDA090411	09/23/2009
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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: D7ZD41RZ19) (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: D7ZD41RZ19) (ROPINIROLE - UNII:030PYR8953)	ROPINIROLE	2 mg

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELOSE 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: D7ZD41RZ19) (ROPINIROLE - UNII:030PYR8953)	ROPINIROLE	3 mg

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELOSE 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-	1000 in 1 BOTTLE; Type 0: Not a Combination	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: D7ZD41RZ19) (ROPINIROLE - UNII:030PYR8953)	ROPINIROLE	4 mg

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELOSE 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)	
FERROSFERRIC 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	Marketing End
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#	Item Code	Package Description	Date	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: D7ZD41RZ19) (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 - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences 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: 11/2022

Zydus Lifesciences Limited