

PRAMIPEXOLE DIHYDROCHLORIDE- pramipexole dihydrochloride tablet
Cadila Healthcare Limited

PRAMIPEXOLE DIHYDROCHLORIDE TABLETS

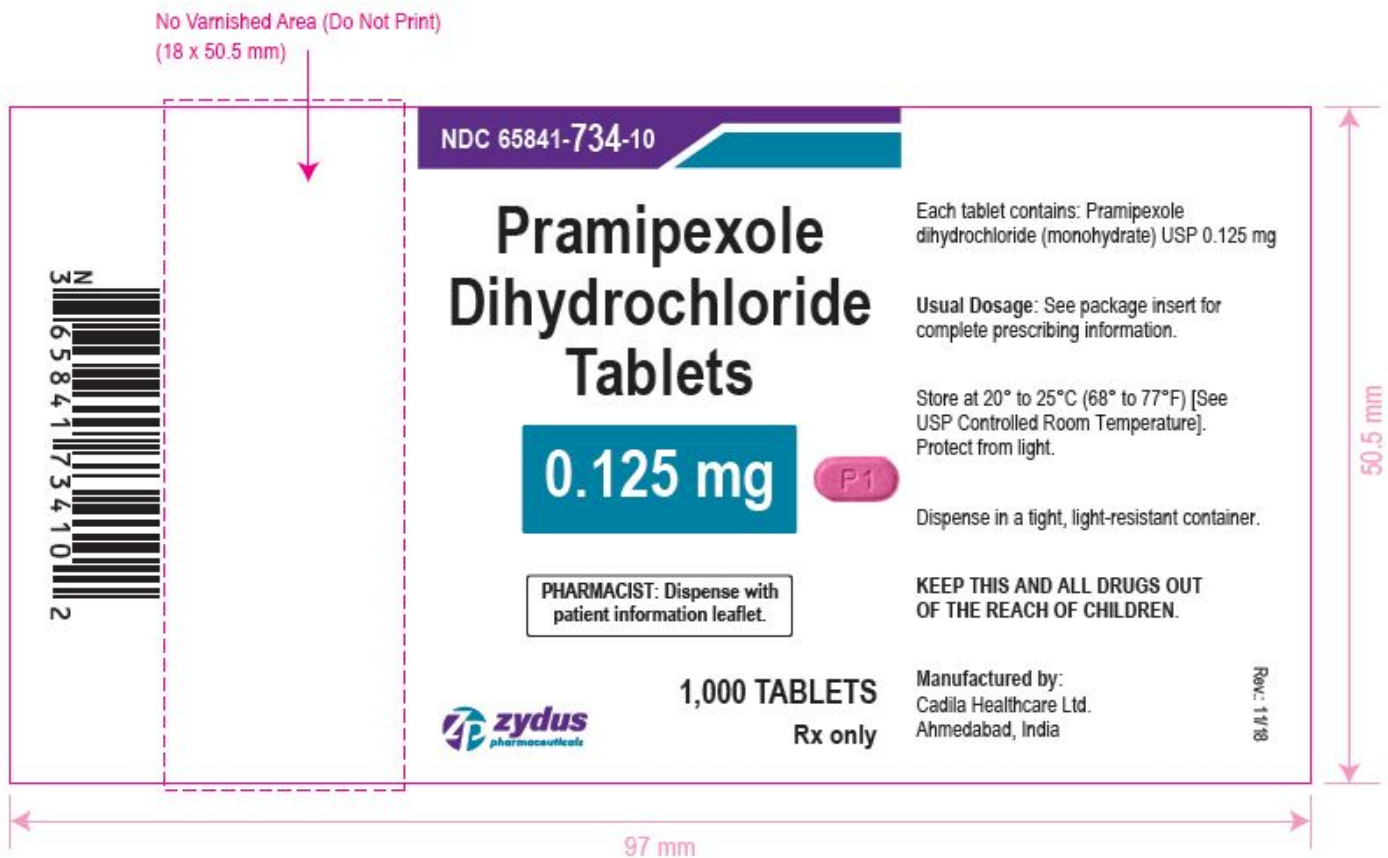
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 65841-734-16 in bottle of 90 tablets

Pramipexole Dihydrochloride Tablets, 0.125 mg

Rx only

90 tablets



NDC 65841-735-16 in bottle of 90 tablets

Pramipexole Dihydrochloride Tablets, 0.25 mg

Rx only

90 tablets

No Varnished Area (Do Not Print)
(18 x 50.5 mm)

NDC 65841-735-10

**Pramipexole
Dihydrochloride
Tablets**

Each tablet contains: Pramipexole dihydrochloride (monohydrate) USP 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.

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: 1/18

PHARMACIST: Dispense with patient information leaflet.

1,000 TABLETS
Rx only

zydus
pharmaceuticals

3
N
6584173510
9

97 mm

50.5 mm

NDC 65841-736-16 in bottle of 90 tablets

Pramipexole Dihydrochloride Tablets, 0.5 mg

Rx only

90 tablets

No Varnished Area (Do Not Print)
(18 x 50.5 mm)

NDC 65841-736-10

Pramipexole Dihydrochloride Tablets

0.5 mg

**PHARMACIST: Dispense with
patient information leaflet.**

1,000 TABLETS
Rx only

zydus
pharmaceuticals

Each tablet contains: Pramipexole dihydrochloride (monohydrate) USP 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.

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: 14/18

97 mm

50.5 mm

NDC 65841-737-16 in bottle of 90 tablets
Pramipexole Dihydrochloride Tablets, 1 mg
Rx only
90 tablets

No Varnished Area (Do Not Print)
(18 x 50.5 mm)

NDC 65841-737-10

**Pramipexole
Dihydrochloride
Tablets**

Each tablet contains: Pramipexole dihydrochloride (monohydrate) USP 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.

Dispense in a tight, light-resistant container.

KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.

PHARMACIST: Dispense with patient information leaflet.

1 mg

1,000 TABLETS
Rx only

Manufactured by:
Cadila Healthcare Ltd.
Ahmedabad, India

Rev.: 11/18

zydus
pharmaceuticals

3
N
65841737101
3

97 mm

50.5 mm

NDC 65841-738-16 in bottle of 90 tablets
 Pramipexole Dihydrochloride Tablets, 1.5 mg
 Rx only
 90 tablets

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

NDC 65841-738-16

**Pramipexole
Dihydrochloride
Tablets**

Each tablet contains: Pramipexole dihydrochloride (monohydrate) USP 1.5 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.

Dispense in a tight, light-resistant container.

KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.

PHARMACIST: Dispense with patient information leaflet.

1.5 mg

90 TABLETS
Rx only

Manufactured by:
Cadila Healthcare Ltd.
Ahmedabad, India

Rev.: 11/18

zydus
pharmaceuticals

3
N
6584173816
2

95 mm

41 mm

PRAMIPEXOLE DIHYDROCHLORIDE

pramipexole dihydrochloride tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:65841-734
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PRAMIPEXOLE DIHYDROCHLORIDE (UNII: 3D867NP06J) (PRAMIPEXOLE - UNII:83619PEU5T)	PRAMIPEXOLE DIHYDROCHLORIDE	0.125 mg

Inactive Ingredients

Ingredient Name	Strength
D&C RED NO. 27 (UNII: 2LRS185U6K)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
POVIDONE (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Product Characteristics

Color	PINK (PINK)	Score	no score
Shape	CAPSULE (CAPSULE)	Size	7mm
Flavor		Imprint Code	P1
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-734-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	07/10/2010	
2	NDC:65841-734-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	07/10/2010	
3	NDC:65841-734-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	07/10/2010	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078920	07/10/2010	

PRAMIPEXOLE DIHYDROCHLORIDE

pramipexole dihydrochloride tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:65841-735
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PRAMIPEXOLE DIHYDROCHLORIDE (UNII: 3D867NP06J) (PRAMIPEXOLE - UNII:83619PEU5T)	PRAMIPEXOLE DIHYDROCHLORIDE	0.25 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
POVIDONE (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Product Characteristics

Color	BLUE (PALE BLUE)	Score	2 pieces
Shape	ROUND (ROUND)	Size	6 mm
Flavor		Imprint Code	P2
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-735-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	07/10/2010	
2	NDC:65841-735-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	07/10/2010	
3	NDC:65841-735-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	07/10/2010	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078920	07/10/2010	

PRAMIPEXOLE DIHYDROCHLORIDE

pramipexole dihydrochloride tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:65841-736
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Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PRAMIPEXOLE DIHYDROCHLORIDE (UNII: 3D867NP06J) (PRAMIPEXOLE - UNII:83619PEU5T)	PRAMIPEXOLE DIHYDROCHLORIDE	0.5 mg

Inactive Ingredients

Ingredient Name	Strength
D&C RED NO. 27 (UNII: 2LRS185U6K)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
POVIDONE (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Product Characteristics

Color	PURPLE (LAVENDER)	Score	2 pieces
Shape	CAPSULE (CAPSULE)	Size	8mm
Flavor		Imprint Code	P;3
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-736-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	07/10/2010	
2	NDC:65841-736-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	07/10/2010	
3	NDC:65841-736-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	07/10/2010	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078920	07/10/2010	

PRAMIPEXOLE DIHYDROCHLORIDE

pramipexole dihydrochloride tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:65841-737
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PRAMIPEXOLE DIHYDROCHLORIDE (UNII: 3D867NP06J) (PRAMIPEXOLE - UNII:83619PEU5T)	PRAMIPEXOLE DIHYDROCHLORIDE	1 mg

Inactive Ingredients

Ingredient Name	Strength
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
POVIDONE (UNII: FZ989GH94E)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
STARCH, CORN (UNII: O8232NY3SJ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Product Characteristics

Color	ORANGE (LIGHT PEACH TO PEACH)	Score	2 pieces
Shape	ROUND (ROUND)	Size	6mm
Flavor		Imprint Code	P4
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-737-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	07/10/2010	
2	NDC:65841-737-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	07/10/2010	
3	NDC:65841-737-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	07/10/2010	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078920	07/10/2010	

PRAMIPEXOLE DIHYDROCHLORIDE

pramipexole dihydrochloride tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:65841-738
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PRAMIPEXOLE DIHYDROCHLORIDE (UNII: 3D867NP06J) (PRAMIPEXOLE - UNII:83619PEU5T)	PRAMIPEXOLE DIHYDROCHLORIDE	1.5 mg

Inactive Ingredients

Ingredient Name	Strength
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
POVIDONE (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Product Characteristics

Color	YELLOW (YELLOW)	Score	2 pieces
Shape	ROUND (ROUND)	Size	7mm
Flavor		Imprint Code	P5
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-738-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	07/10/2010	
2	NDC:65841-738-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	07/10/2010	
3	NDC:65841-738-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	07/10/2010	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078920	07/10/2010	

Labeler - Cadila Healthcare Limited (918596198)

Registrant - Cadila Healthcare Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Cadila Healthcare Limited		918596198	ANALYSIS(65841-734, 65841-735, 65841-736, 65841-737, 65841-738) , MANUFACTURE(65841-734, 65841-735, 65841-736, 65841-737, 65841-738)