

**PRAMIPEXOLE DIHYDROCHLORIDE - pramipexole dihydrochloride tablet,
extended release
Zydus Lifesciences Limited**

PRAMIPEXOLE DIHYDROCHLORIDE EXTENDED-RELEASE TABLETS

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1328-3

Pramipexole Dihydrochloride Extended-release Tablets, 0.375 mg

R_x only

30 tablets

ZyGenerics
NDC 70771-1328-3
Once Daily

**Pramipexole
Dihydrochloride
Extended-release
Tablets**

0.375 mg

Each extended-release tablet contains 0.375 mg of pramipexole dihydrochloride, USP (Monohydrate)

Usual Dosage: See package insert for complete prescribing information. Tablets must be swallowed whole and must not be chewed, crushed, or divided.

Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].

Protect from exposure to high humidity.

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

Dispense in this ORIGINAL Unit of Use container.

PHARMACIST: Dispense the Patient Information provided separately to each patient

Rx only
30 Tablets

Manufactured by:
Cadila Healthcare Ltd.
Ahmedabad, India

Lot:
Exp:
Rev.: 04/18

NDC 70771-1329-3

Pramipexole Dihydrochloride Extended-release Tablets, 0.75 mg

R_x only

30 tablets

ZyGenerics
NDC 70771-1329-3
Once Daily

**Pramipexole
Dihydrochloride
Extended-release
Tablets**
0.75 mg

Dispense in this ORIGINAL Unit of Use container.
PHARMACIST: Dispense the Patient Information provided separately to each patient

Rx only
30 Tablets

Each extended-release tablet contains 0.75 mg of pramipexole dihydrochloride, USP (Monohydrate)

Usual Dosage: See package insert for complete prescribing information. Tablets must be swallowed whole and must not be chewed, crushed, or divided.

Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].

Protect from exposure to high humidity.

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

Manufactured by:
Cadila Healthcare Ltd.
Ahmedabad, India

Lot:
Exp:
Rev.: 04/18

NDC 70771-1330-3

Pramipexole Dihydrochloride Extended-release Tablets, 1.5 mg

R_x only

30 tablets

ZyGenerics
NDC 70771-1330-3
Once Daily

**Pramipexole
Dihydrochloride
Extended-release
Tablets**
1.5 mg

Dispense in this ORIGINAL Unit of Use container.
PHARMACIST: Dispense the Patient Information provided separately to each patient

Rx only
30 Tablets

Each extended-release tablet contains 1.5 mg of pramipexole dihydrochloride, USP (Monohydrate)

Usual Dosage: See package insert for complete prescribing information. Tablets must be swallowed whole and must not be chewed, crushed, or divided.

Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].

Protect from exposure to high humidity.

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

Manufactured by:
Cadila Healthcare Ltd.
Ahmedabad, India

Lot:
Exp:
Rev.: 04/18

NDC 70771-1331-3

Pramipexole Dihydrochloride Extended-release Tablets, 2.25 mg

R_x only

30 tablets

ZyGenerics
NDC 70771-1331-3
Once Daily
**Pramipexole
Dihydrochloride
Extended-release
Tablets**
2.25 mg

Each extended-release tablet contains 2.25 mg of pramipexole dihydrochloride, USP (Monohydrate)

Usual Dosage: See package insert for complete prescribing information. Tablets must be swallowed whole and must not be chewed, crushed, or divided.

Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].

Protect from exposure to high humidity.

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

Dispense in this ORIGINAL Unit of Use container.

PHARMACIST: Dispense the Patient Information provided separately to each patient

Rx only
30 Tablets

Manufactured by:
Cadila Healthcare Ltd.
Ahmedabad, India

Lot: _____
Exp: _____
Rev.: 04/18

NDC 70771-1332-3

Pramipexole Dihydrochloride Extended-release Tablets, 3 mg

R_x only

30 tablets

ZyGenerics
NDC 70771-1332-3
Once Daily
**Pramipexole
Dihydrochloride
Extended-release
Tablets**
3 mg

Each extended-release tablet contains 3 mg of pramipexole dihydrochloride, USP (Monohydrate)

Usual Dosage: See package insert for complete prescribing information. Tablets must be swallowed whole and must not be chewed, crushed, or divided.

Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].

Protect from exposure to high humidity.

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

Dispense in this ORIGINAL Unit of Use container.

PHARMACIST: Dispense the Patient Information provided separately to each patient

Rx only
30 Tablets

Manufactured by:
Cadila Healthcare Ltd.
Ahmedabad, India

Lot: _____
Exp: _____
Rev.: 04/18

NDC 70771-1333-3

Pramipexole Dihydrochloride Extended-release Tablets, 3.75 mg

R_x only

30 tablets

ZyGenerics
NDC 70771-1333-3
Once Daily
**Pramipexole
Dihydrochloride
Extended-release
Tablets**
3.75 mg

Each extended-release tablet contains 3.75 mg of pramipexole dihydrochloride, USP (Monohydrate)

Usual Dosage: See package insert for complete prescribing information. Tablets must be swallowed whole and must not be chewed, crushed, or divided.

Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].
Protect from exposure to high humidity.

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

Manufactured by:
Cadila Healthcare Ltd.
Ahmedabad, India

Dispense in this ORIGINAL Unit of Use container.
PHARMACIST: Dispense the Patient Information provided separately to each patient

**Rx only
30 Tablets**

Lot:
Exp:
Rev.: 04/18

NDC 70771-1334-3

Pramipexole Dihydrochloride Extended-release Tablets, 4.5 mg

R_x only

30 tablets



ZyGenerics

NDC 70771-1334-3
Once Daily

Pramipexole Dihydrochloride Extended-release Tablets

4.5 mg

Dispense in this ORIGINAL Unit of Use container.

PHARMACIST: Dispense the Patient
Information provided separately to each patient

Lot:

Exp:

Rev.: 04/18

Rx only
30 Tablets

Each extended-release tablet contains 4.5 mg of pramipexole dihydrochloride, USP (Monohydrate)

Usual Dosage: See package insert for complete prescribing information. Tablets must be swallowed whole and must not be chewed, crushed, or divided.

Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].

Protect from exposure to high humidity.

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

Manufactured by:
Cadila Healthcare Ltd.
Ahmedabad, India

PRAMIPEXOLE DIHYDROCHLORIDE

pramipexole dihydrochloride tablet, extended release

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1328
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PRAMIPEXOLE DIHYDROCHLORIDE (UNII: 3D867NP06J) (PRAMIPEXOLE - UNII:83619PEU5T)	PRAMIPEXOLE DIHYDROCHLORIDE	0.375 mg

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE) , BROWN (Buff to light brown speckles)	Score	no score
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Shape	OVAL (oval)	Size	11mm
Flavor		Imprint Code	474
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1328-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	04/24/2018	
2	NDC:70771-1328-4	10 in 1 CARTON	04/24/2018	
2	NDC:70771-1328-2	10 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	ANDA202891	04/24/2018	

PRAMIPEXOLE DIHYDROCHLORIDE

pramipexole dihydrochloride tablet, extended release

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1329
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
PRAMIPEXOLE DIHYDROCHLORIDE (UNII: 3D867NP06J) (PRAMIPEXOLE - UNII:83619PEU5T)	PRAMIPEXOLE DIHYDROCHLORIDE	0.75 mg

Inactive Ingredients	
Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE) , BROWN (Buff to light brown speckles)	Score	no score
Shape	OVAL (oval)	Size	11mm
Flavor		Imprint Code	475
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1329-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	04/24/2018	
2	NDC:70771-1329-4	10 in 1 CARTON	04/24/2018	
2	NDC:70771-1329-2	10 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	ANDA202891	04/24/2018	

PRAMIPEXOLE DIHYDROCHLORIDE

pramipexole dihydrochloride tablet, extended release

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1330
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
STARCH, CORN (UNII: O8232NY3SJ)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE) , BROWN (Buff to light brown speckles)	Score	no score
Shape	OVAL (oval)	Size	13mm
Flavor		Imprint Code	476
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1330-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	04/24/2018	
2	NDC:70771-1330-4	10 in 1 CARTON	04/24/2018	
2	NDC:70771-1330-2	10 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	ANDA202891	04/24/2018	

PRAMIPEXOLE DIHYDROCHLORIDE

pramipexole dihydrochloride tablet, extended release

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1332
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6130)	
MANNITOL (UNII: 3OWL53L36A)	

STEARYL ALCOHOL (UNII: 2KR89I4H1Y)

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE) , BROWN (Buff to light brown speckles)	Score	no score
Shape	OVAL (oval)	Size	13mm
Flavor		Imprint Code	477
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1332-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	04/24/2018	
2	NDC:70771-1332-4	10 in 1 CARTON	04/24/2018	
2	NDC:70771-1332-2	10 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	ANDA202891	04/24/2018	

PRAMIPEXOLE DIHYDROCHLORIDE

pramipexole dihydrochloride tablet, extended release

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1334
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PRAMIPEXOLE DIHYDROCHLORIDE (UNII: 3D867NP06J) (PRAMIPEXOLE - UNII:83619PEU5T)	PRAMIPEXOLE DIHYDROCHLORIDE	4.5 mg

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)	
ANHYDROUS LACTOSE (UNII: 3S5YLH9PMK)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	

MAGNESIUM STEARATE (UNII: 70097M6I30)

MANNITOL (UNII: 3OWL53L36A)

STEARYL ALCOHOL (UNII: 2KR89I4H1Y)

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE) , BROWN (Buff to light brown speckles)	Score	no score
Shape	OVAL (oval)	Size	16mm
Flavor		Imprint Code	478
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1334-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	04/24/2018	
2	NDC:70771-1334-4	10 in 1 CARTON	04/24/2018	
2	NDC:70771-1334-2	10 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	ANDA202891	04/24/2018	

PRAMIPEXOLE DIHYDROCHLORIDE

pramipexole dihydrochloride tablet, extended release

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1331
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PRAMIPEXOLE DIHYDROCHLORIDE (UNII: 3D867NP06J) (PRAMIPEXOLE - UNII:83619PEU5T)	PRAMIPEXOLE DIHYDROCHLORIDE	2.25 mg

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)	

LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)

MAGNESIUM STEARATE (UNII: 70097M6I30)

MANNITOL (UNII: 3OWL53L36A)

STARCH, CORN (UNII: O8232NY3SJ)

STEARYL ALCOHOL (UNII: 2KR89I4H1Y)

Product Characteristics

Color	WHITE (OFF-WHITE)	Score	no score
Shape	OVAL (OVAL)	Size	13mm
Flavor		Imprint Code	874
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1331-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	04/24/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA202891	04/24/2018	

PRAMIPEXOLE DIHYDROCHLORIDE

pramipexole dihydrochloride tablet, extended release

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1333
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PRAMIPEXOLE DIHYDROCHLORIDE (UNII: 3D867NP06J) (PRAMIPEXOLE - UNII:83619PEU5T)	PRAMIPEXOLE DIHYDROCHLORIDE	3.75 mg

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

MANNITOL (UNII: 3OWL53L36A)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	

Product Characteristics			
Color	WHITE (OFF-WHITE)	Score	no score
Shape	OVAL (OVAL)	Size	13mm
Flavor		Imprint Code	875
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1333-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	04/24/2018	
2	NDC:70771-1333-4	10 in 1 CARTON	04/24/2018	
2	NDC:70771-1333-2	10 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	ANDA202891	04/24/2018	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment			
Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		918596198	ANALYSIS(70771-1328, 70771-1329, 70771-1330, 70771-1331, 70771-1332, 70771-1333, 70771-1334) , MANUFACTURE(70771-1328, 70771-1329, 70771-1330, 70771-1331, 70771-1332, 70771-1333, 70771-1334)