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

PRAMIPEXOLE DIHYDROCHLORIDE EXTENDED-RELEASE TABLETS

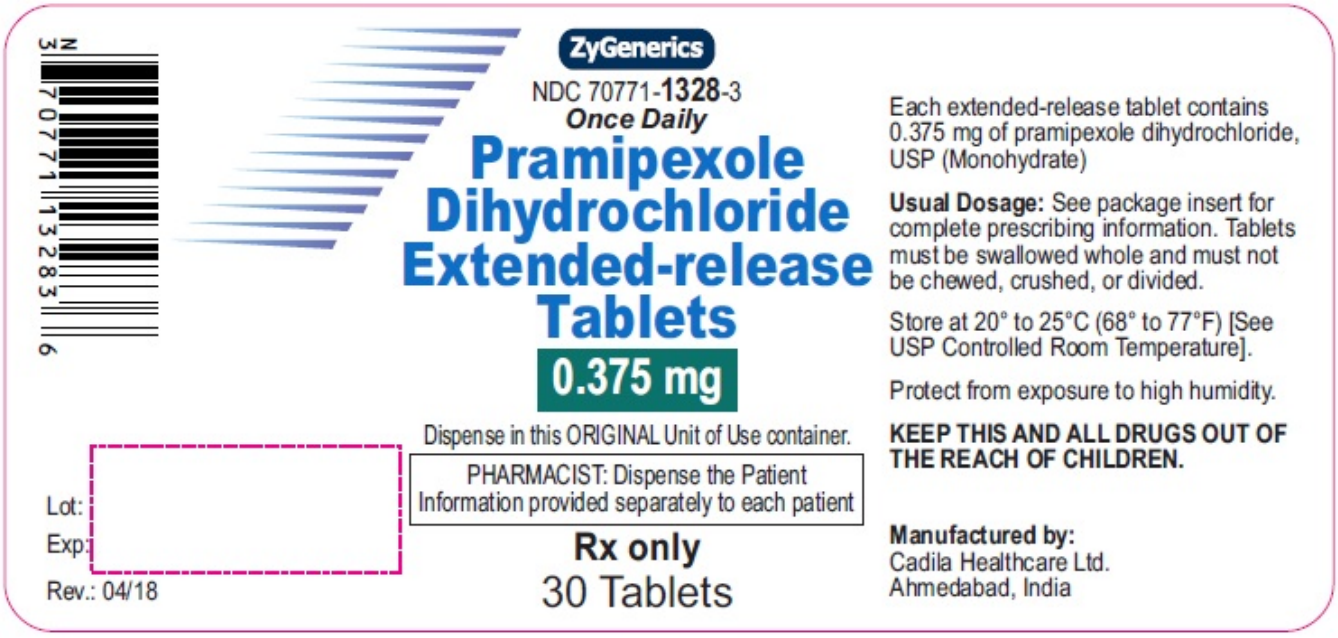
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1328-3

Pramipexole Dihydrochloride Extended-release Tablets, 0.375 mg

R_x only

30 tablets

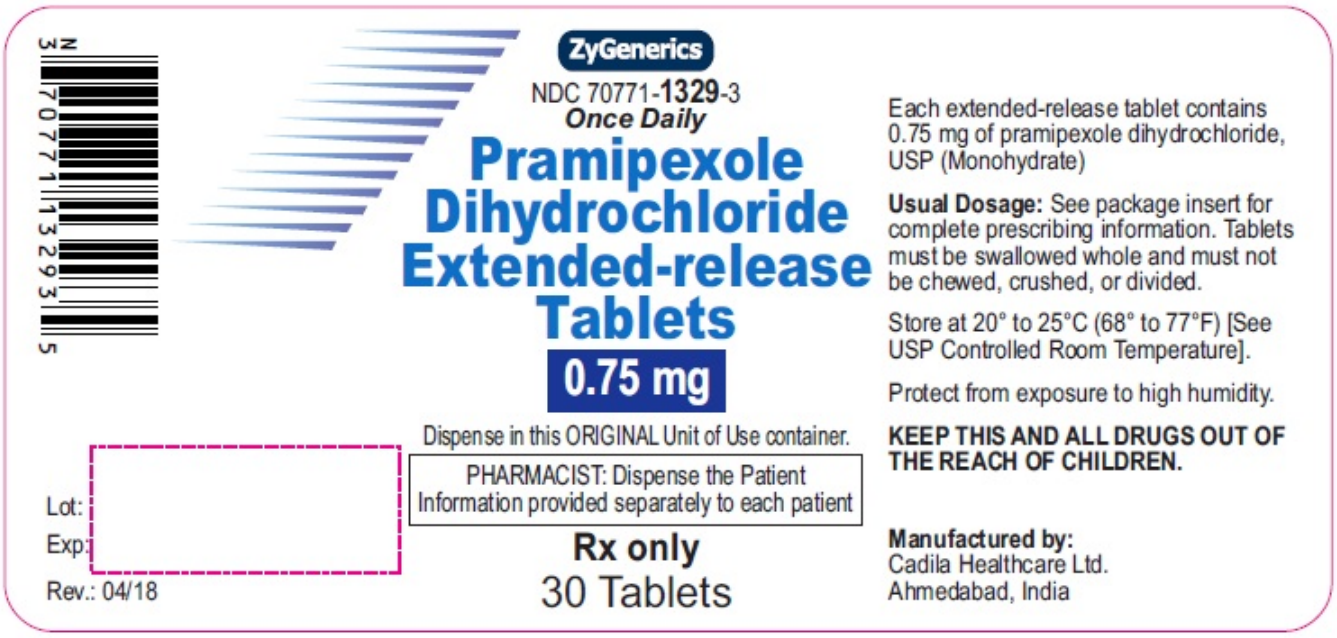


NDC 70771-1329-3

Pramipexole Dihydrochloride Extended-release Tablets, 0.75 mg

R_x only

30 tablets

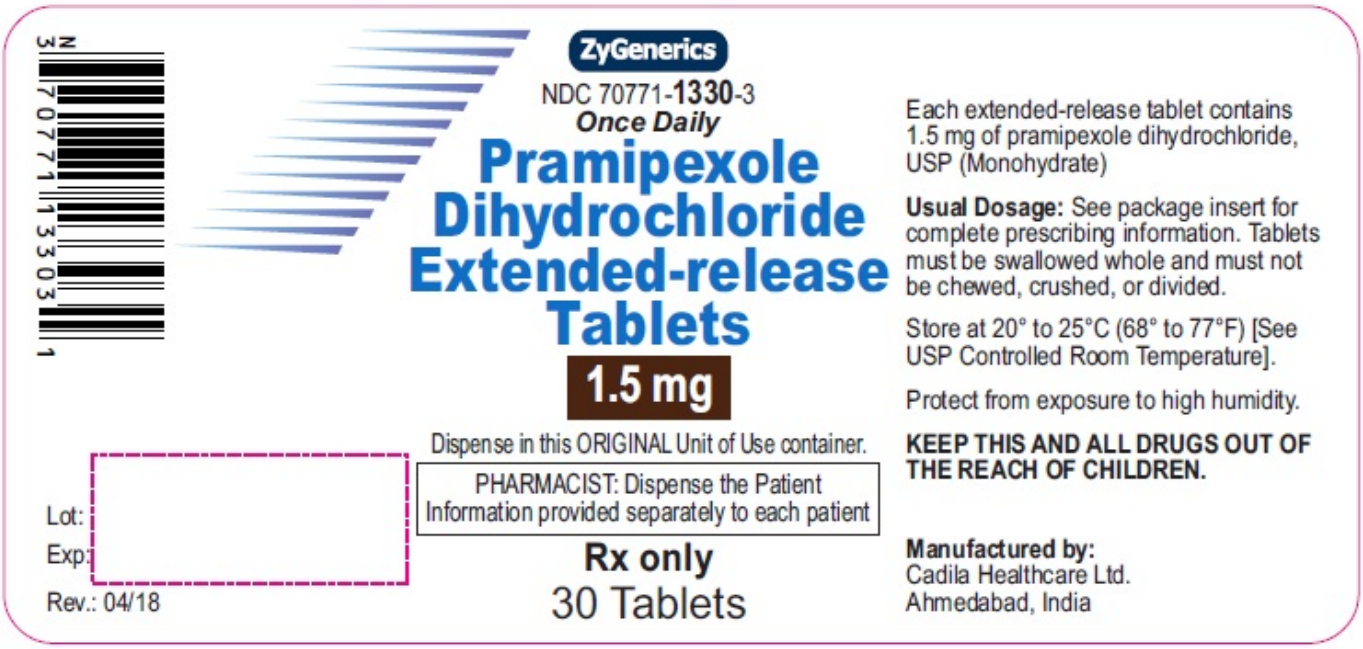


NDC 70771-1330-3

Pramipexole Dihydrochloride Extended-release Tablets, 1.5 mg

R_x only

30 tablets

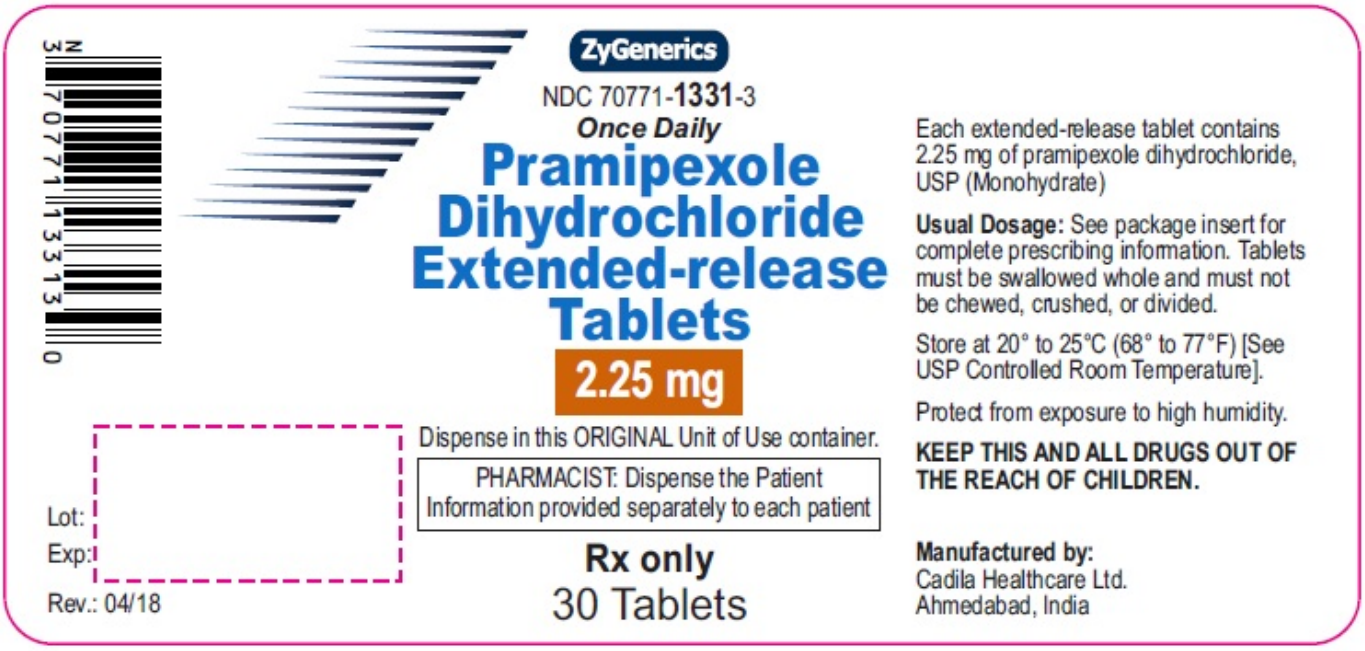


NDC 70771-1331-3

Pramipexole Dihydrochloride Extended-release Tablets, 2.25 mg

R_x only

30 tablets

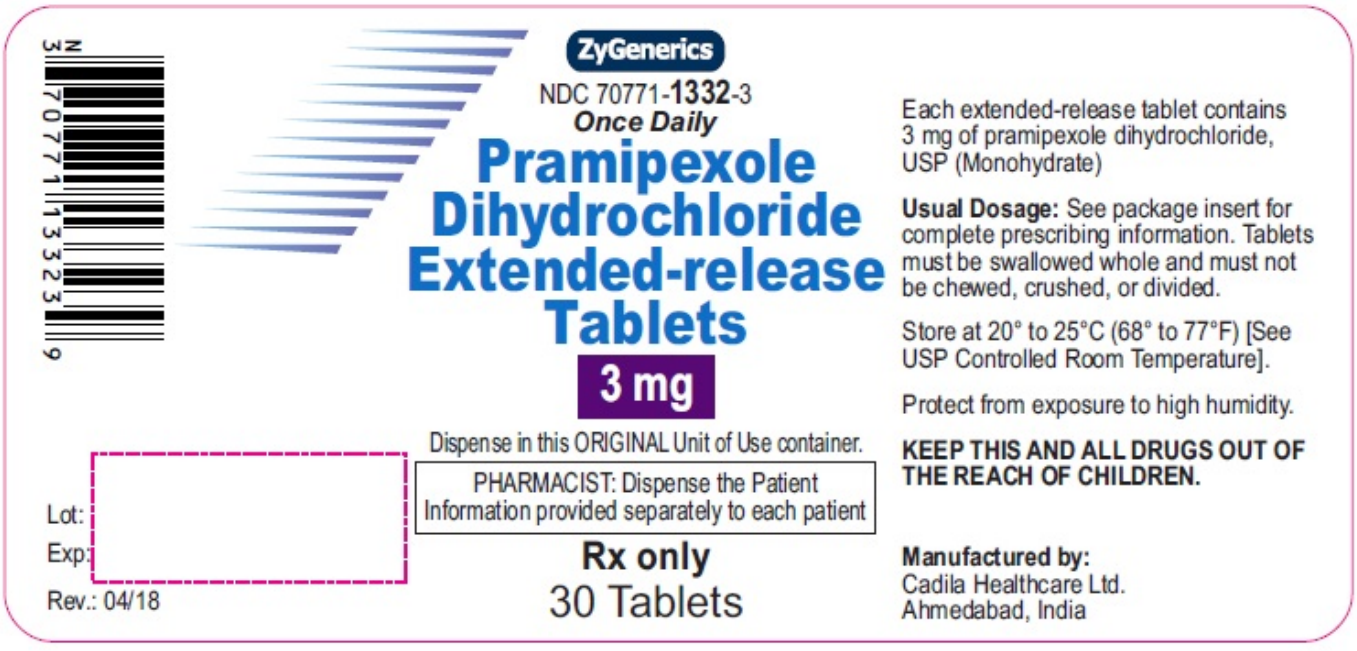


NDC 70771-1332-3

Pramipexole Dihydrochloride Extended-release Tablets, 3 mg

R_x only

30 tablets

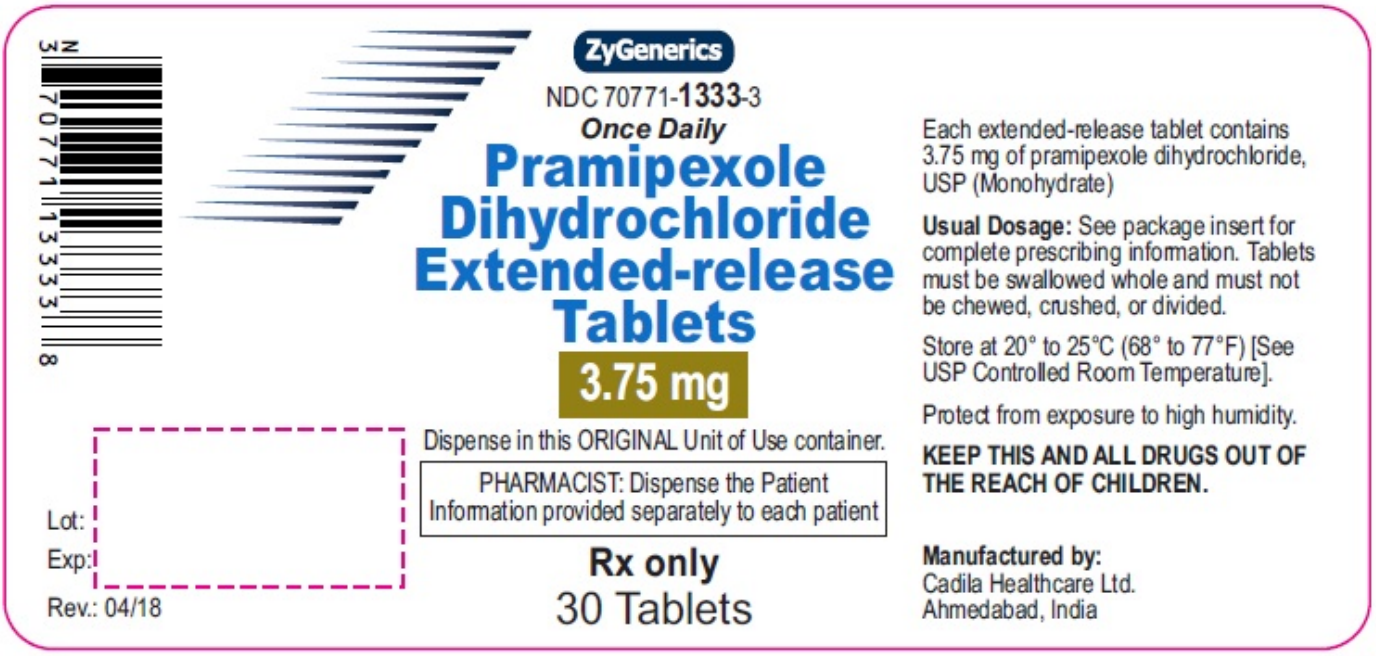


NDC 70771-1333-3

Pramipexole Dihydrochloride Extended-release Tablets, 3.75 mg

R_x only

30 tablets

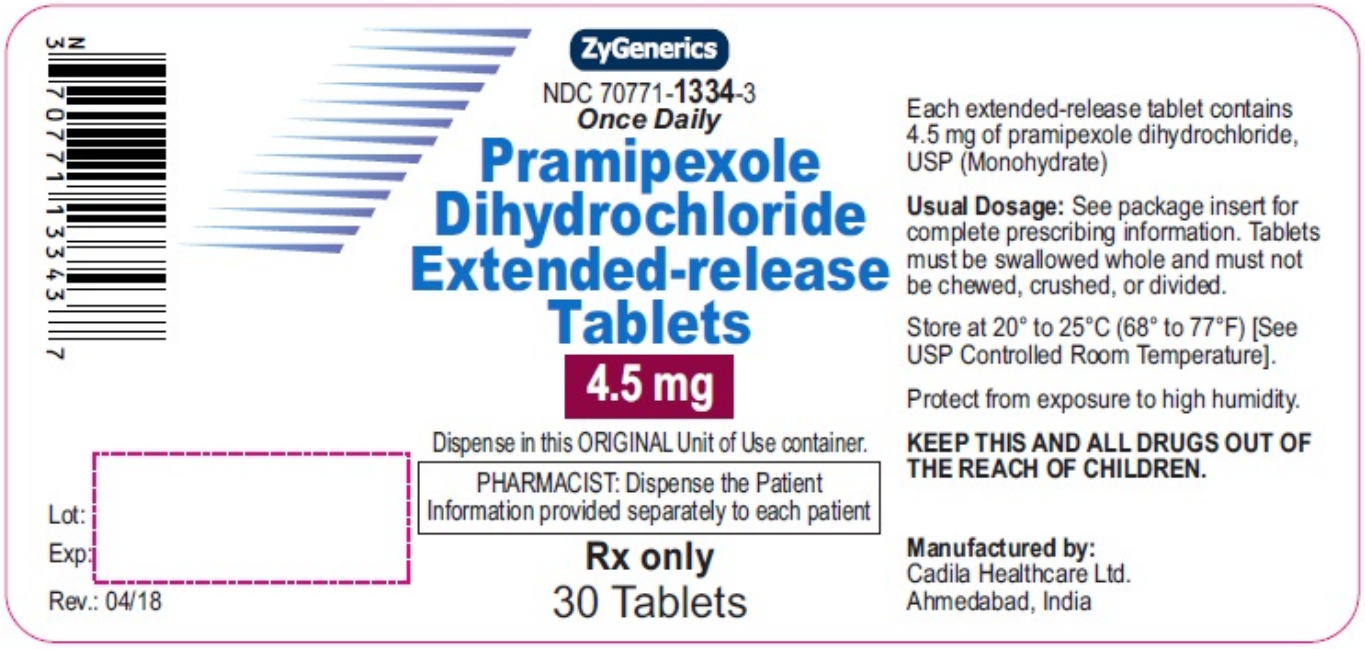


NDC 70771-1334-3

Pramipexole Dihydrochloride Extended-release Tablets, 4.5 mg

R_x only

30 tablets



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

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: 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**	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: 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**	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)

Revised: 10/2022 Zydus Lifesciences Limited