PRAMIPEXOLE DIHYDROCHLORIDE- pramipexole dihydrochloride tablet
Zydus Lifesciences Limited

PRAMIPEXOLE DIHYDROCHLORIDE TABLETS

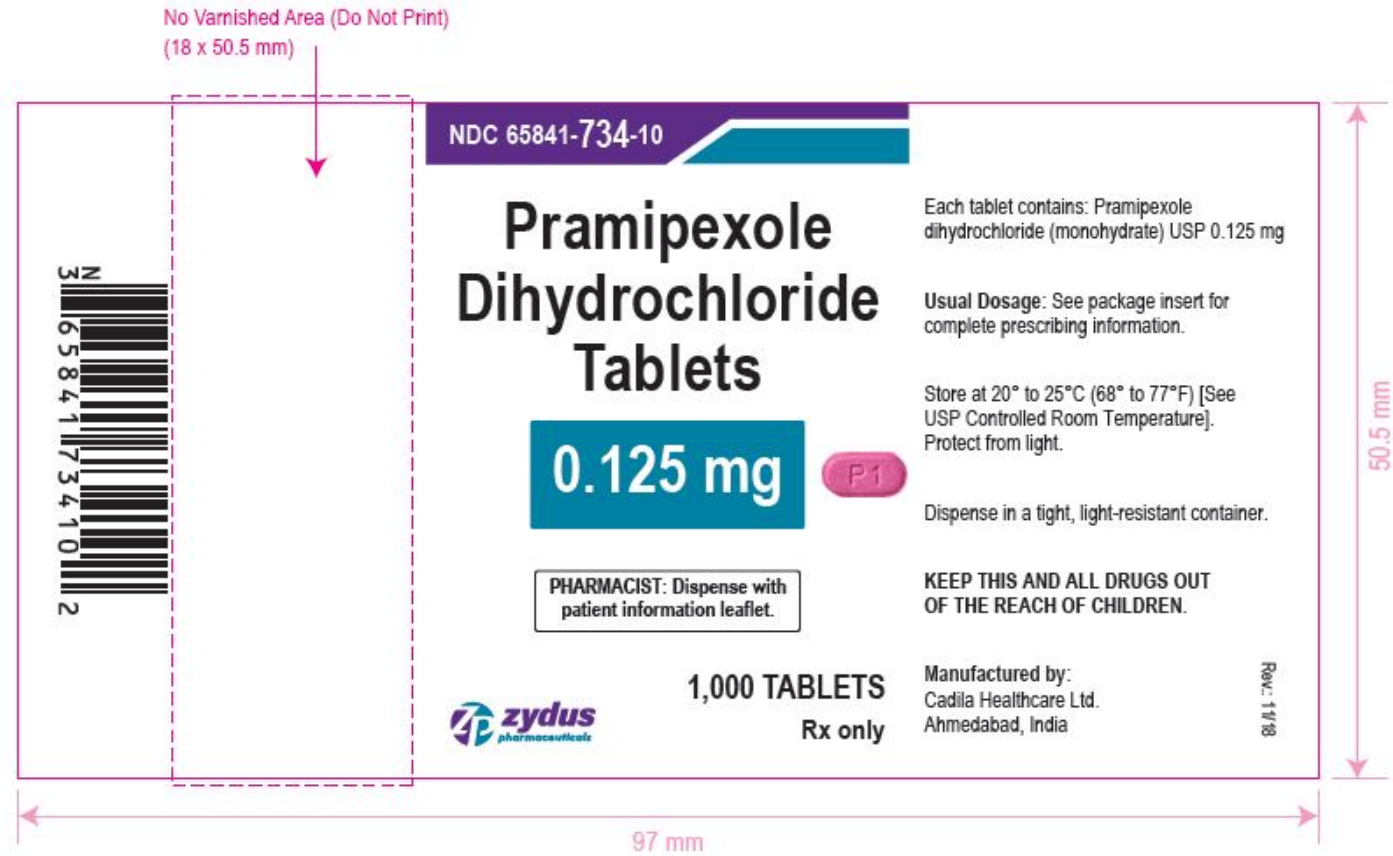
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 65841-734-10 in bottle of 1000 tablets

Pramipexole Dihydrochloride Tablets, 0.125 mg

Rx only

1000 tablets



NDC 65841-735-10 in bottle of 1000 tablets

Pramipexole Dihydrochloride Tablets, 0.25 mg

Rx only

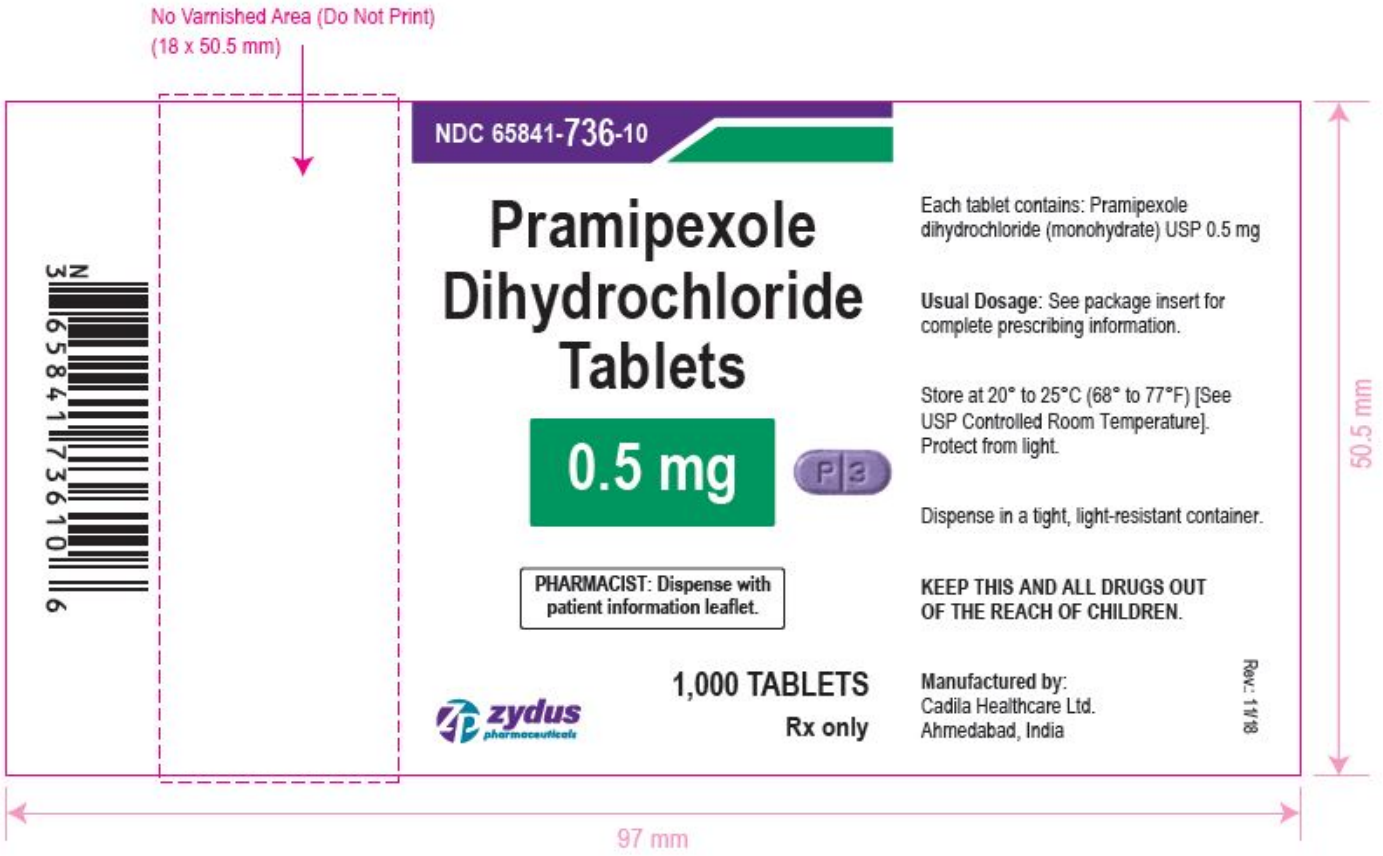
1000 tablets

NDC 65841-736-10 in bottle of 1000 tablets

Pramipexole Dihydrochloride Tablets, 0.5 mg

Rx only

1000 tablets

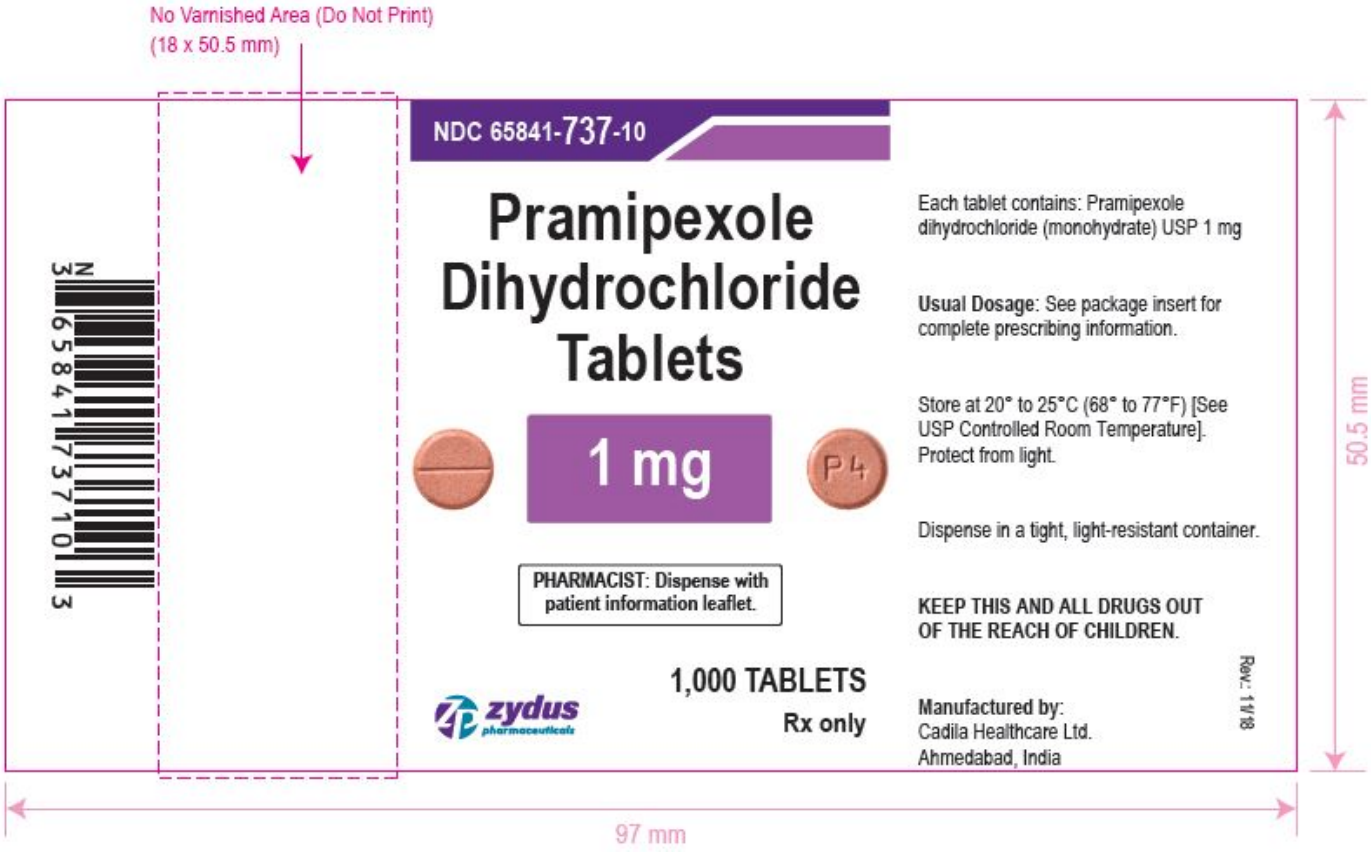


NDC 65841-737-10 in bottle of 1000 tablets

Pramipexole Dihydrochloride Tablets, 1 mg

Rx only

1000 tablets



NDC 65841-738-16 in bottle of 90 tablets

Pramipexole Dihydrochloride Tablets, 1.5 mg

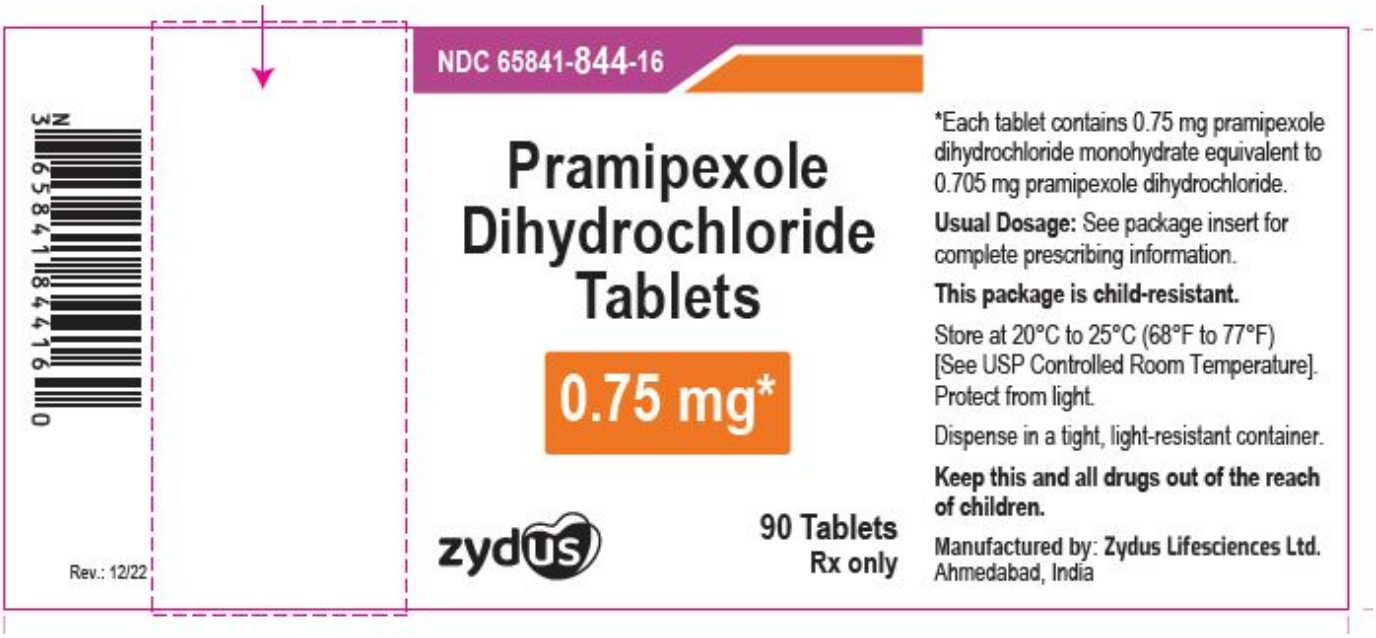
Rx only

90 tablets

NDC 65841-844-16 in bottle of 90 tablets

Pramipexole Dihydrochloride Tablets, 0.75 mg

Rx only



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**	6mm
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
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	

PRAMIPEXOLE DIHYDROCHLORIDE

pramipexole dihydrochloride tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-844
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
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
POVIDONE (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

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:65841-844-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	11/23/2022	
2	NDC:65841-844-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	11/30/2022	
3	NDC:65841-844-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	11/30/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078920	11/23/2022	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		918596198	ANALYSIS(65841-734, 65841-735, 65841-736, 65841-737, 65841-738, 65841-844), MANUFACTURE(65841-734, 65841-735, 65841-736, 65841-737, 65841-738, 65841-844)

Revised: 12/2024

Zydus Lifesciences Limited