

**PRAMIPEXOLE DIHYDROCHLORIDE- pramipexole dihydrochloride tablet**  
**Zydus Lifesciences Limited**

**PRAMIPEXOLE DIHYDROCHLORIDE TABLETS**

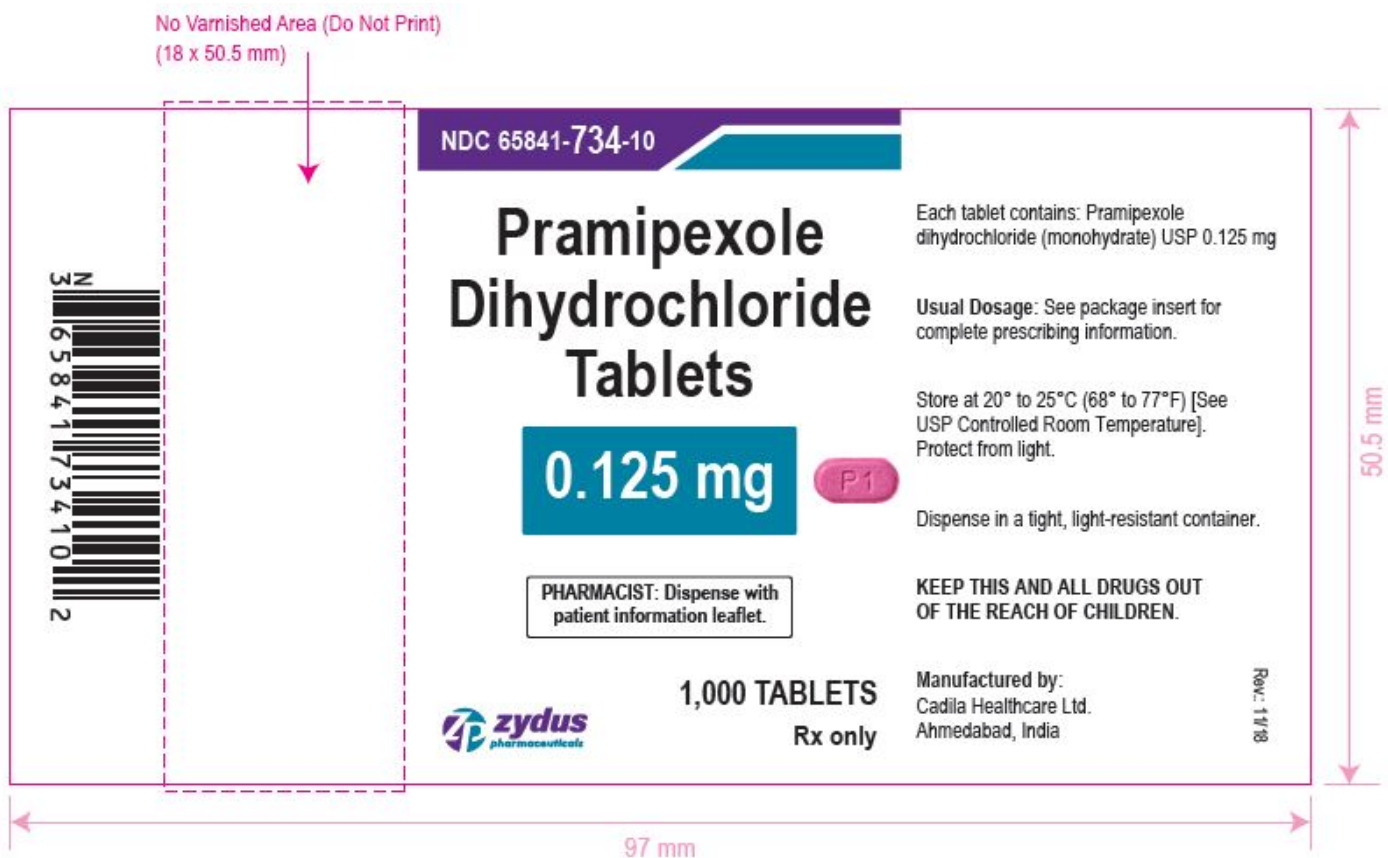
**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

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

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 65841-736-10 in bottle of 1000 tablets  
 Pramipexole Dihydrochloride Tablets, 0.5 mg  
 Rx only  
 1000 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 65841-737-10 in bottle of 1000 tablets  
Pramipexole Dihydrochloride Tablets, 1 mg  
Rx only  
1000 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.**

Rev: 1/18

Manufactured by:  
Cadila Healthcare Ltd.  
Ahmedabad, India

**1 mg**

PHARMACIST: Dispense with patient information leaflet.

**1,000 TABLETS**  
Rx only

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**

**1.5 mg**

PHARMACIST: Dispense with patient information leaflet.

**zydus**  
pharmaceuticals

**90 TABLETS  
Rx only**

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.**

Manufactured by: Cadila Healthcare Ltd. Ahmedabad, India

Rev.: 11/18

95 mm

41 mm

NDC 65841-844-16 in bottle of 90 tablets  
Pramipexole Dihydrochloride Tablets, 0.75 mg  
Rx only

NDC 65841-844-16

**Pramipexole  
Dihydrochloride  
Tablets**

**0.75 mg\***

**zydus**

**90 Tablets  
Rx only**

\*Each tablet contains 0.75 mg pramipexole dihydrochloride monohydrate equivalent to 0.705 mg pramipexole dihydrochloride.

**Usual Dosage:** See package insert for complete prescribing information.

**This package is child-resistant.**

Store at 20°C to 25°C (68°F 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: Zydus Lifesciences Ltd. Ahmedabad, India

Rev.: 12/22

95 mm

## PRAMIPEXOLE DIHYDROCHLORIDE

pramipexole dihydrochloride tablet

**Product Information**

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

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
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**

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

**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**

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

**PRAMIPEXOLE DIHYDROCHLORIDE**

pramipexole dihydrochloride tablet

## Product Information

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

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
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

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

## 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

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

## PRAMIPEXOLE DIHYDROCHLORIDE

pramipexole dihydrochloride tablet

## Product Information

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

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

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

## Product Characteristics

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

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
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

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

## PRAMIPEXOLE DIHYDROCHLORIDE

pramipexole dihydrochloride tablet



## Product Information

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

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

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

## Product Characteristics

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

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
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

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

## PRAMIPEXOLE DIHYDROCHLORIDE

pramipexole dihydrochloride tablet

## Product Information

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

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

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

## Product Characteristics

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

## 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

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

## PRAMIPEXOLE DIHYDROCHLORIDE

pramipexole dihydrochloride tablet

## Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:65841-844
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>PRAMIPEXOLE DIHYDROCHLORIDE</b> (UNII: 3D867NP06J) (PRAMIPEXOLE - UNII:83619PEU5T)	PRAMIPEXOLE DIHYDROCHLORIDE	0.75 mg

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I3O)	
<b>MANNITOL</b> (UNII: 3OWL53L36A)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	

## Product Characteristics

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

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
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

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
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