

**PHENTERMINE HYDROCHLORIDE - phentermine hydrochloride tablet, orally disintegrating**

**Zydus Lifesciences Limited**

**PHENTERAMINE HYDROCHLORIDE ORALLY DISINTEGRATING TABLETS**

**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

NDC 70771-1200-1 in bottle of 100 Tablets

Phentermine Hydrochloride Orally Disintegrating Tablets, 15 mg

Rx only

100 Tablets

**ZyGenerics**  
NDC 70771-1200-1  
**PHENTERMINE  
HYDROCHLORIDE**  
**ORALLY DISINTEGRATING**  
Tablets **IV**  
**15 mg**  
Rx only  
100 Tablets

Each orally disintegrating tablet contains 15 mg of Phentermine hydrochloride USP (equivalent to 12 mg of phentermine base)  
**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 moisture.  
Dispense in tight, light-resistant container with child-resistant cap.  
**KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.**  
**Manufactured by:**  
Cadila Healthcare Limited,  
Survey no. 417, 419 & 420,  
Sarkhej Bavla National Highway No. 8 A,  
Village - Moraiya, Tal - Sanand,  
Dist. - Ahmedabad, India

Lot:  
Exp:  
Rev.: 02/18

NDC 70771-1201-1 in bottle of 100 Tablets

Phentermine Hydrochloride Orally Disintegrating Tablets, 30 mg

Rx only

100 Tablets



**ZyGenerics**  
NDC 70771-1201-1

**PHENTERMINE  
HYDROCHLORIDE  
ORALLY DISINTEGRATING**

Tablets 

**30 mg**

Rx only

**100 Tablets**

Lot:  
Exp:  
Rev.: 02/18

Each orally disintegrating tablet contains 30 mg of Phentermine hydrochloride USP (equivalent to 24 mg of phentermine base)

**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 moisture.

Dispense in tight, light-resistant container with child-resistant cap.

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

**Manufactured by:**  
Cadila Healthcare Limited,  
Survey no. 417, 419 & 420,  
Sarkhej Bavla National Highway No. 8 A,  
Village - Moraiya, Tal - Sanand,  
Dist. - Ahmedabad, India

NDC 70771-1202-1 in bottle of 100 Tablets

Phentermine Hydrochloride Orally Disintegrating Tablets, 37.5 mg


Rx only

100 Tablets



**ZyGenerics**  
NDC 70771-1202-1

**PHENTERMINE  
HYDROCHLORIDE  
ORALLY DISINTEGRATING**

Tablets 

**37.5 mg**

Rx only

**100 Tablets**

Lot:  
Exp:  
Rev.: 02/18

Each orally disintegrating tablet contains 37.5 mg of Phentermine hydrochloride USP (equivalent to 30 mg of phentermine base)

**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 moisture.

Dispense in tight, light-resistant container with child-resistant cap.

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

**Manufactured by:**  
Cadila Healthcare Limited,  
Survey no. 417, 419 & 420,  
Sarkhej Bavla National Highway No. 8 A,  
Village - Moraiya, Tal - Sanand,  
Dist. - Ahmedabad, India

**PHENTERMINE HYDROCHLORIDE**

phentermine hydrochloride tablet, orally disintegrating

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:70771-1200
<b>Route of Administration</b>	ORAL	<b>DEA Schedule</b>	CIV

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>PHENTERMINE HYDROCHLORIDE</b> (UNII: 0K2I505OTV) (PHENTERMINE - UNII:C045TQL4WP)	PHENTERMINE	15 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>CROSPVIDONE (15 MPA.S AT 5%)</b> (UNII: 68401960MK)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MANNITOL</b> (UNII: 3OWL53L36A)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>PEPPERMINT</b> (UNII: V95R5KMY2B)	
<b>POVIDONE K30</b> (UNII: U725QWY32X)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
<b>SODIUM STEARYL FUMARATE</b> (UNII: 7CV7WJK4UI)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	

### Product Characteristics

<b>Color</b>	WHITE (white to off-white)	<b>Score</b>	no score
<b>Shape</b>	ROUND (round)	<b>Size</b>	8mm
<b>Flavor</b>	PEPPERMINT (peppermint flavour)	<b>Imprint Code</b>	703
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1200-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	02/08/2018	
2	NDC:70771-1200-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	02/08/2018	
3	NDC:70771-1200-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	02/08/2018	
4	NDC:70771-1200-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	02/08/2018	
5	NDC:70771-1200-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	02/08/2018	
	NDC:70771-			

6	NDC: 70771-1200-4	10 in 1 CARTON	02/08/2018	
6	NDC: 70771-1200-2	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	ANDA204663	02/08/2018	

## PHENTERMINE HYDROCHLORIDE

phentermine hydrochloride tablet, orally disintegrating

### Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1201
Route of Administration	ORAL	DEA Schedule	CIV

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PHENTERMINE HYDROCHLORIDE (UNII: 0K2I5050TV) (PHENTERMINE - UNII:C045TQL4WP)	PHENTERMINE	30 mg

### Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSPVIDONE (15 MPA.S AT 5%) (UNII: 68401960MK)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
PEPPERMINT (UNII: V95R5KMY2B)	
POVIDONE K30 (UNII: U725QWY32X)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TALC (UNII: 7SEV7J4R1U)	

### Product Characteristics

Color	WHITE (white to off-white)	Score	no score
Shape	OVAL (oval)	Size	14mm
Flavor	PEPPERMINT (peppermint flavour)	Imprint Code	704
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1201-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	02/08/2018	
2	NDC:70771-1201-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	02/08/2018	
3	NDC:70771-1201-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	02/08/2018	
4	NDC:70771-1201-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	02/08/2018	
5	NDC:70771-1201-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	02/08/2018	
6	NDC:70771-1201-4	10 in 1 CARTON	02/08/2018	
6	NDC:70771-1201-2	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	ANDA204663	02/08/2018	

## PHENTERMINE HYDROCHLORIDE

phentermine hydrochloride tablet, orally disintegrating

### Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1202
Route of Administration	ORAL	DEA Schedule	CIV

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PHENTERMINE HYDROCHLORIDE (UNII: 0K2I505OTV) (PHENTERMINE - UNII:C045TQL4WP)	PHENTERMINE	37.5 mg

### Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSPROVIDONE (15 MPAS AT 5%) (UNII: 68401960MK)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
PEPPERMINT (UNII: V95R5KMY2B)	

<b>POVIDONE K30</b> (UNII: U725QWY32X)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
<b>SODIUM STEARYL FUMARATE</b> (UNII: 7CV7WJK4UI)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	

### Product Characteristics

<b>Color</b>	WHITE (WHITE TO OFF-WHITE)	<b>Score</b>	no score
<b>Shape</b>	ROUND (ROUND)	<b>Size</b>	11mm
<b>Flavor</b>	PEPPERMINT (PEPPERMINT)	<b>Imprint Code</b>	670
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1202-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	02/08/2018	
2	NDC:70771-1202-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	02/08/2018	
3	NDC:70771-1202-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	02/08/2018	
4	NDC:70771-1202-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	02/08/2018	
5	NDC:70771-1202-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	02/08/2018	
6	NDC:70771-1202-4	10 in 1 CARTON	02/08/2018	
6	NDC:70771-1202-2	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	ANDA204663	02/08/2018	

**Labeler** - Zydus Lifesciences Limited (918596198)

**Registrant** - Zydus Lifesciences Limited (918596198)

### Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		918596198	ANALYSIS(70771-1200, 70771-1201, 70771-1202) , MANUFACTURE(70771-1200, 70771-1201, 70771-1202)