PHENTERMINE HYDROCHLORIDE - phentermine hydrochloride tablet, orally disintegrating
Zydus Lifesciences Limited

PHENTERAMINE HYDROCHLORIDE ORALLY DISINTEGRATING TABLETS

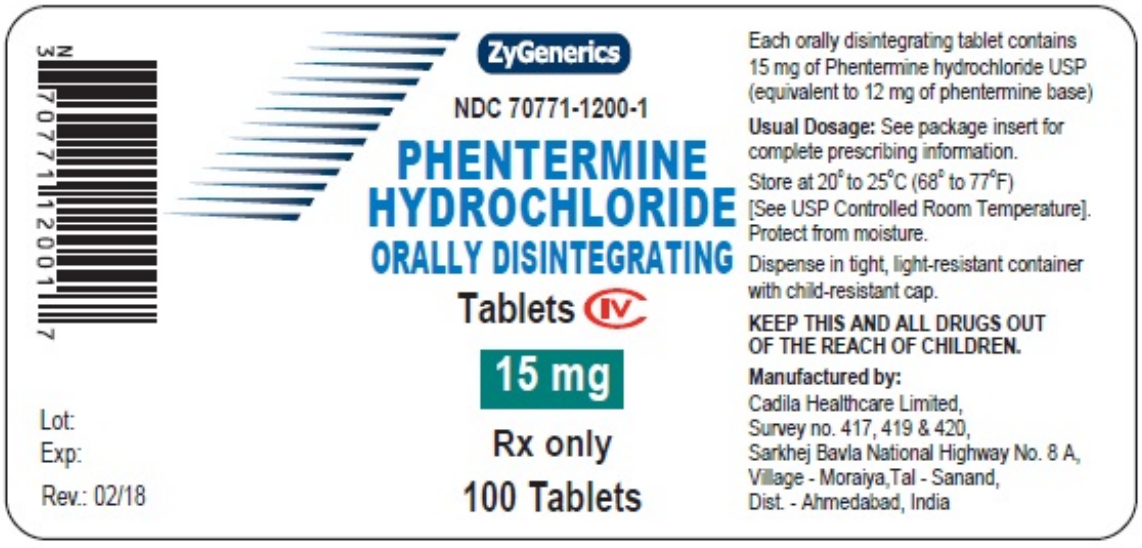
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1200-1 in bottle of 100 Tablets

Phentermine Hydrochloride Orally Disintegrating Tablets, 15 mg

Rx only

100 Tablets

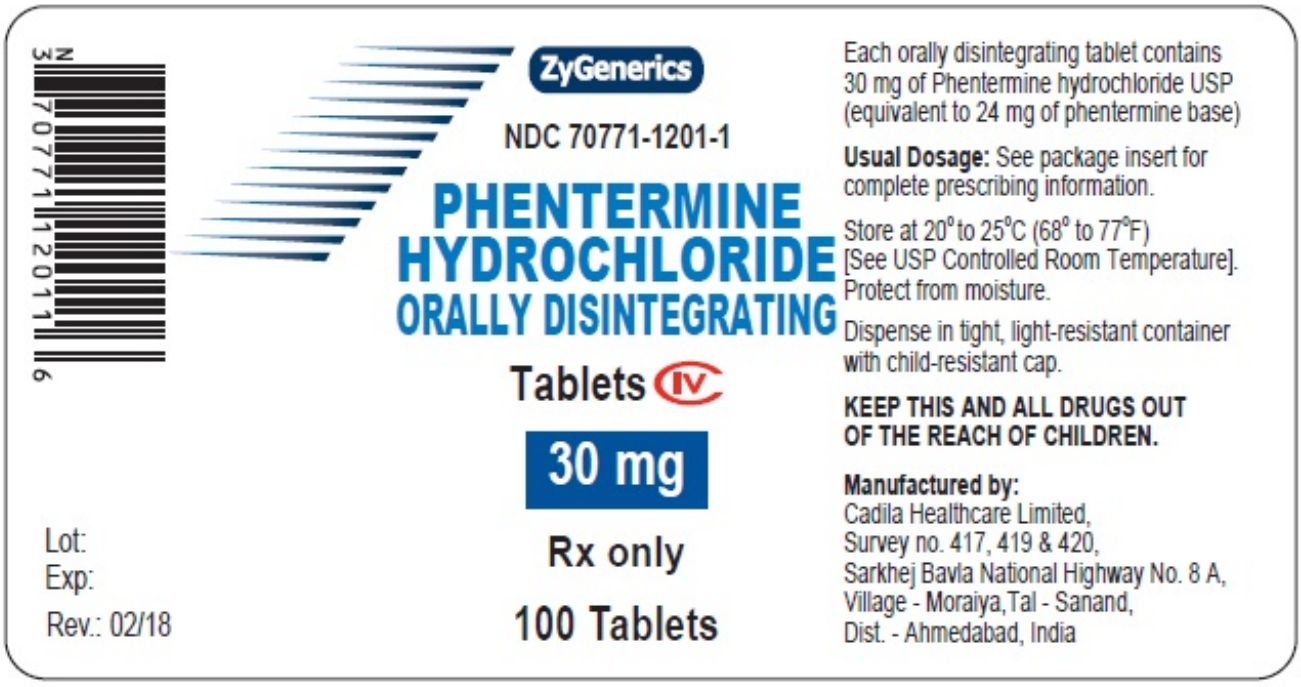


NDC 70771-1201-1 in bottle of 100 Tablets

Phentermine Hydrochloride Orally Disintegrating Tablets, 30 mg

Rx only

100 Tablets

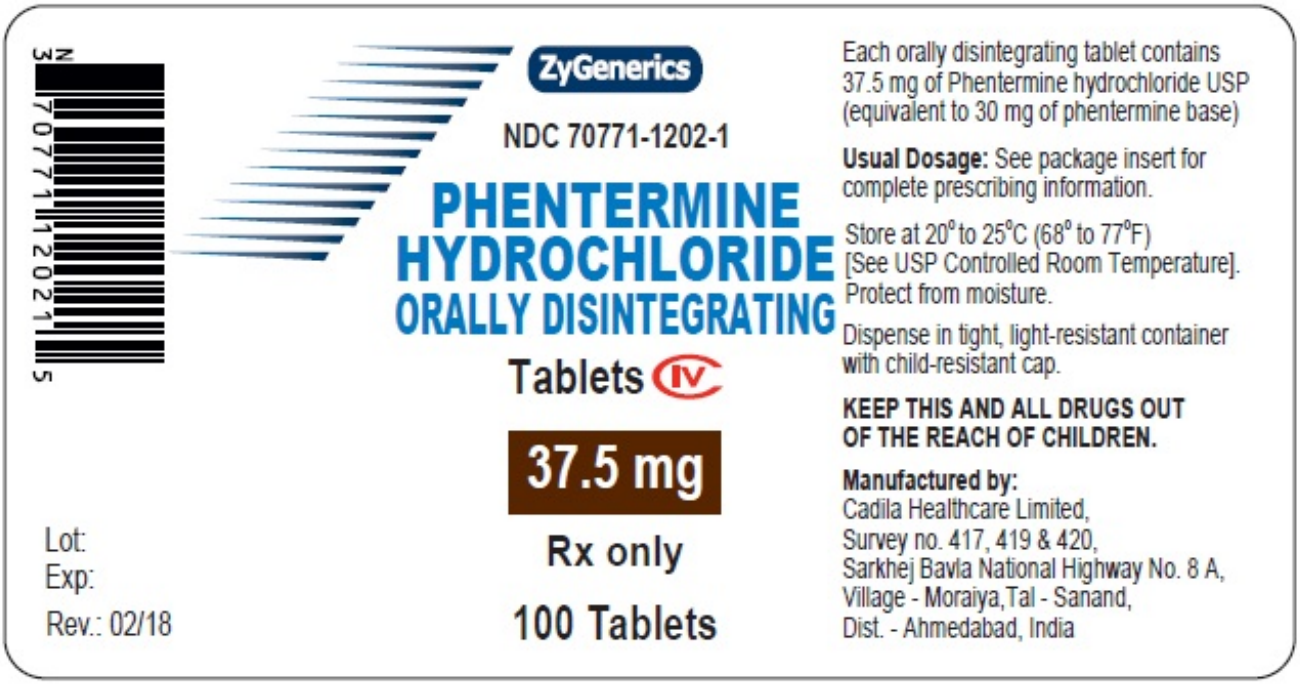


NDC 70771-1202-1 in bottle of 100 Tablets

Phentermine Hydrochloride Orally Disintegrating Tablets, 37.5 mg

Rx only

100 Tablets



PHENTERMINE HYDROCHLORIDE

phentermine hydrochloride tablet, orally disintegrating

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1200
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	15 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSPOVIDONE (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	ROUND (round)	**Size**	8mm
Flavor	PEPPERMINT (peppermint flavour)	**Imprint Code**	703
Contains			

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: 0K2I505OTV) (PHENTERMINE - UNII:C045TQL4WP)	PHENTERMINE	30 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSPOVIDONE (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)	
CROSPOVIDONE (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	ROUND (ROUND)	**Size**	11mm
Flavor	PEPPERMINT (PEPPERMINT)	**Imprint Code**	670
Contains			

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)