

BROMOCRIPTINE MESYLATE- bromocriptine mesylate capsule
Zydus Lifesciences Limited

Bromocriptine Mesylate Capsules, USP

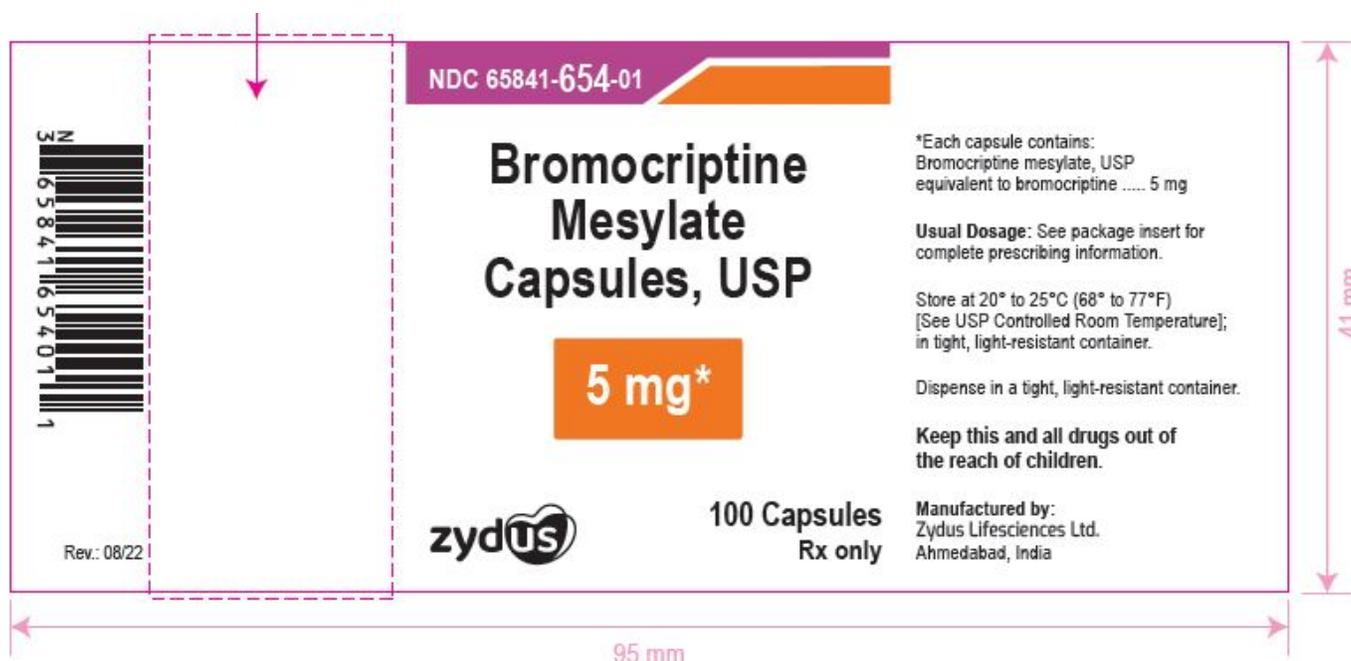
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 65841-654-01 in bottle of 100 Capsules

Bromocriptine Mesylate Capsules USP, 5 mg

R_x only

100 Capsules



BROMOCRIPTINE MESYLATE

bromocriptine mesylate capsule

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:65841-654
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BROMOCRIPTINE MESYLATE (UNII: FFP983J3OD) (BROMOCRIPTINE - UNII:3A64E3G5ZO)	BROMOCRIPTINE	5 mg

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
AMMONIA (UNII: 5138Q19F1X)	
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)	
CARRAGEENAN (UNII: 5C69YCD2YJ)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
HYPROMELLOSE 2910 (15 MPA.S) (UNII: 36SFW2JZ0W)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALEIC ACID (UNII: 91XW058U2C)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0K00R)	

Product Characteristics

Color	BROWN (TAN) , WHITE (WHITE)	Score	no score
Shape	CAPSULE (CAPSULE)	Size	16mm
Flavor		Imprint Code	ZA17;5mg
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-654-06	30 in 1 BOTTLE; Type 0: Not a Combination Product	01/23/2009	
2	NDC:65841-654-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	01/23/2009	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078899	01/23/2009	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		918596198	ANALYSIS(65841-654) , MANUFACTURE(65841-654)

Revised: 11/2024

Zydus Lifesciences Limited