

DUTASTERIDE AND TAMSULOSIN HYDROCHLORIDE- dutasteride and tamsulosin hydrochloride capsule
Zydus Lifesciences Limited

DUTASTERIDE AND TAMSULOSIN HYDROCHLORIDE CAPSULES

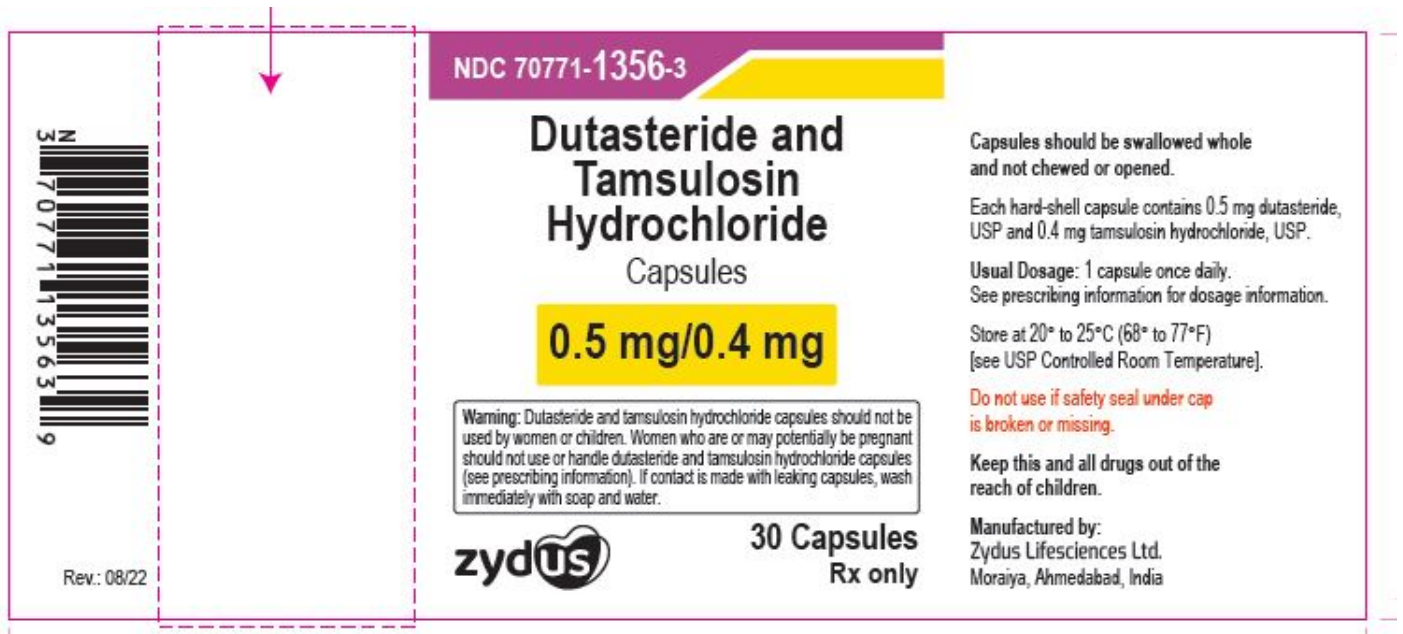
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1356-3

Dutasteride and tamsulosin hydrochloride Capsules, 0.4/0.5 mg

Rx only

30 Capsules



DUTASTERIDE AND TAMSULOSIN HYDROCHLORIDE

dutasteride and tamsulosin hydrochloride capsule

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1356
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DUTASTERIDE (UNII: O0J6XJN02I) (DUTASTERIDE - UNII:O0J6XJN02I)	DUTASTERIDE	0.5 mg
TAMSULOSIN HYDROCHLORIDE (UNII: 11SV1951MR) (TAMSULOSIN - UNII:G3P28OML5I)	TAMSULOSIN HYDROCHLORIDE	0.4 mg

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
AMMONIA (UNII: 5138Q19F1X)	
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CARRAGEENAN (UNII: 5C69YCD2YJ)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONO- AND DICAPRYLOCAPRATE (UNII: U72Q2I8C85)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
METHACRYLIC ACID AND ETHYL ACRYLATE COPOLYMER (UNII: NX76LV5T8J)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SHELLAC (UNII: 46N107B71O)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	

Product Characteristics

Color	YELLOW (OPAQUE YELLOW CAP) , WHITE (OPAQUE WHITE BODY)	Score	no score
Shape	CAPSULE (CAPSULE)	Size	23mm
Flavor		Imprint Code	640
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1356-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	06/04/2018	
2	NDC:70771-1356-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	06/04/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA207769	06/04/2018	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		918596198	ANALYSIS(70771-1356) , MANUFACTURE(70771-1356)

Revised: 11/2024

Zydus Lifesciences Limited