

**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**

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

**Active Ingredient/Active Moiety**

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

## Inactive Ingredients

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

## Product Characteristics

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

## 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**

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

Revised: 8/2022

Zydus Lifesciences Limited