

# DUTASTERIDE - dutasteride capsule, liquid filled

Zydus Lifesciences Limited

## DUTASTERIDE CAPSULES

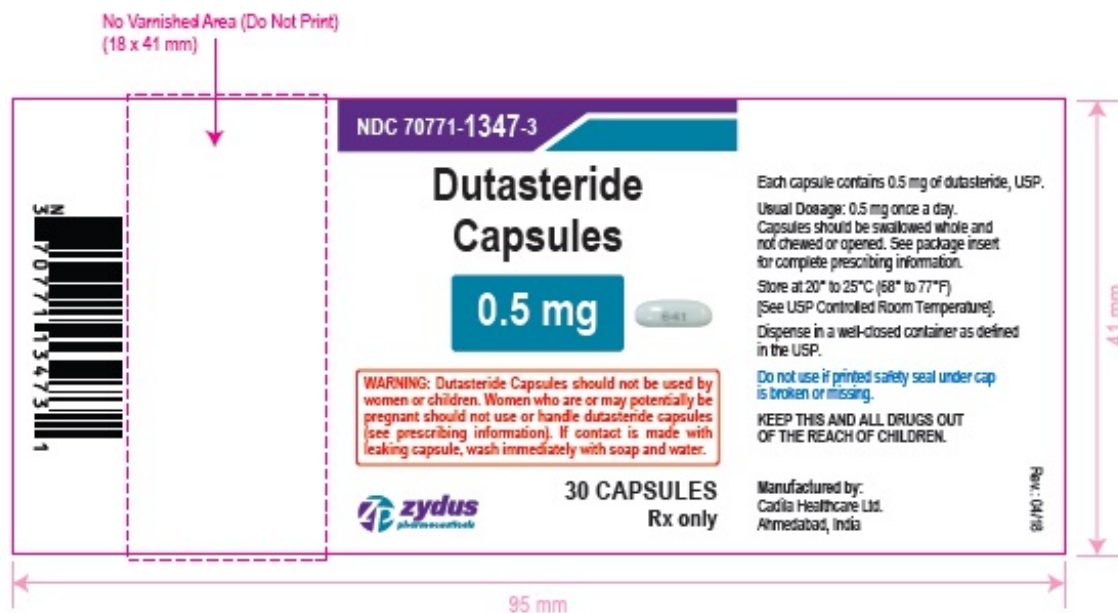
### PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1347-3 in bottle of 30 capsules

Dutasteride Capsules, 0.5 mg

R<sub>x</sub> only

30 Capsules



Colours:  PANTONE 2597 C  PANTONE 314 C  C M Y K

 Die Cut Line (Do Not Print)  No Varnished Area (Do Not Print)

**DUTASTERIDE**

dutasteride capsule, liquid filled

## Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:70771-1347
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>DUTASTERIDE</b> (UNII: O0J6XJN02I) (DUTASTERIDE - UNII:O0J6XJN02I)	DUTASTERIDE	0.5 mg

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>BUTYLATED HYDROXYTOLUENE</b> (UNII: 1P9D0Z171K)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>FERROSFERRIC OXIDE</b> (UNII: XM0M87F357)	
<b>ISOPROPYL ALCOHOL</b> (UNII: ND2M416302)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POLYVINYL ACETATE PHTHALATE</b> (UNII: 58QVG85GW3)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>CAPRYLIC/CAPRIC MONO/DI-GLYCERIDES</b> (UNII: U72Q2I8C85)	
<b>AMMONIA</b> (UNII: 5138Q19F1X)	
<b>WATER</b> (UNII: 059QF0KO0R)	

## Product Characteristics

<b>Color</b>	WHITE (OPAQUE-WHITE)	<b>Score</b>	no score
<b>Shape</b>	CAPSULE (Oblong Shaped)	<b>Size</b>	20mm
<b>Flavor</b>		<b>Imprint Code</b>	641
<b>Contains</b>			

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:70771-1347-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	05/16/2018	
2	NDC:70771-1347-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	05/16/2018	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA204373	05/16/2018	

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

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

### Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		918596198	ANALYSIS(70771-1347) , MANUFACTURE(70771-1347)

Revised: 11/2022

Zydus Lifesciences Limited