

**DUTASTERIDE- dutasteride capsule, liquid filled**  
**Cadila Healthcare Limited**

**DUTASTERIDE CAPSULES**

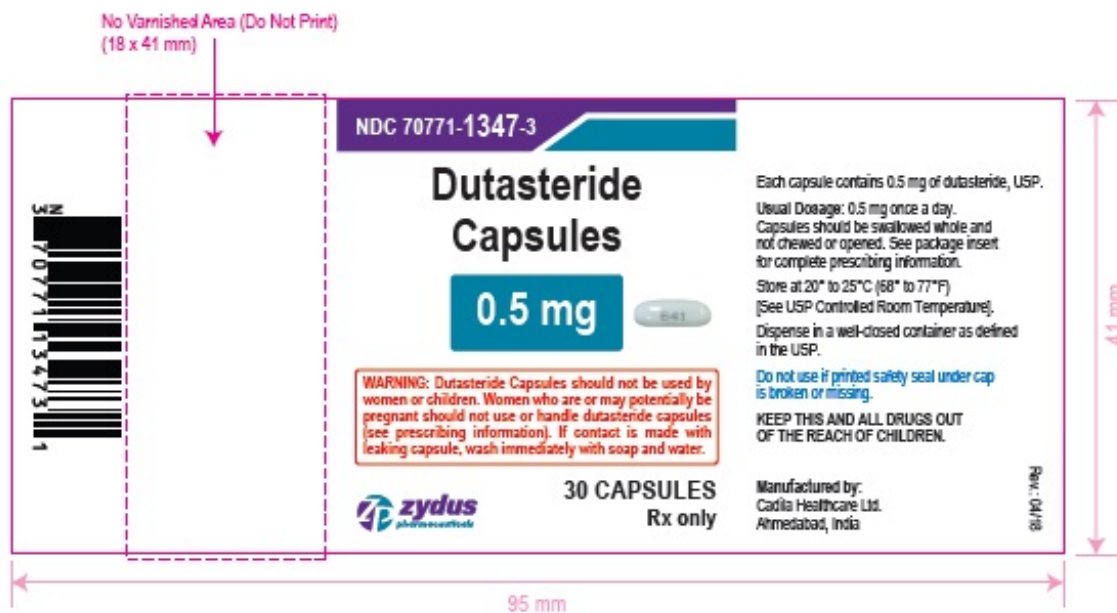
**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

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>
DUTASTERIDE (UNII: O0J6XJN02I) (DUTASTERIDE - UNII:O0J6XJN02I)	DUTASTERIDE	0.5 mg

**Inactive Ingredients**

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

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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**

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

**Labeler** - Cadila Healthcare Limited (918596198)

**Registrant** - Cadila Healthcare Limited (918596198)

**Establishment**

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

Revised: 8/2020

Cadila Healthcare Limited