

TAMSULOSIN HYDROCHLORIDE - tamsulosin hydrochloride capsule
Zydus Lifesciences Limited

TAMSULOSIN HYDROCHLORIDE CAPSULES, USP

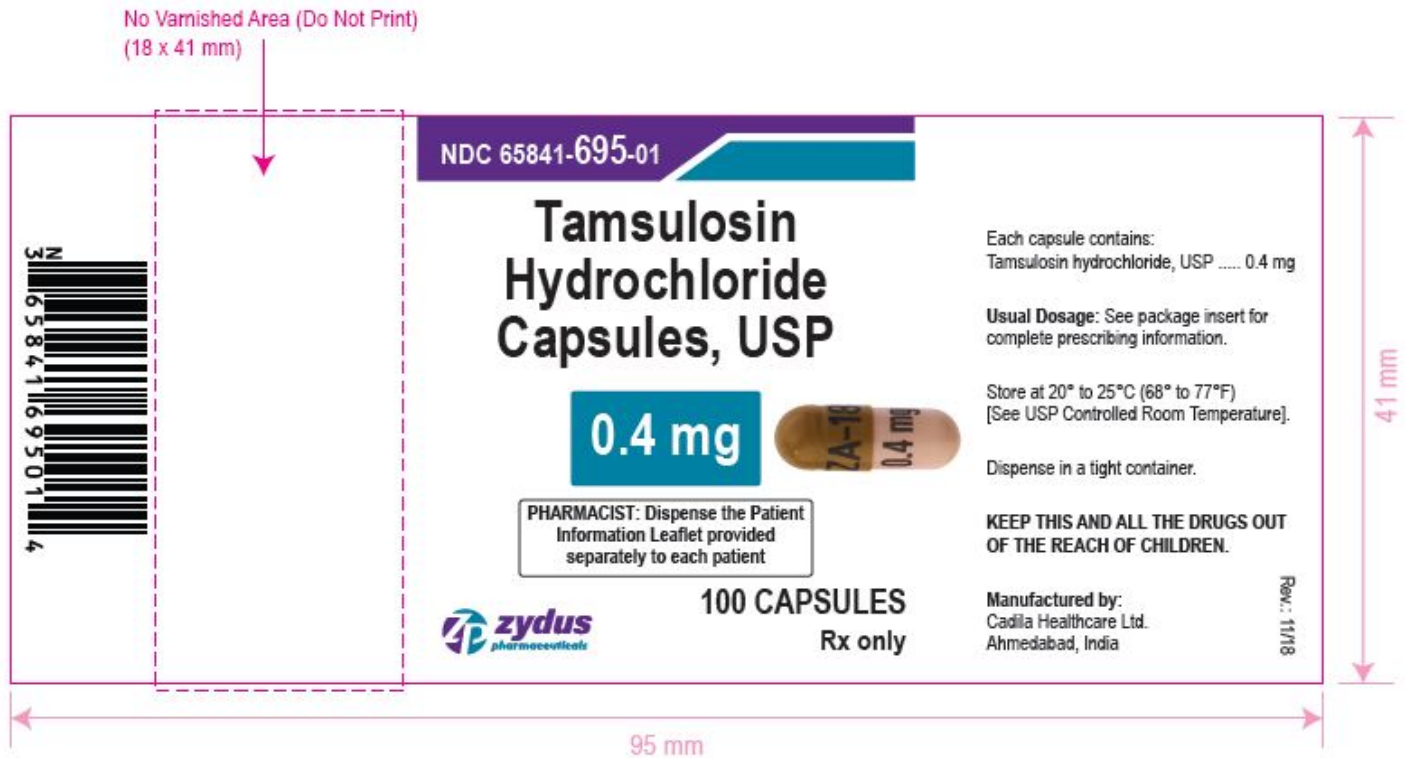
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 65841-695-01 in bottle of 100 Capsules

Tamsulosin Hydrochloride Capsules USP, 0.4 mg

R_x only

100 Capsules



TAMSULOSIN HYDROCHLORIDE

tamsulosin hydrochloride capsule

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:65841-695
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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TAMSULOSIN HYDROCHLORIDE (UNII: 11SV1951MR) (TAMSULOSIN - UNII:G3P28OML5I)	TAMSULOSIN HYDROCHLORIDE	0.4 mg
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Inactive Ingredients

Ingredient Name	Strength
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
METHACRYLIC ACID (UNII: 1CS02G8656)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
GELATIN (UNII: 2G86QN327L)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	

Product Characteristics

Color	GREEN (GREEN) , ORANGE (PEACH)	Score	no score
Shape	CAPSULE (CAPSULE)	Size	18mm
Flavor		Imprint Code	ZA;18;0;4mg
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-695-06	30 in 1 BOTTLE; Type 0: Not a Combination Product	04/27/2010	
2	NDC:65841-695-14	60 in 1 BOTTLE; Type 0: Not a Combination Product	04/27/2010	
3	NDC:65841-695-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	04/27/2010	
4	NDC:65841-695-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	04/27/2010	
5	NDC:65841-695-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	04/27/2010	
6	NDC:65841-695-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	04/27/2010	
7	NDC:65841-695-77	10 in 1 CARTON	04/27/2010	
7		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

ANDA	ANDA078225	04/27/2010	
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Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		918596198	ANALYSIS(65841-695) , MANUFACTURE(65841-695)

Revised: 10/2022

Zydus Lifesciences Limited