

BOSENTAN- bosentan tablet
Cadila Healthcare Limited

BOSENTAN TABLETS

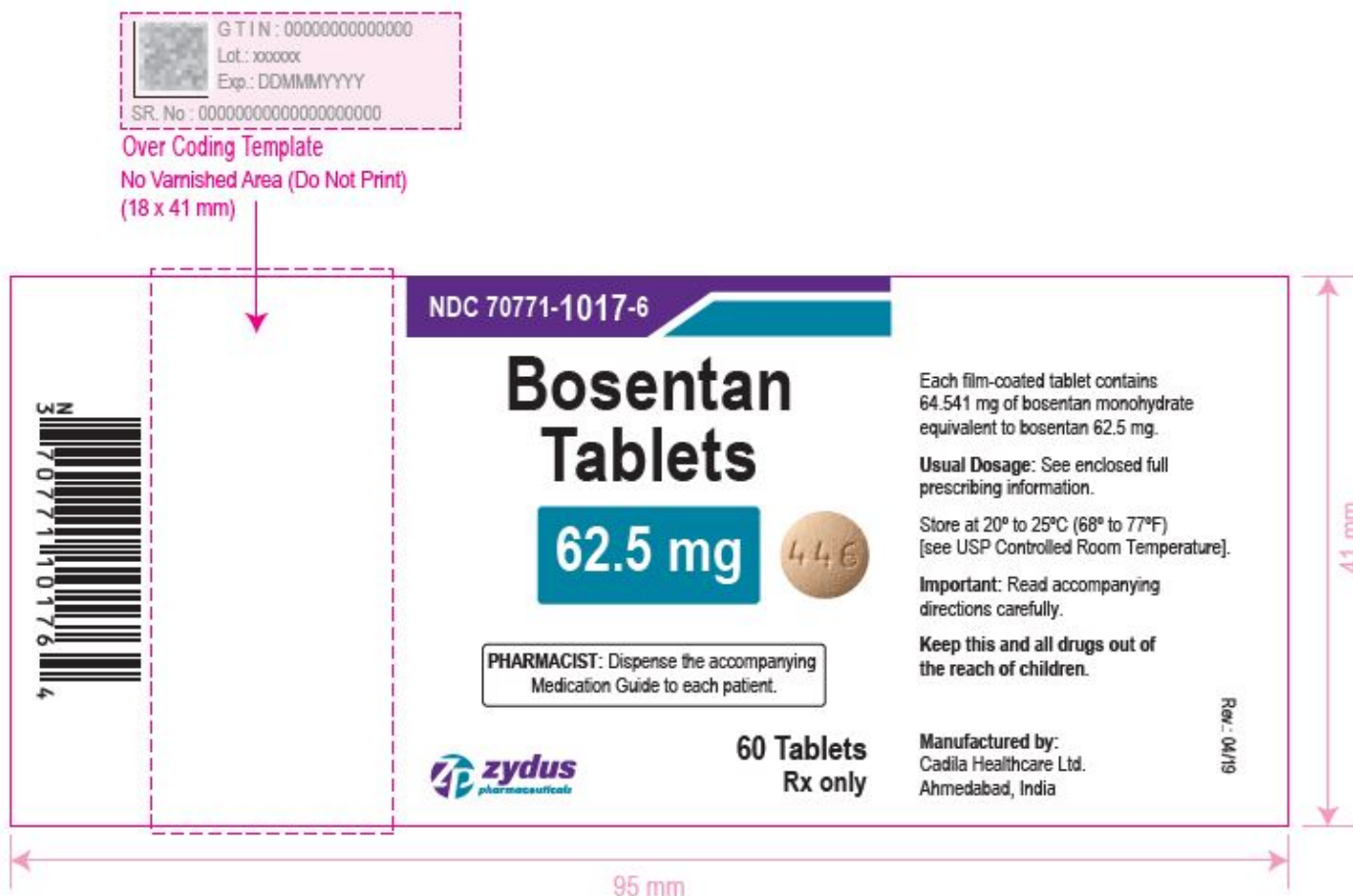
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1017-6

Bosentan tablets, 62.5 mg

60 tablets

Rx only



NDC 70771-1018-6

Bosentan tablets, 125 mg

60 tablets

Rx only

GTIN : 00000000000000
 Lot : xxxxxx
 Exp : DDMMYYYY
 SR. No : 000000000000000000

Over Coding Template
 No Varnished Area (Do Not Print)
 (18 x 41 mm)

NDC 70771-1018-6

Bosentan Tablets

125 mg

60 Tablets Rx only

zydus pharmaceuticals

Each film-coated tablet contains 129.082 mg of bosentan monohydrate equivalent to bosentan 125 mg.

Usual Dosage: See enclosed full prescribing information.

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

Important: Read accompanying directions carefully.

Keep this and all drugs out of the reach of children.

PHARMACIST: Dispense the accompanying Medication Guide to each patient.

Manufactured by: Cadila Healthcare Ltd. Ahmedabad, India

Rev: 04/19

95 mm (width), 41 mm (height)

BOSENTAN

bosentan tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1017
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BOSENTAN (UNII: Q326023R30) (BOSENTAN ANHYDROUS - UNII:XUL93R30K2)	BOSENTAN ANHYDROUS	62.5 mg

Inactive Ingredients

Ingredient Name	Strength
ETHYLCELLULOSE, UNSPECIFIED (UNII: 7Z8S9VYZ4B)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
GLYCERYL DIBEHENATE (UNII: R8WTH25YS2)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POVIDONE (UNII: FZ989GH94E)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	

Product Characteristics

Color	PINK (LIGHT PINK)	Score	no score
Shape	ROUND (BICONVEX)	Size	7mm
Flavor		Imprint Code	446
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1017-6	60 in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2019	
2	NDC:70771-1017-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2019	
3	NDC:70771-1017-8	180 in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2019	
4	NDC:70771-1017-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2019	
5	NDC:70771-1017-4	10 in 1 CARTON	05/01/2019	
5	NDC:70771-1017-2	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	ANDA207760	05/01/2019	

BOSENTAN

bosentan tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1018
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BOSENTAN (UNII: Q326023R30) (BOSENTAN ANHYDROUS - UNII:XUL93R30K2)	BOSENTAN ANHYDROUS	125 mg

Inactive Ingredients

Ingredient Name	Strength
ETHYLCELLULOSE, UNSPECIFIED (UNII: 7Z8S9VYZ4B)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
GLYCERYL DIBEHENATE (UNII: R8WTH25YS2)	

HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)
MAGNESIUM STEARATE (UNII: 70097M6I30)
POVIDONE (UNII: FZ989GH94E)
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)
STARCH, CORN (UNII: O8232NY3SJ)
TALC (UNII: 7SEV7J4R1U)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
TRIACETIN (UNII: XHX3C3X673)

Product Characteristics

Color	PINK (LIGHT PINK)	Score	no score
Shape	OVAL (BICONVEX)	Size	11mm
Flavor		Imprint Code	447
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-10-18-6	60 in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2019	
2	NDC:70771-10-18-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2019	
3	NDC:70771-10-18-8	180 in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2019	
4	NDC:70771-10-18-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2019	
5	NDC:70771-10-18-4	10 in 1 CARTON	05/01/2019	
5	NDC:70771-10-18-2	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	ANDA207760	05/01/2019	

Labeler - Cadila Healthcare Limited (918596198)

Registrant - Cadila Healthcare Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Cadila Healthcare Limited		863362789	ANALYSIS(70771-1017, 70771-1018) , MANUFACTURE(70771-1017, 70771-1018)