BOSENTAN- bosentan tablet
Zydus Lifesciences Limited

BOSENTAN TABLETS

SPL MEDGUIDE

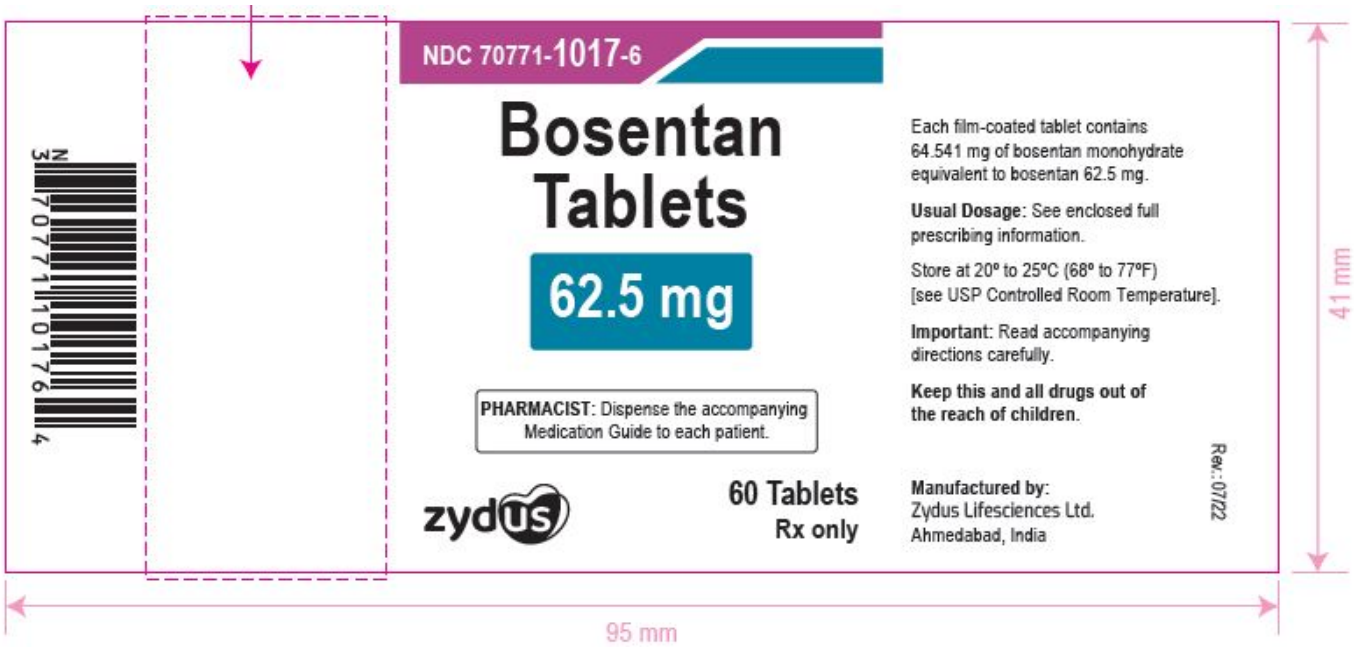
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

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

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:70771-1018-6	60 in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2019	
2	NDC:70771-1018-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2019	
3	NDC:70771-1018-8	180 in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2019	
4	NDC:70771-1018-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2019	
5	NDC:70771-1018-4	10 in 1 CARTON	05/01/2019	
5	NDC:70771-1018-2	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 - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

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