AMBRISENTAN- ambrisentan tablet, film coated
Zydus Lifesciences Limited

AMBRISENTAN Tablets

SPL MEDGUIDE

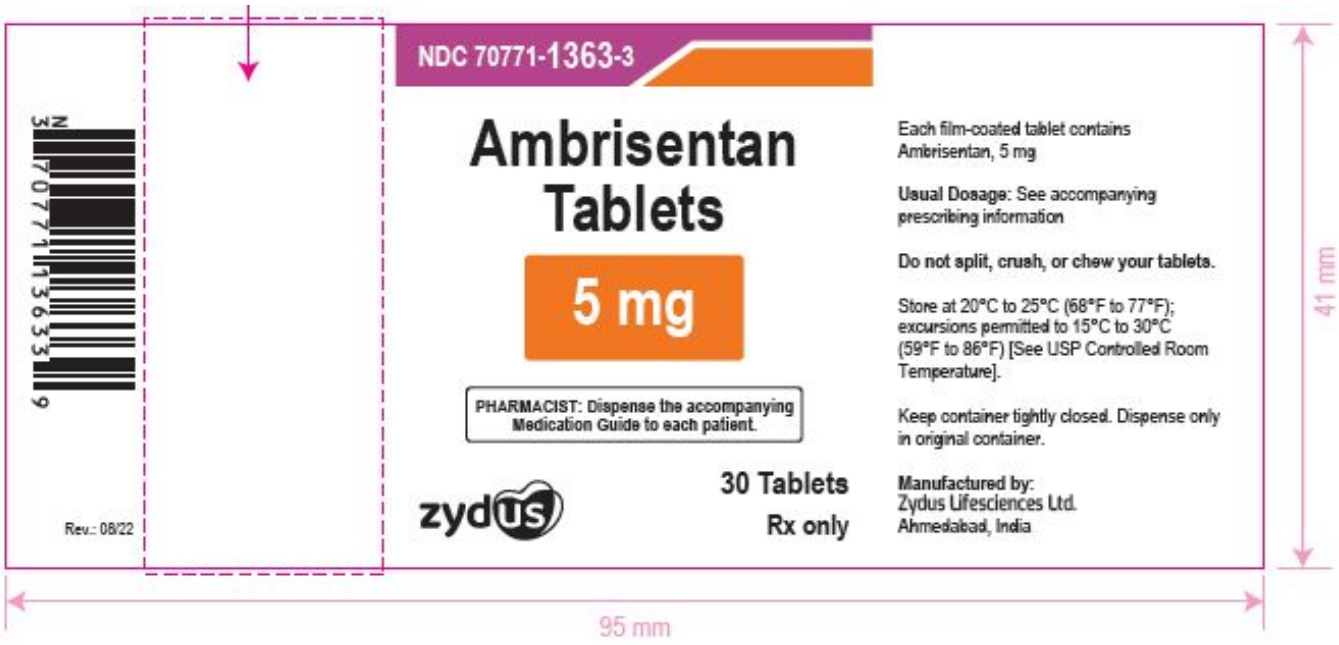
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1363-3

Ambrisentan Tablets, 5 mg

30 Tablets

Rx only



NDC 70771-1364-3

Ambrisentan Tablets, 10 mg

30 Tablets

Rx only

AMBRISENTAN

ambrisentan tablet, film coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1363
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
AMBRISENTAN (UNII: HW6NV07QEC) (AMBRISENTAN - UNII:HW6NV07QEC)	AMBRISENTAN	5 mg

Inactive Ingredients	
Ingredient Name	**Strength**
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	

Product Characteristics

Color	PINK (PINK)	**Score**	no score
Shape	ROUND (ROUND)	**Size**	8mm
Flavor		**Imprint Code**	1179
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1363-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	04/12/2019	
2	NDC:70771-1363-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	04/12/2019	
3	NDC:70771-1363-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	04/12/2019	
4	NDC:70771-1363-8	3 in 1 CARTON	04/12/2019	
4		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
5	NDC:70771-1363-7	1 in 1 CARTON	04/12/2019	
5		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	ANDA210058	04/12/2019	

AMBRISENTAN

ambrisentan tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1364
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AMBRISENTAN (UNII: HW6NV07QEC) (AMBRISENTAN - UNII:HW6NV07QEC)	AMBRISENTAN	10 mg

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	

MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	

Product Characteristics

Color	WHITE (OFF WHITE)	**Score**	no score
Shape	OVAL (OVAL)	**Size**	10mm
Flavor		**Imprint Code**	1180
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1364-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	04/12/2019	
2	NDC:70771-1364-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	04/12/2019	
3	NDC:70771-1364-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	04/12/2019	
4	NDC:70771-1364-8	3 in 1 CARTON	04/12/2019	
4		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
5	NDC:70771-1364-7	1 in 1 CARTON	04/12/2019	
5		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	ANDA210058	04/12/2019	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		863362789	ANALYSIS(70771-1363, 70771-1364) , MANUFACTURE(70771-1363, 70771-1364)