IVABRADINE- ivabradine tablet
Zydus Lifesciences Limited

Ivabradine Tablets

SPL MEDGUIDE

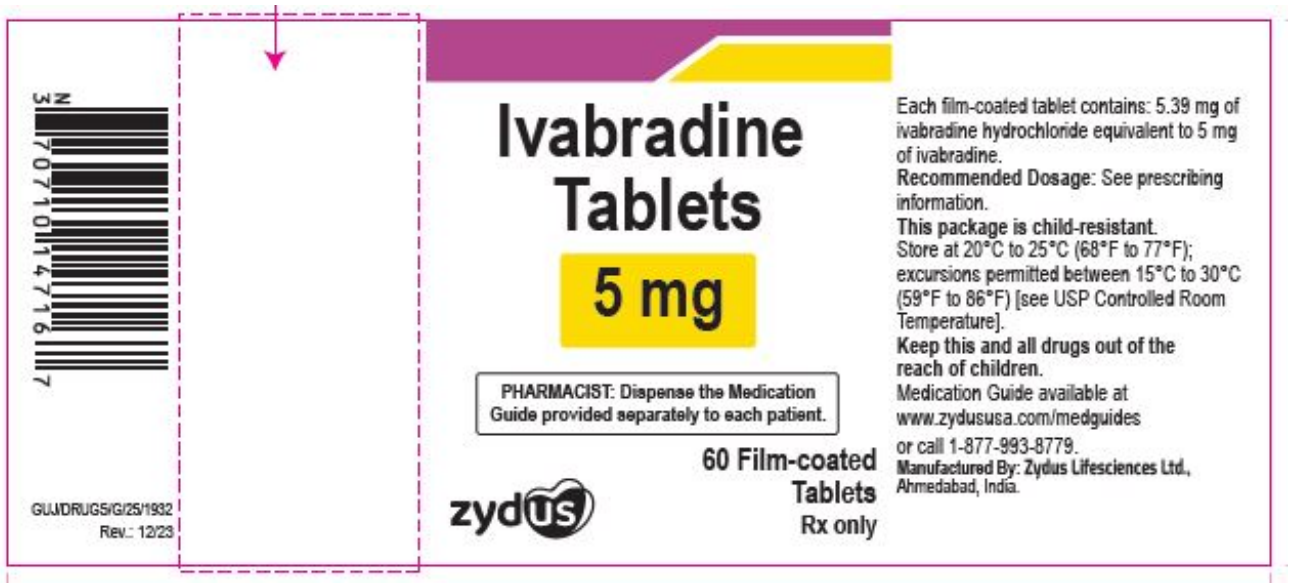
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Ivabradine Tablets, 5 mg

NDC 70771-1863-6

60 tablets

Rx only



Ivabradine Tablets, 5 mg

NDC 70771-1864-6

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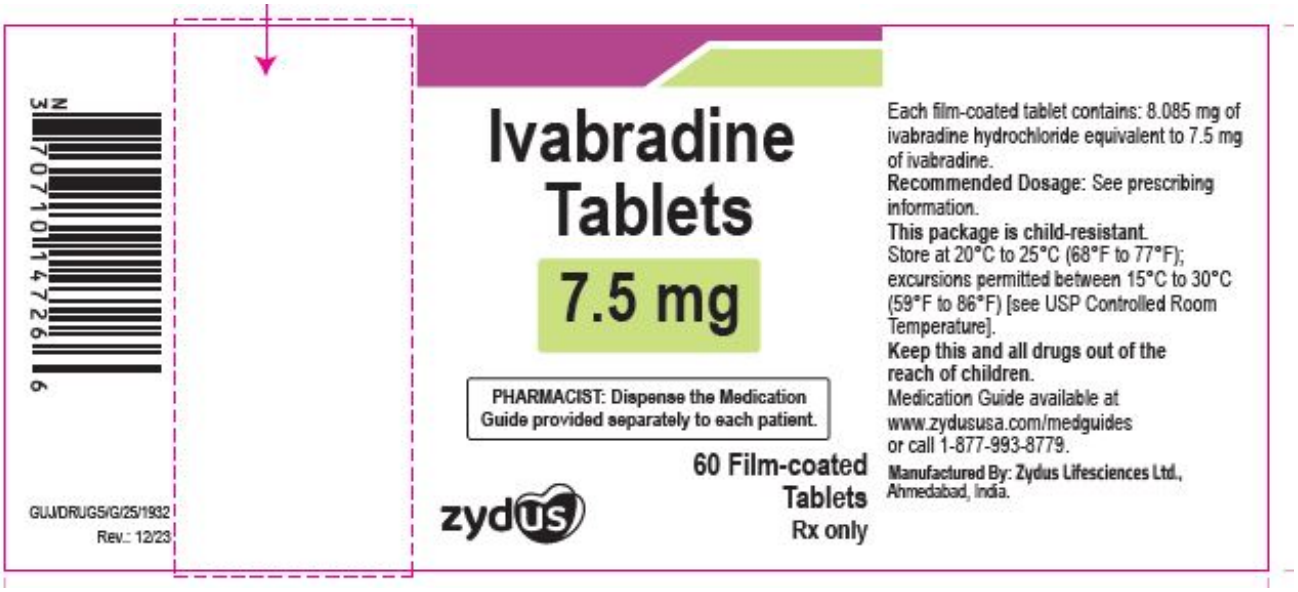

IVABRADINE

ivabradine tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1863
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
IVABRADINE HYDROCHLORIDE (UNII: TP19837BZK) (IVABRADINE - UNII:3H48L0LPZQ)	IVABRADINE	5 mg

Inactive Ingredients	
Ingredient Name	**Strength**
ALUMINUM OXIDE (UNII: LMI26O6933)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
D&C RED NO. 27 ALUMINUM LAKE (UNII: ZK64F7XSTX)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 4000 (UNII: 4R4HFI6D95)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	ORANGE	**Score**	2 pieces
Shape	OVAL	**Size**	9mm
Flavor		**Imprint Code**	1471
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:70771-1863-6	60 in 1 BOTTLE; Type 0: Not a Combination Product	07/02/2024	
2	NDC:70771-1863-8	180 in 1 BOTTLE; Type 0: Not a Combination Product	07/02/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA213442	07/02/2024	

IVABRADINE

ivabradine tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1864
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
IVABRADINE HYDROCHLORIDE (UNII: TP19837BZK) (IVABRADINE - UNII:3H48L0LPZQ)	IVABRADINE	7.5 mg

Inactive Ingredients	
Ingredient Name	**Strength**
ALUMINUM OXIDE (UNII: LMI26O6933)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
D&C RED NO. 27 ALUMINUM LAKE (UNII: ZK64F7XSTX)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 4000 (UNII: 4R4HFI6D95)	

SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	ORANGE	**Score**	no score
Shape	ROUND	**Size**	7mm
Flavor		**Imprint Code**	1472
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1864-6	60 in 1 BOTTLE; Type 0: Not a Combination Product	07/02/2024	
2	NDC:70771-1864-8	180 in 1 BOTTLE; Type 0: Not a Combination Product	07/02/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA213442	07/02/2024	

Labeler - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		863362789	ANALYSIS(70771-1863, 70771-1864) , MANUFACTURE(70771-1863, 70771-1864)

Revised: 12/2023 Zydus Lifesciences Limited