

IVABRADINE- ivabradine tablet
Zydus Lifesciences Limited

Ivabradine Tablets

SPL MEDGUIDE

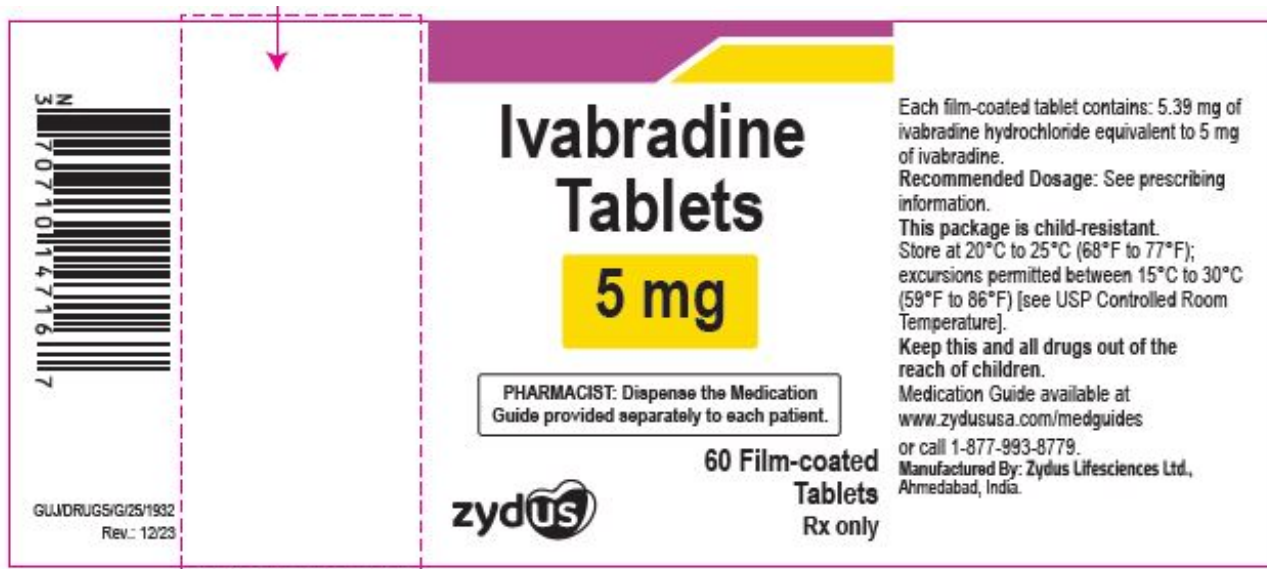
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Ivabradine Tablets, 5 mg

NDC 70771-1863-6

60 tablets

Rx only



Ivabradine Tablets, 5 mg

NDC 70771-1864-6

60 tablets

Rx only

Ivabradine Tablets
7.5 mg

PHARMACIST: Dispense the Medication Guide provided separately to each patient.

60 Film-coated Tablets
Rx only

Each film-coated tablet contains: 8.085 mg of ivabradine hydrochloride equivalent to 7.5 mg of ivabradine.
Recommended Dosage: See prescribing information.
This package is child-resistant.
Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature].
Keep this and all drugs out of the reach of children.
Medication Guide available at www.zydususa.com/medguides or call 1-877-993-8779.
Manufactured By: Zydus Lifesciences Ltd., Ahmedabad, India.

GUJDRUGS/G/25/1932
Rev.: 12/23

zydus

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: 4R4HF16D95)	
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