BISOPROLOL FUMARATE- bisoprolol fumarate tablet, film coated
Zydus Lifesciences Limited

Bisoprolol Fumarate Tablets, USP

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

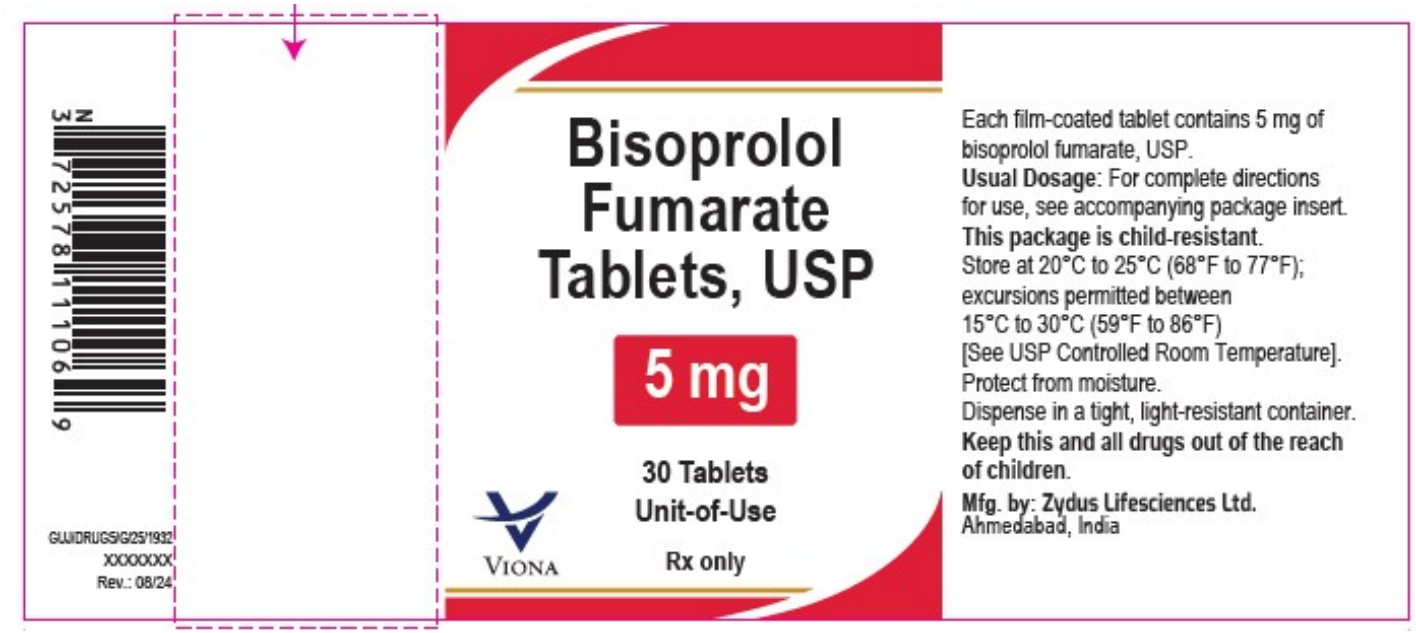
NDC 70771-1726-3

Bisoprolol Fumarate Tablets USP, 5 mg

30 Tablets

Unit-of-Use

Rx only



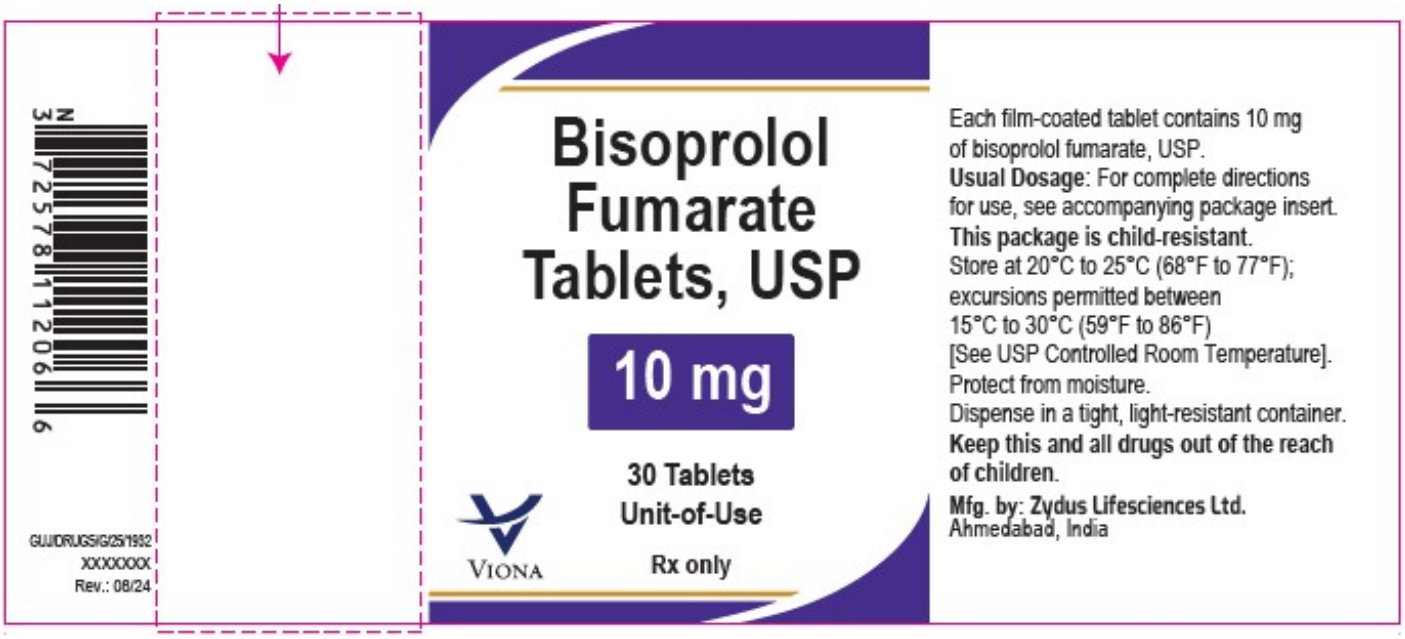
NDC 70771-1727-3

Bisoprolol Fumarate Tablets USP, 10 mg

30 Tablets

Unit-of-Use

Rx only



BISOPROLOL FUMARATE

bisoprolol fumarate tablet, film coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1726
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BISOPROLOL FUMARATE (UNII: UR59KN573L) (BISOPROLOL - UNII:Y41JS2NL6U)	BISOPROLOL FUMARATE	5 mg

Inactive Ingredients	
Ingredient Name	**Strength**
ALUMINUM OXIDE (UNII: LMI26O6933)	
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
CROSPOVIDONE (12 MPA.S AT 5%) (UNII: 40UAA97IT9)	
D&C YELLOW NO. 10 ALUMINUM LAKE (UNII: CQ3XH3DET6)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 6000 (UNII: 30IQX730WE)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	PINK (light pink to pink)	**Score**	2 pieces
Shape	ROUND	**Size**	6mm
Flavor		**Imprint Code**	111
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1726-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	09/15/2022	
2	NDC:70771-1726-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	09/15/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA215680	09/15/2022	

BISOPROLOL FUMARATE

bisoprolol fumarate tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1727
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BISOPROLOL FUMARATE (UNII: UR59KN573L) (BISOPROLOL - UNII:Y41JS2NL6U)	BISOPROLOL FUMARATE	10 mg

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
CROSPOVIDONE (12 MPA.S AT 5%) (UNII: 40UAA97IT9)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 6000 (UNII: 30IQX730WE)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	WHITE (white to off white colored with occasional greyish)	**Score**	no score
Shape	ROUND	**Size**	7mm
Flavor		**Imprint Code**	112
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1727-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	09/15/2022	
2	NDC:70771-1727-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	09/15/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA215680	09/15/2022	

Labeler - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		863362789	ANALYSIS(70771-1726, 70771-1727) , MANUFACTURE(70771-1726, 70771-1727)

Revised: 8/2024 Zydus Lifesciences Limited