BISOPROLOL FUMARATE AND HYDROCHLOROTHIAZIDE - bisoprolol fumarate and hydrochlorothiazide tablet, film coated
Zydus Lifesciences Limited

Bisoprolol Fumarate and Hydrochlorothiazide Tablets, USP

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1760-3

Bisoprolol Fumarate and Hydrochlorothiazide Tablets, USP 2.5 mg/6.25 mg

30 Tablets Unit-of-Use

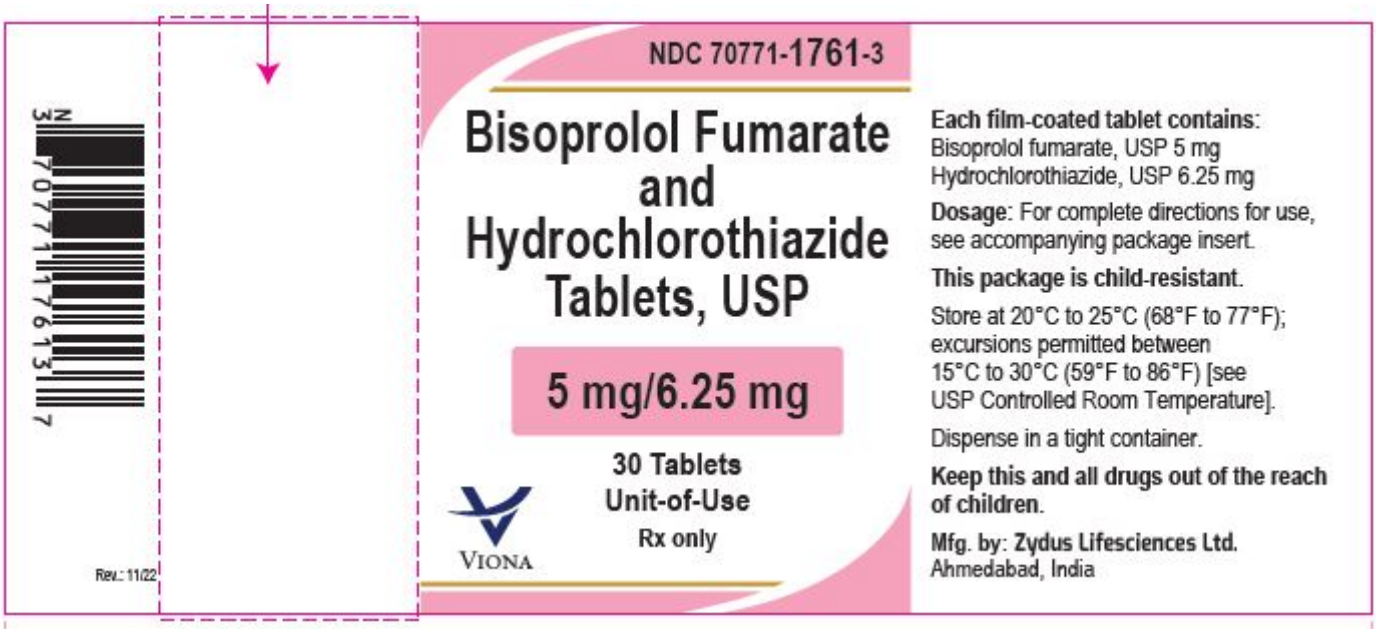
Rx only

NDC 70771-1761-3

Bisoprolol Fumarate and Hydrochlorothiazide Tablets, USP 5 mg/6.25 mg

30 Tablets Unit-of-Use

Rx only



NDC 70771-1762-3

Bisoprolol Fumarate and Hydrochlorothiazide Tablets, USP 10 mg/6.25 mg

30 Tablets Unit-of-Use

Rx only

BISOPROLOL FUMARATE AND HYDROCHLOROTHIAZIDE

bisoprolol fumarate and hydrochlorothiazide tablet, film coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1760

Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BISOPROLOL FUMARATE (UNII: UR59KN573L) (BISOPROLOL - UNII:Y41JS2NL6U)	BISOPROLOL FUMARATE	2.5 mg
HYDROCHLOROTHIAZIDE (UNII: 0J48LPH2TH) (HYDROCHLOROTHIAZIDE - UNII:0J48LPH2TH)	HYDROCHLOROTHIAZIDE	6.25 mg

Inactive Ingredients

Ingredient Name	Strength
MICROCRYSTALLINE CELLULOSE 102 (UNII: PNR0YF693Y)	
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSPOVIDONE (35 .MU.M) (UNII: 40UAA97IT9)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYETHYLENE GLYCOL 8000 (UNII: Q662QK8M3B)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

Product Characteristics

Color	YELLOW (with occasional greyish to black speckles)	**Score**	no score
Shape	ROUND (round)	**Size**	7mm
Flavor		**Imprint Code**	113
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1760-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	03/01/2023	
2	NDC:70771-1760-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	03/01/2023	
3	NDC:70771-1760-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	03/01/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA215666	03/01/2023	

BISOPROLOL FUMARATE AND HYDROCHLOROTHIAZIDE

bisoprolol fumarate and hydrochlorothiazide tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1761
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
HYDROCHLOROTHIAZIDE (UNII: 0J48LPH2TH) (HYDROCHLOROTHIAZIDE - UNII:0J48LPH2TH)	HYDROCHLOROTHIAZIDE	6.25 mg

Inactive Ingredients

Ingredient Name	Strength
MICROCRYSTALLINE CELLULOSE 102 (UNII: PNR0YF693Y)	
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSPOVIDONE (35 .MU.M) (UNII: 40UAA97IT9)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYETHYLENE GLYCOL 8000 (UNII: Q662QK8M3B)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
D&C YELLOW NO. 10 ALUMINUM LAKE (UNII: CQ3XH3DET6)	
ALUMINUM OXIDE (UNII: LMI26O6933)	

Product Characteristics

Color	PINK (light pink to pink)	**Score**	no score
Shape	ROUND (round)	**Size**	7mm
Flavor		**Imprint Code**	114
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1761-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	03/01/2023	
2	NDC:70771-1761-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	03/01/2023	
3	NDC:70771-1761-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	03/01/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA215666	03/01/2023	

BISOPROLOL FUMARATE AND HYDROCHLOROTHIAZIDE

bisoprolol fumarate and hydrochlorothiazide tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1762
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
HYDROCHLOROTHIAZIDE (UNII: 0J48LPH2TH) (HYDROCHLOROTHIAZIDE - UNII:0J48LPH2TH)	HYDROCHLOROTHIAZIDE	6.25 mg

Inactive Ingredients

Ingredient Name	Strength
MICROCRYSTALLINE CELLULOSE 102 (UNII: PNR0YF693Y)	
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSPOVIDONE (35 .MU.M) (UNII: 40UAA97IT9)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYETHYLENE GLYCOL 8000 (UNII: Q662QK8M3B)	

Product Characteristics

Color	WHITE (with occasional greyish to black speckles)	**Score**	no score
Shape	ROUND (round)	**Size**	7mm
Flavor		**Imprint Code**	115
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1762-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	03/01/2023	
2	NDC:70771-1762-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	03/01/2023	

3	NDC:70771-1762-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	03/01/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA215666	03/01/2023	

Labeler - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		863362789	ANALYSIS(70771-1760, 70771-1761, 70771-1762) , MANUFACTURE(70771-1760, 70771-1761, 70771-1762)

Revised: 11/2022 Zydus Lifesciences Limited