BENAZEPRIL HYDROCHLORIDE - benazepril hydrochloride tablet, film coated
Zydus Lifesciences Limited

BENAZEPRIL HYDROCHLORIDE TABLETS

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1148-9

Benazepril Hydrochloride Tablets, 5 mg

90 Tablets

Rx only

NDC 70771-1149-9

Benazepril Hydrochloride Tablets, 10 mg

90 Tablets

Rx only

NDC 70771-1150-9

Benazepril Hydrochloride Tablets, 20 mg

90 Tablets

Rx only

NDC 70771-1151-9

Benazepril Hydrochloride Tablets, 40 mg

90 Tablets

Rx only

BENAZEPRIL HYDROCHLORIDE

benazepril hydrochloride tablet, film coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1148
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BENAZEPRIL HYDROCHLORIDE (UNII: N1SN99T69T) (BENAZEPRILAT - UNII:JRM708L703)	BENAZEPRIL HYDROCHLORIDE	5 mg

Inactive Ingredients	
Ingredient Name	**Strength**
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
HYDROGENATED COTTONSEED OIL (UNII: Z82Y2C65EA)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	
SHELLAC (UNII: 46N107B71O)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
SILICON (UNII: Z4152N8IUI)	
CROSPOVIDONE (UNII: 2S7830E561)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	

Product Characteristics			
Color	YELLOW (LIGHT YELLOW)	**Score**	no score
Shape	ROUND (ROUND)	**Size**	6mm
Flavor		**Imprint Code**	B1
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1148-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	11/13/2017	
2	NDC:70771-1148-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	11/13/2017	
3	NDC:70771-1148-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	11/13/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078848	11/13/2017	

BENAZEPRIL HYDROCHLORIDE

benazepril hydrochloride tablet, film coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1149
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENAZEPRIL HYDROCHLORIDE (UNII: N1SN99T69T) (BENAZEPRILAT - UNII:JRM708L703)	BENAZEPRIL HYDROCHLORIDE	10 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYDROGENATED COTTONSEED OIL (UNII: Z82Y2C65EA)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	
SHELLAC (UNII: 46N107B71O)	

LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
SILICON (UNII: Z4152N8IUI)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
CROSPOVIDONE (UNII: 2S7830E561)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE)	**Score**	no score
Shape	ROUND (ROUND)	**Size**	6mm
Flavor		**Imprint Code**	B2
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1149-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	11/13/2017	
2	NDC:70771-1149-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	11/13/2017	
3	NDC:70771-1149-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	11/13/2017	
4	NDC:70771-1149-4	100 in 1 CARTON	11/13/2017	
4	NDC:70771-1149-2	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	ANDA078848	11/13/2017	

BENAZEPRIL HYDROCHLORIDE

benazepril hydrochloride tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1150
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENAZEPRIL HYDROCHLORIDE (UNII: N1SN99T69T) (BENAZEPRILAT - UNII:JRM708L703)	BENAZEPRIL HYDROCHLORIDE	20 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYDROGENATED COTTONSEED OIL (UNII: Z82Y2C65EA)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	
SHELLAC (UNII: 46N107B71O)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
SILICON (UNII: Z4152N8IUI)	
CROSPOVIDONE (UNII: 2S7830E561)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE)	**Score**	no score
Shape	ROUND (ROUND)	**Size**	8mm
Flavor		**Imprint Code**	B3
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1150-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	11/13/2017	
2	NDC:70771-1150-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	11/13/2017	
3	NDC:70771-1150-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	11/13/2017	
4	NDC:70771-1150-4	100 in 1 CARTON	11/13/2017	
4	NDC:70771-1150-2	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	ANDA078848	11/13/2017	

BENAZEPRIL HYDROCHLORIDE

benazepril hydrochloride tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1151

Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENAZEPRIL HYDROCHLORIDE (UNII: N1SN99T69T) (BENAZEPRILAT - UNII:JRM708L703)	BENAZEPRIL HYDROCHLORIDE	40 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYDROGENATED COTTONSEED OIL (UNII: Z82Y2C65EA)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	
SHELLAC (UNII: 46N107B71O)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
SILICON (UNII: Z4152N8IUI)	
CROSPOVIDONE (UNII: 2S7830E561)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE)	**Score**	no score
Shape	ROUND (ROUND)	**Size**	10mm
Flavor		**Imprint Code**	B4
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1151-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	11/13/2017	
2	NDC:70771-1151-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	11/13/2017	
3	NDC:70771-1151-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	11/13/2017	
4	NDC:70771-1151-4	100 in 1 CARTON	11/13/2017	
4	NDC:70771-1151-2	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	ANDA078848	11/13/2017	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		918596198	ANALYSIS(70771-1148, 70771-1149, 70771-1150, 70771-1151) , MANUFACTURE(70771-1148, 70771-1149, 70771-1150, 70771-1151)

Revised: 11/2022 Zydus Lifesciences Limited