GLIPIZIDE - glipizide tablet, extended release
Zydus Lifesciences Limited

Glipizide Extended-Release Tablets

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

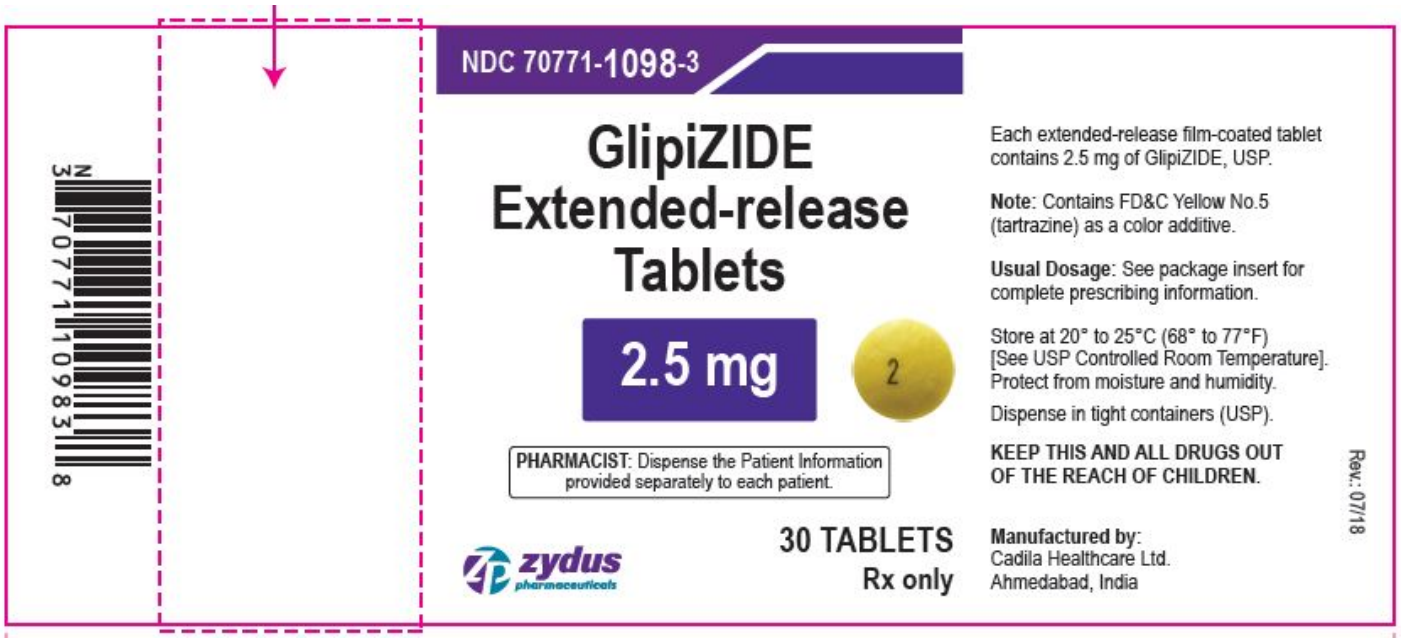
NDC 70771-1098-3 in bottle of 30 tablets

Glipizide Tablets, 2.5 mg

R_x only

30 tablets

ZYDUS



NDC 70771-1099-3 in bottle of 30 tablets

Glipizide Tablets, 5 mg

R_x only

30 tablets

ZYDUS

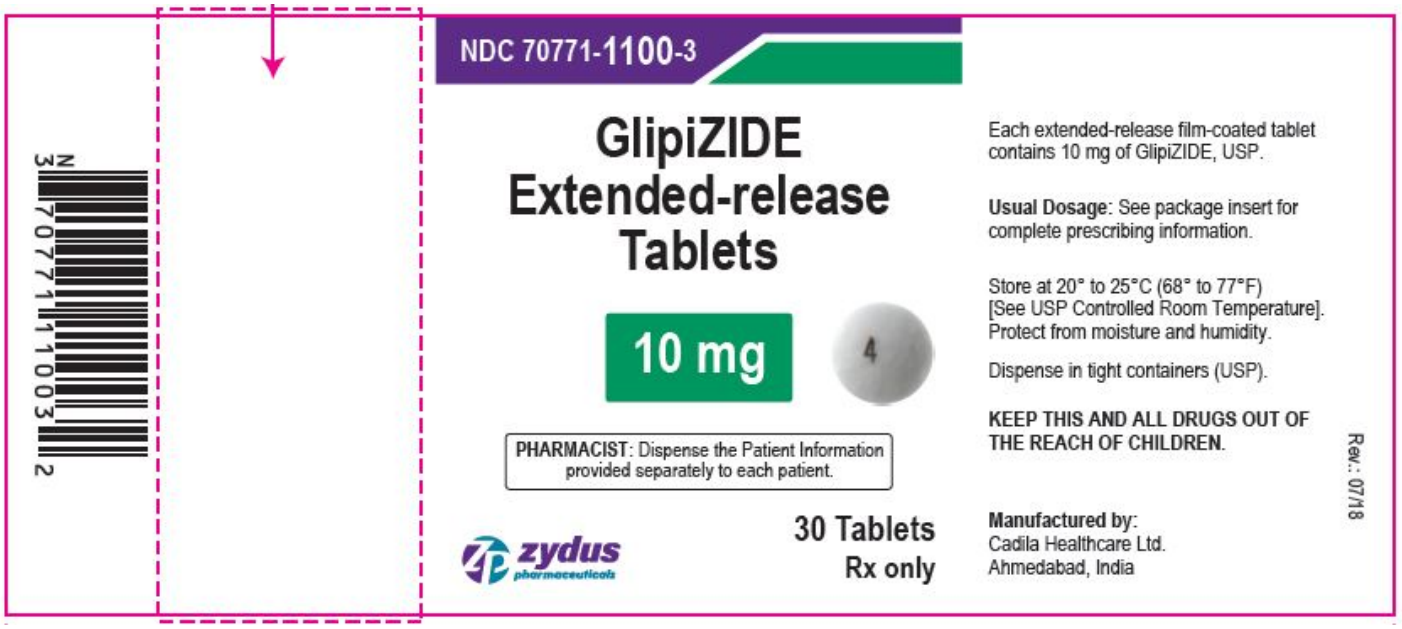
NDC 70771-1100-3 in bottle of 30 tablets

Glipizide Tablets, 10 mg

R_X only

30 tablets

ZYDUS



GLIPIZIDE

glipizide tablet, extended release

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1098
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GLIPIZIDE (UNII: X7WDT95N5C) (GLIPIZIDE - UNII:X7WDT95N5C)	GLIPIZIDE	2.5 mg

Inactive Ingredients

Ingredient Name	Strength
ACETYLTRIBUTYL CITRATE (UNII: 0ZBX0N59RZ)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
AMMONIA (UNII: 5138Q19F1X)	
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
HYDROXYETHYL CELLULOSE (2000 CPS AT 1%) (UNII: S38J6RZN16)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:1) (UNII: 74G4R6TH13)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	YELLOW (Yellow)	**Score**	no score
Shape	ROUND (Round)	**Size**	6mm
Flavor		**Imprint Code**	2
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1098-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	07/25/2018	
2	NDC:70771-1098-6	60 in 1 BOTTLE; Type 0: Not a Combination Product	07/25/2018	
3	NDC:70771-1098-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	07/25/2018	
4	NDC:70771-1098-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	07/25/2018	
5	NDC:70771-	500 in 1 BOTTLE; Type 0: Not a Combination	07/25/2018	

5	1098-5	Product	07/25/2018	
6	NDC:70771-1098-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	07/25/2018	
7	NDC:70771-1098-4	10 in 1 CARTON	07/25/2018	
7	NDC:70771-1098-2	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	ANDA203499	07/25/2018	

GLIPIZIDE

glipizide tablet, extended release

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1099
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GLIPIZIDE (UNII: X7WDT95N5C) (GLIPIZIDE - UNII:X7WDT95N5C)	GLIPIZIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
ACETYLTRIBUTYL CITRATE (UNII: 0ZBX0N59RZ)	
AMMONIA (UNII: 5138Q19F1X)	
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
HYDROXYETHYL CELLULOSE (2000 CPS AT 1%) (UNII: S38J6RZN16)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:1) (UNII: 74G4R6TH13)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	ORANGE (Orange)	**Score**	no score
Shape	ROUND (Round)	**Size**	6mm
Flavor		**Imprint Code**	3
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1099-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	07/25/2018	
2	NDC:70771-1099-6	60 in 1 BOTTLE; Type 0: Not a Combination Product	07/25/2018	
3	NDC:70771-1099-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	07/25/2018	
4	NDC:70771-1099-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	07/25/2018	
5	NDC:70771-1099-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	07/25/2018	
6	NDC:70771-1099-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	07/25/2018	
7	NDC:70771-1099-4	10 in 1 CARTON	07/25/2018	
7	NDC:70771-1099-2	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	ANDA203499	07/25/2018	

GLIPIZIDE

glipizide tablet, extended release

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1100
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GLIPIZIDE (UNII: X7WDT95N5C) (GLIPIZIDE - UNII:X7WDT95N5C)	GLIPIZIDE	10 mg

Inactive Ingredients

Ingredient Name	Strength

ACETYLTRIBUTYL CITRATE (UNII: 0ZBX0N59RZ)	
AMMONIA (UNII: 5138Q19F1X)	
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
HYDROXYETHYL CELLULOSE (2000 CPS AT 1%) (UNII: S38J6RZN16)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:1) (UNII: 74G4R6TH13)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Product Characteristics

Color	WHITE (White)	**Score**	no score
Shape	ROUND (Round)	**Size**	6mm
Flavor		**Imprint Code**	4
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1100-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	07/25/2018	
2	NDC:70771-1100-6	60 in 1 BOTTLE; Type 0: Not a Combination Product	07/25/2018	
3	NDC:70771-1100-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	07/25/2018	
4	NDC:70771-1100-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	07/25/2018	
5	NDC:70771-1100-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	07/25/2018	
6	NDC:70771-1100-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	07/25/2018	
7	NDC:70771-1100-4	10 in 1 CARTON	07/25/2018	
7	NDC:70771-1100-2	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	ANDA203499	07/25/2018	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		918596198	ANALYSIS(70771-1098, 70771-1099, 70771-1100) , MANUFACTURE(70771-1098, 70771-1099, 70771-1100)

Revised: 10/2022 Zydus Lifesciences Limited