GLIPIZIDE AND METFORMIN HYDROCHLORIDE- glipizide and metformin hydrochloride tablet, film coated
GLIPIZIDE AND METFORMIN HYDROCHLORIDE- glipizide and metformin hydrochloride tablet, film coated
Zydus Lifesciences Limited

Glipizide and Metformin Hydrochloride Tablets, USP

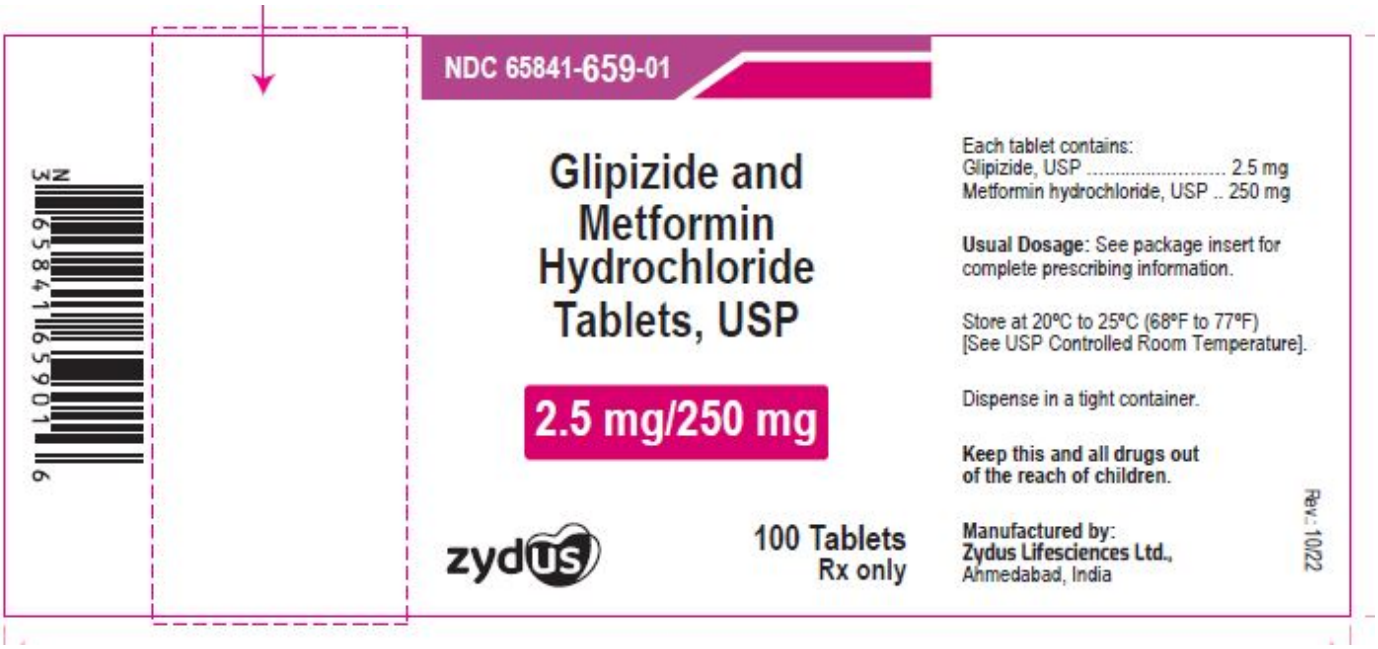
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 65841-659-01 in bottle of 100 tablets

Glipizide and Metformin Hydrochloride Tablets USP, 2.5 mg/250 mg

R_x only

100 tablets

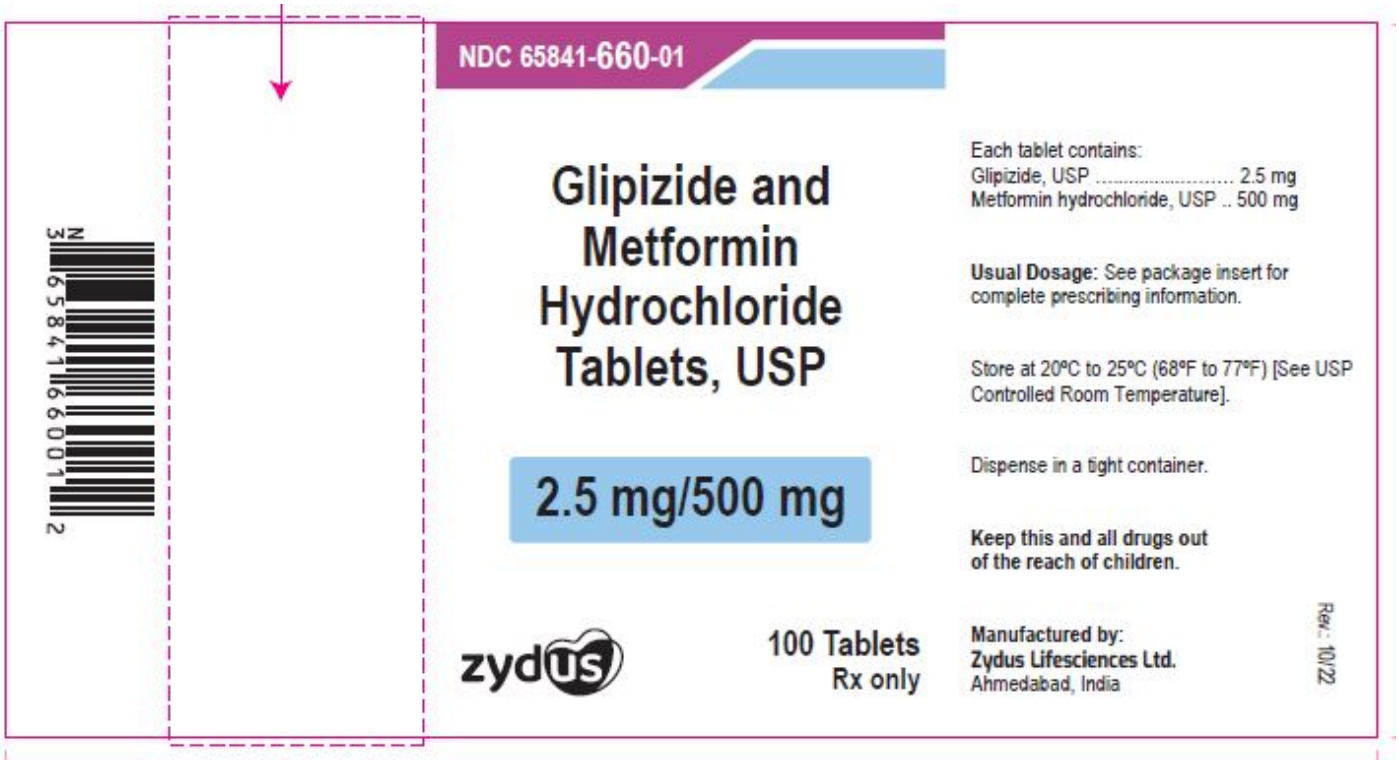


NDC 65841-660-01 in bottle of 100 tablets

Glipizide and Metformin Hydrochloride Tablets USP, 2.5 mg/500 mg

R_x only

100 tablets

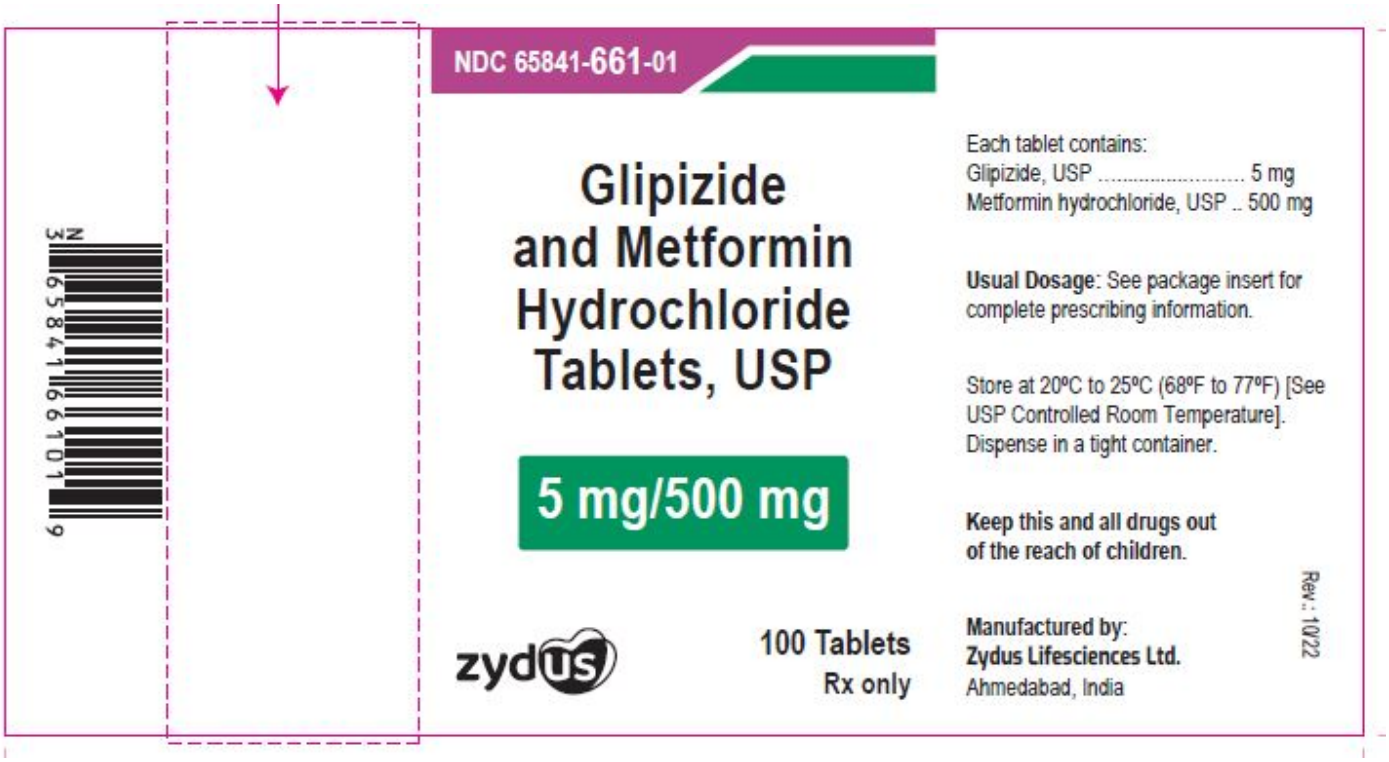


NDC 65841-661-01 in bottle of 100 tablets

Glipizide and Metformin Hydrochloride Tablets USP, 5 mg/500 mg

R_x only

100 tablets



GLIPIZIDE AND METFORMIN HYDROCHLORIDE

glipizide and metformin hydrochloride tablet, film coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-659
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
GLIPIZIDE (UNII: X7WDT95N5C) (GLIPIZIDE - UNII:X7WDT95N5C)	GLIPIZIDE	2.5 mg
METFORMIN HYDROCHLORIDE (UNII: 786Z46389E) (METFORMIN - UNII:9100L32L2N)	METFORMIN HYDROCHLORIDE	250 mg

Inactive Ingredients	
Ingredient Name	**Strength**
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

Product Characteristics			
Color	PINK (PINK)	**Score**	no score
Shape	CAPSULE (CAPSULE)	**Size**	11mm
Flavor		**Imprint Code**	ZE68
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:65841-659-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	05/05/2016	
2	NDC:65841-659-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/05/2016	
3	NDC:65841-659-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	05/05/2016	
4	NDC:65841-659-77	10 in 1 CARTON	05/05/2016	
4	NDC:65841-659-30	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	ANDA078905	05/05/2016	

GLIPIZIDE AND METFORMIN HYDROCHLORIDE

glipizide and metformin hydrochloride tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-660
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GLIPIZIDE (UNII: X7WDT95N5C) (GLIPIZIDE - UNII:X7WDT95N5C)	GLIPIZIDE	2.5 mg
METFORMIN HYDROCHLORIDE (UNII: 786Z46389E) (METFORMIN - UNII:9100L32L2N)	METFORMIN HYDROCHLORIDE	500 mg

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	

Product Characteristics

Color	WHITE (WHITE)	**Score**	no score
Shape	CAPSULE (CAPSULE)	**Size**	15mm
Flavor		**Imprint Code**	ZE67
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-660-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	05/05/2016	
2	NDC:65841-660-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/05/2016	
3	NDC:65841-660-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	05/05/2016	

4	NDC:65841-660-77	10 in 1 CARTON	05/05/2016	
4	NDC:65841-660-30	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	ANDA078905	05/05/2016	

GLIPIZIDE AND METFORMIN HYDROCHLORIDE

glipizide and metformin hydrochloride tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-661
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GLIPIZIDE (UNII: X7WDT95N5C) (GLIPIZIDE - UNII:X7WDT95N5C)	GLIPIZIDE	5 mg
METFORMIN HYDROCHLORIDE (UNII: 786Z46389E) (METFORMIN - UNII:9100L32L2N)	METFORMIN HYDROCHLORIDE	500 mg

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	PINK (PINK)	**Score**	no score
Shape	CAPSULE (CAPSULE)	**Size**	15mm
Flavor		**Imprint Code**	ZE66
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-661-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	05/05/2016	
2	NDC:65841-661-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/05/2016	
3	NDC:65841-661-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	05/05/2016	
4	NDC:65841-661-77	10 in 1 CARTON	05/05/2016	
4	NDC:65841-661-30	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	ANDA078905	05/05/2016	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		918596198	ANALYSIS(65841-659, 65841-660, 65841-661) , MANUFACTURE(65841-659, 65841-660, 65841-661)

Revised: 11/2024 Zydus Lifesciences Limited