

**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**

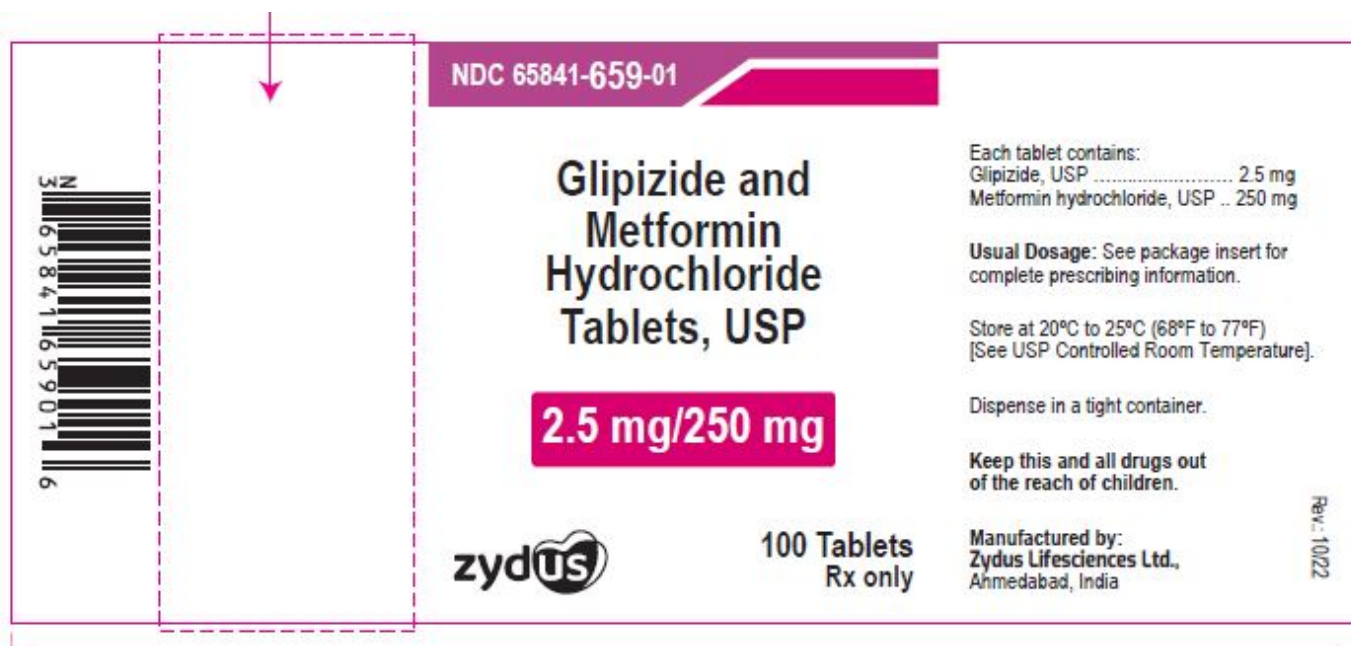
**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

NDC 65841-659-01 in bottle of 100 tablets

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

R<sub>x</sub> only

100 tablets



NDC 65841-660-01 in bottle of 100 tablets

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

R<sub>x</sub> only

100 tablets

NDC 65841-660-01

**Glipizide and Metformin Hydrochloride Tablets, USP**

**2.5 mg/500 mg**

zydUS

100 Tablets  
Rx only

Manufactured by:  
Zydus Lifesciences Ltd.  
Ahmedabad, India

Rev.: 10/22

Each tablet contains:  
Glipizide, USP ..... 2.5 mg  
Metformin hydrochloride, USP .. 500 mg

**Usual Dosage:** See package insert for complete prescribing information.

Store at 20°C to 25°C (68°F to 77°F) [See USP Controlled Room Temperature].

Dispense in a tight container.

Keep this and all drugs out of the reach of children.

N  
3 65841 66001 2

NDC 65841-661-01 in bottle of 100 tablets

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

R<sub>x</sub> only

100 tablets

NDC 65841-661-01

**Glipizide and Metformin Hydrochloride Tablets, USP**

**5 mg/500 mg**

zydUS

100 Tablets  
Rx only

Manufactured by:  
Zydus Lifesciences Ltd.  
Ahmedabad, India

Rev.: 10/22

Each tablet contains:  
Glipizide, USP ..... 5 mg  
Metformin hydrochloride, USP .. 500 mg

**Usual Dosage:** See package insert for complete prescribing information.

Store at 20°C to 25°C (68°F to 77°F) [See USP Controlled Room Temperature].  
Dispense in a tight container.

Keep this and all drugs out of the reach of children.

N  
3 65841 66101 9

# GLIPIZIDE AND METFORMIN HYDROCHLORIDE

glipizide and metformin hydrochloride tablet, film coated

## Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:65841-659
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>GLIPIZIDE</b> (UNII: X7WDT95N5C) (GLIPIZIDE - UNII:X7WDT95N5C)	GLIPIZIDE	2.5 mg
<b>METFORMIN HYDROCHLORIDE</b> (UNII: 786Z46389E) (METFORMIN - UNII:9100L32L2N)	METFORMIN HYDROCHLORIDE	250 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>CROSCARMELOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6130)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	

## Product Characteristics

<b>Color</b>	PINK (PINK)	<b>Score</b>	no score
<b>Shape</b>	CAPSULE (CAPSULE)	<b>Size</b>	11mm
<b>Flavor</b>		<b>Imprint Code</b>	ZE68
<b>Contains</b>			

## 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
<b>GLIPIZIDE</b> (UNII: X7WDT95N5C) (GLIPIZIDE - UNII:X7WDT95N5C)	GLIPIZIDE	2.5 mg
<b>METFORMIN HYDROCHLORIDE</b> (UNII: 786Z46389E) (METFORMIN - UNII:9100L32L2N)	METFORMIN HYDROCHLORIDE	500 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>CROSCARMELOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>POLYSORBATE 80</b> (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

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:65841-661
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>CROSCARMELLOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ05DW1A)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

### Product Characteristics

<b>Color</b>	PINK (PINK)	<b>Score</b>	no score
<b>Shape</b>	CAPSULE (CAPSULE)	<b>Size</b>	15mm
<b>Flavor</b>		<b>Imprint Code</b>	ZE66
<b>Contains</b>			

### Packaging

		Marketing Start	Marketing End
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#	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: 10/2022

Zydus Lifesciences Limited