METFORMIN HYDROCHLORIDE - metformin hydrochloride tablet, film coated
Zydus Lifesciences Limited

METFORMIN HYDROCHLORIDE TABLETS

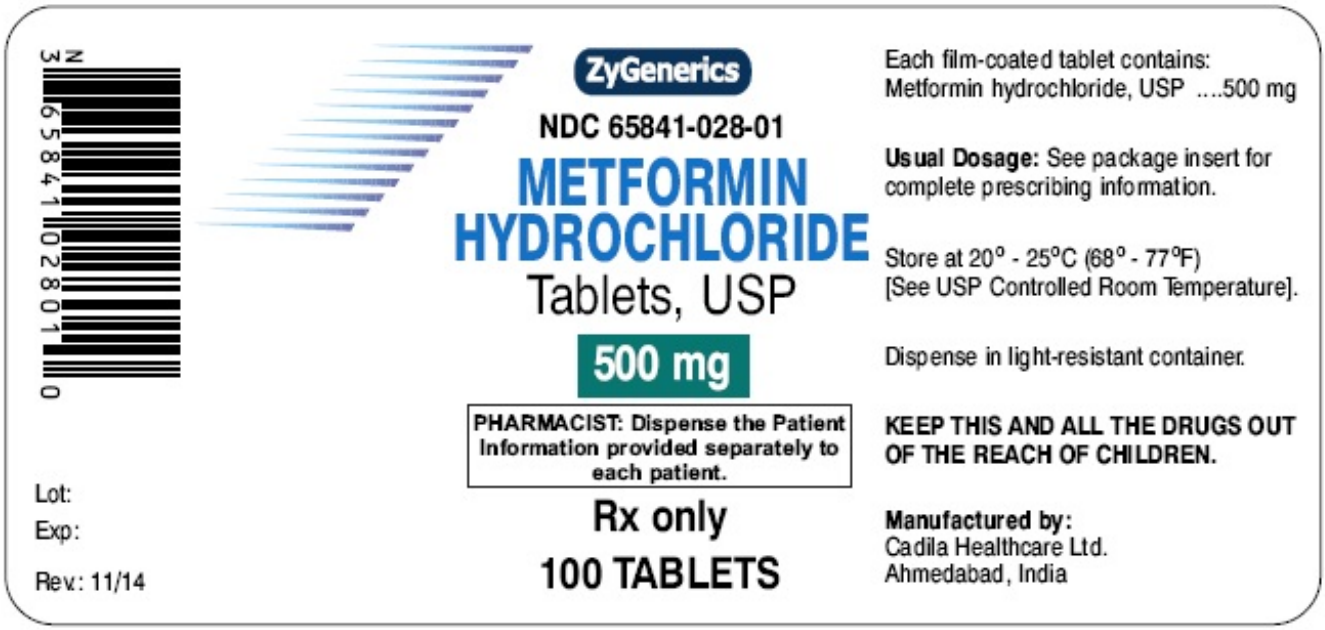
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 65841-028-01 in bottle of 100 tablets

Metformin Hydrochloride Tablets USP, 500 mg

Rx only

100 tablets

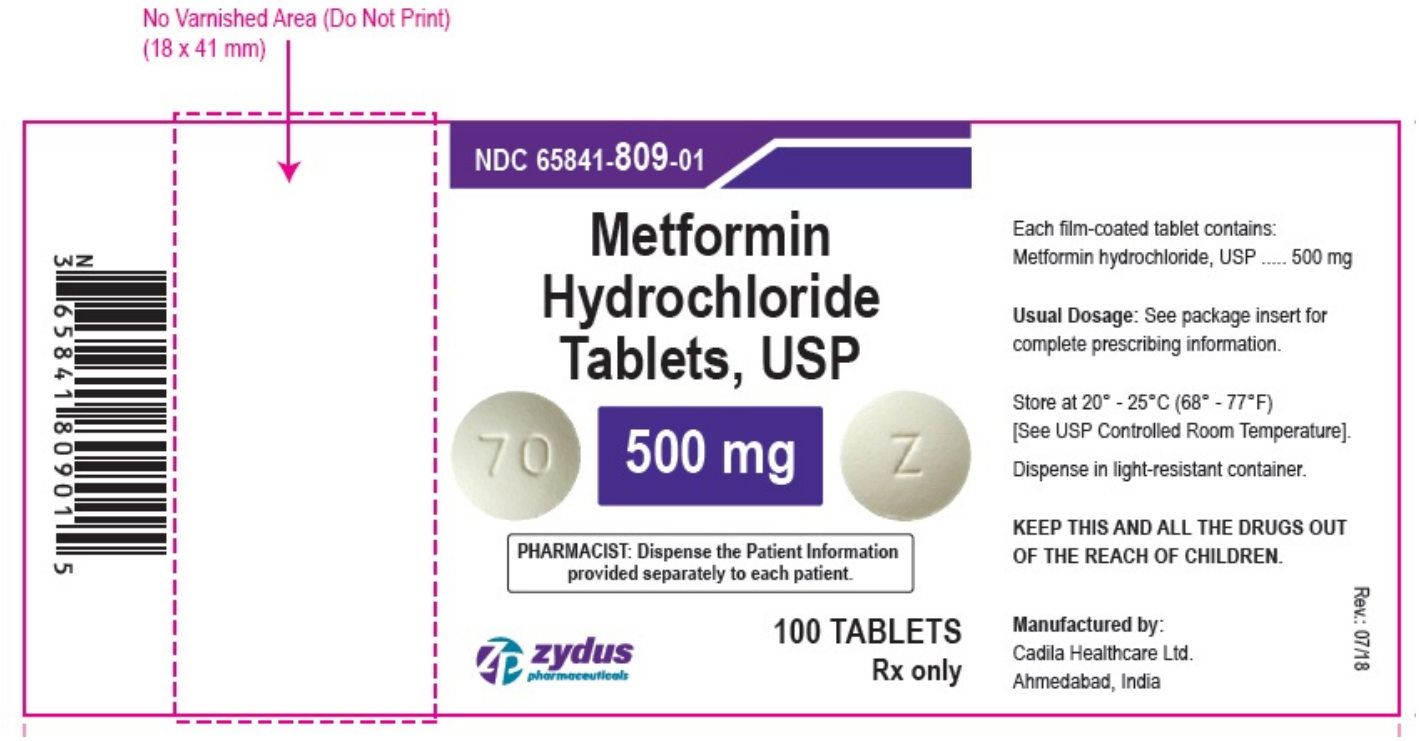


NDC 65841-809-01 in bottle of 100 tablets

Metformin Hydrochloride Tablets USP, 500 mg

Rx only

100 tablets

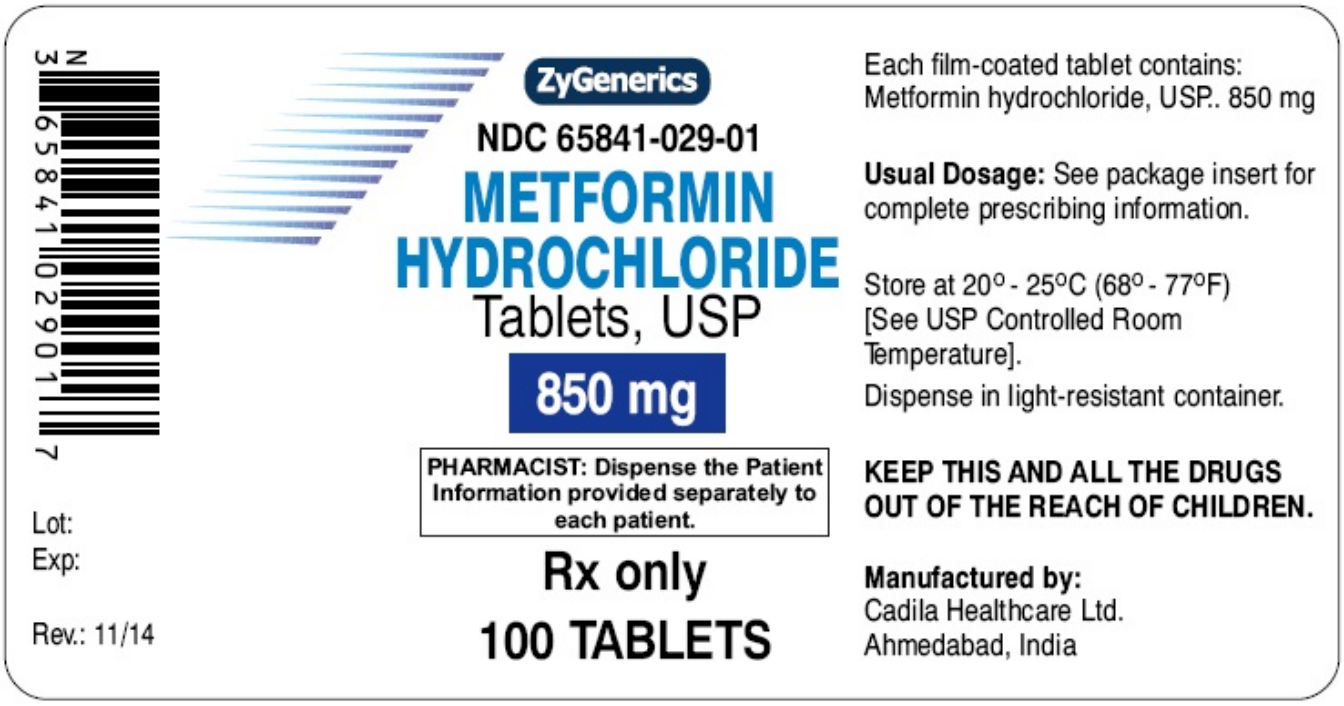


NDC 65841-029-01 in bottle of 100 tablets

Metformin Hydrochloride Tablets USP, 850 mg

Rx only

100 tablets

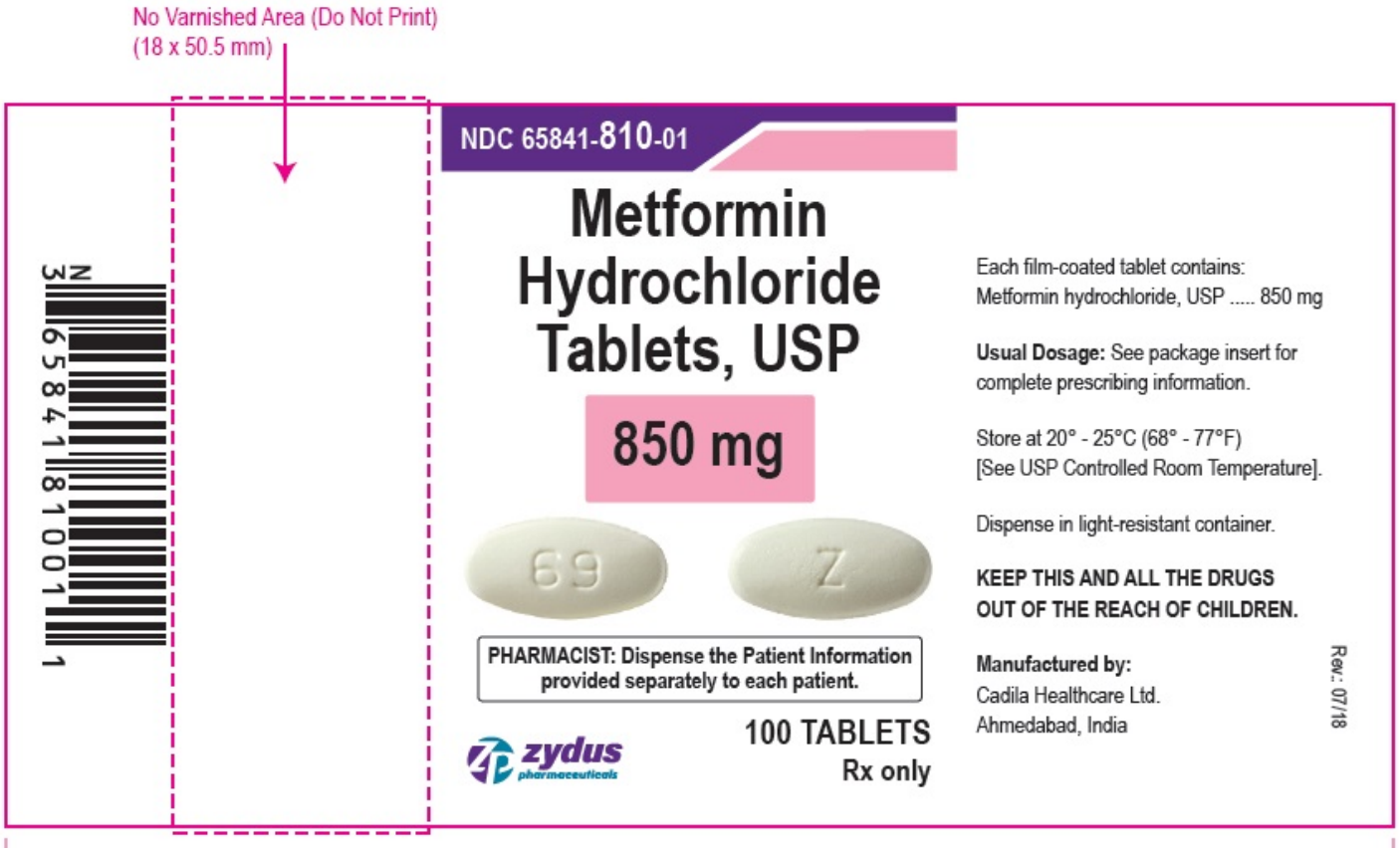


NDC 65841-810-01 in bottle of 100 tablets

Metformin Hydrochloride Tablets USP, 850 mg

Rx only

100 tablets

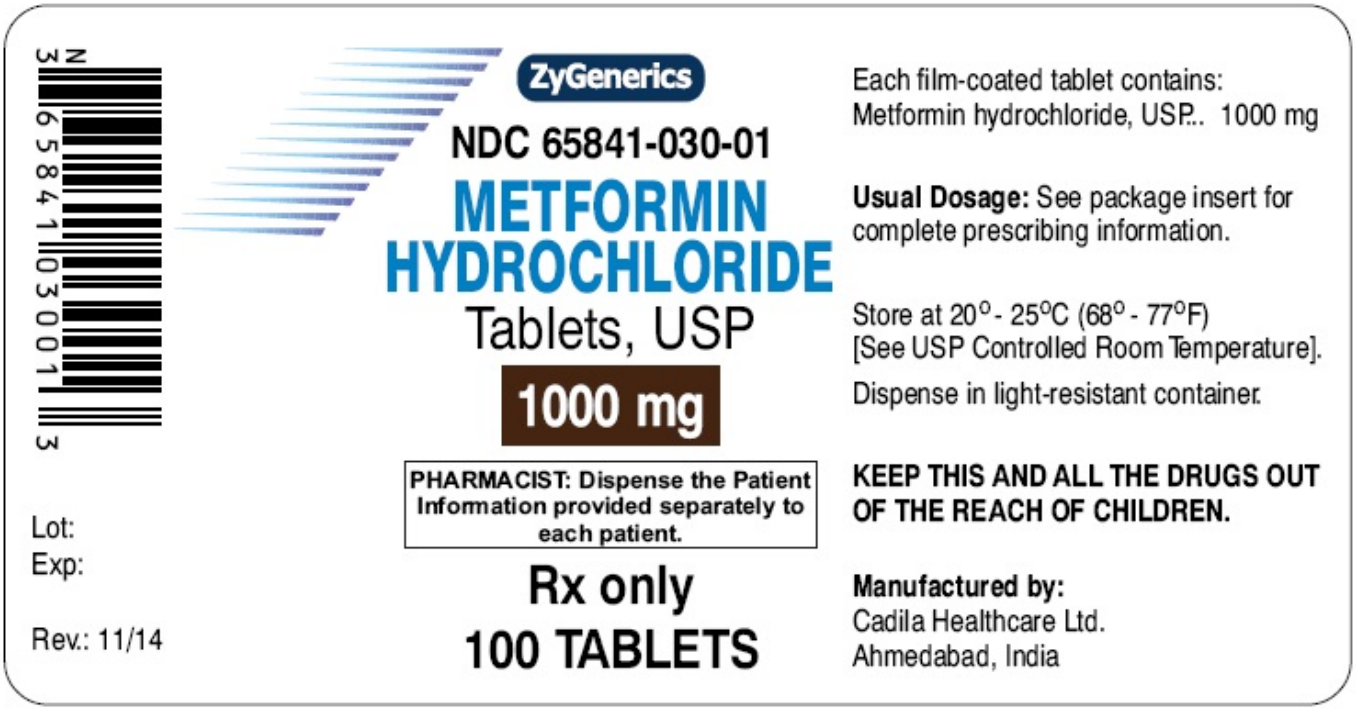


NDC 65841-030-01 in bottle of 100 tablets

Metformin Hydrochloride Tablets USP, 1000 mg

Rx only

100 tablets

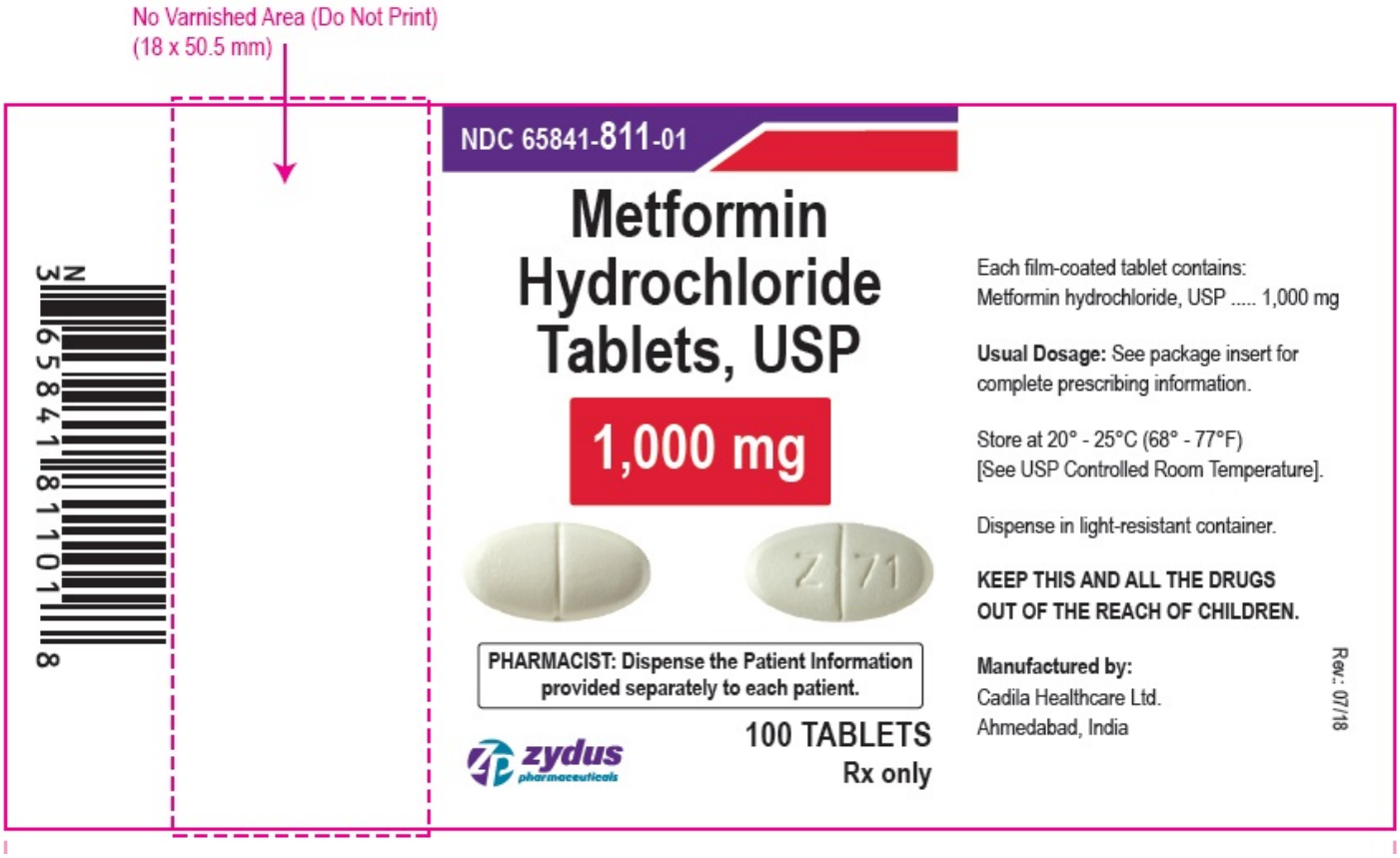


NDC 65841-811-01 in bottle of 100 tablets

Metformin Hydrochloride Tablets USP, 1000 mg

Rx only

100 tablets



METFORMIN HYDROCHLORIDE

metformin hydrochloride tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-028
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE)	**Score**	no score
Shape	ROUND (ROUND)	**Size**	13mm
Flavor		**Imprint Code**	70;Z
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-028-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	09/28/2005	
2	NDC:65841-028-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	09/28/2005	
3	NDC:65841-028-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	09/28/2005	
4	NDC:65841-028-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	09/28/2005	
5	NDC:65841-028-77	100 in 1 CARTON	09/28/2005	
5	NDC:65841-028-30	1 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	ANDA077064	09/28/2005	

METFORMIN HYDROCHLORIDE

metformin hydrochloride tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-029
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
METFORMIN HYDROCHLORIDE (UNII: 786Z46389E) (METFORMIN - UNII:9100L32L2N)	METFORMIN HYDROCHLORIDE	850 mg

Inactive Ingredients

Ingredient Name	Strength
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE)	**Score**	no score
Shape	OVAL (OVAL)	**Size**	19mm
Flavor		**Imprint Code**	69;Z
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-029-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	09/28/2005	
2	NDC:65841-029-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	09/28/2005	
3	NDC:65841-029-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	09/28/2005	

4	NDC:65841-029-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	09/28/2005	
5	NDC:65841-029-77	100 in 1 CARTON	09/28/2005	
5	NDC:65841-029-30	1 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	ANDA077064	09/28/2005	

METFORMIN HYDROCHLORIDE

metformin hydrochloride tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-030
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
METFORMIN HYDROCHLORIDE (UNII: 786Z46389E) (METFORMIN - UNII:9100L32L2N)	METFORMIN HYDROCHLORIDE	1000 mg

Inactive Ingredients

Ingredient Name	Strength
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE)	**Score**	2 pieces
Shape	OVAL (OVAL)	**Size**	19mm
Flavor		**Imprint Code**	Z;71
Contains			

Packaging

#	Item Code	Package Description	Marketing Start	Marketing End

#	Item Code	Package Description	Date	Date
1	NDC:65841-030-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	09/28/2005	
2	NDC:65841-030-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	09/28/2005	
3	NDC:65841-030-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	09/28/2005	
4	NDC:65841-030-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	09/28/2005	
5	NDC:65841-030-77	100 in 1 CARTON	09/28/2005	
5	NDC:65841-030-30	1 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	ANDA077064	09/28/2005	

METFORMIN HYDROCHLORIDE

metformin hydrochloride tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-809
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE)	**Score**	no score
Shape	ROUND (ROUND)	**Size**	13mm

Flavor		**Imprint Code**	70;Z
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-809-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	12/09/2014	
2	NDC:65841-809-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	12/09/2014	
3	NDC:65841-809-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	12/09/2014	
4	NDC:65841-809-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	12/09/2014	
5	NDC:65841-809-77	100 in 1 CARTON	12/09/2014	
5	NDC:65841-809-30	1 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	ANDA203686	12/09/2014	

METFORMIN HYDROCHLORIDE

metformin hydrochloride tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-810
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
METFORMIN HYDROCHLORIDE (UNII: 786Z46389E) (METFORMIN - UNII:9100L32L2N)	METFORMIN HYDROCHLORIDE	850 mg

Inactive Ingredients

Ingredient Name	Strength
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics			
Color	WHITE (WHITE TO OFF-WHITE)	**Score**	no score
Shape	OVAL (OVAL)	**Size**	19mm
Flavor		**Imprint Code**	69;Z
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-810-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	12/09/2014	
2	NDC:65841-810-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	12/09/2014	
3	NDC:65841-810-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	12/09/2014	
4	NDC:65841-810-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	12/09/2014	
5	NDC:65841-810-77	100 in 1 CARTON	12/09/2014	
5	NDC:65841-810-30	1 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	ANDA203686	12/09/2014	

METFORMIN HYDROCHLORIDE

metformin hydrochloride tablet, film coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-811
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
METFORMIN HYDROCHLORIDE (UNII: 786Z46389E) (METFORMIN - UNII:9100L32L2N)	METFORMIN HYDROCHLORIDE	1000 mg

Inactive Ingredients

Ingredient Name	Strength

HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE)	**Score**	2 pieces
Shape	OVAL (OVAL)	**Size**	19mm
Flavor		**Imprint Code**	Z;71
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-811-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	12/09/2014	
2	NDC:65841-811-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	12/09/2014	
3	NDC:65841-811-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	12/09/2014	
4	NDC:65841-811-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	12/09/2014	
5	NDC:65841-811-77	100 in 1 CARTON	12/09/2014	
5	NDC:65841-811-30	1 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	ANDA203686	12/09/2014	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		918596198	ANALYSIS(65841-028, 65841-029, 65841-030, 65841-809, 65841-810, 65841-811) , MANUFACTURE(65841-028, 65841-029, 65841-030, 65841-809, 65841-810, 65841-811)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		863362789	ANALYSIS(65841-028, 65841-029, 65841-030, 65841-809, 65841-810, 65841-811) , MANUFACTURE(65841-028, 65841-029, 65841-030, 65841-809, 65841-810, 65841-811)