SITAGLIPTIN AND METFORMIN HYDROCHLORIDE- sitagliptin and metformin hydrochloride tablet, film coated, extended release
Zydus Lifesciences Limited

Sitagliptin and Metformin Hydrochloride Extended-Release Tablets, for oral use

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

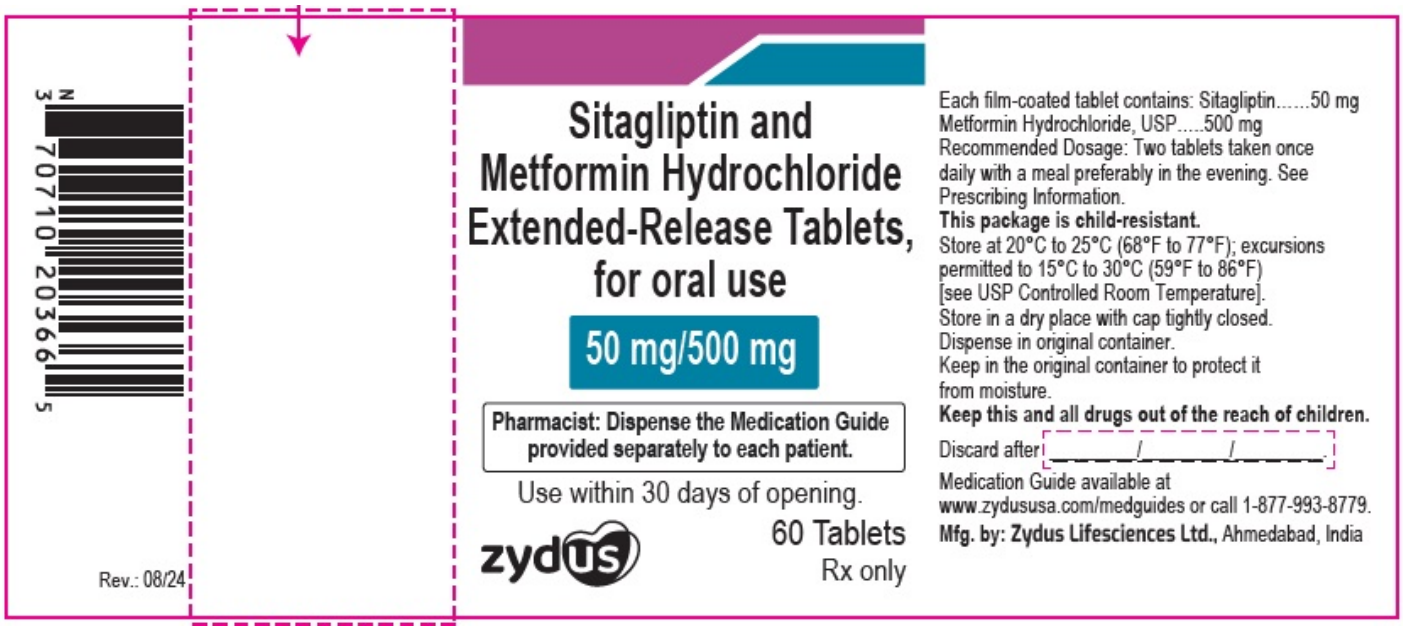
NDC 70771-1886-6

Sitagliptin and metformin hydrochloride extended-release tablets for oral use

50 mg/500 mg

60 Tablets

Rx only



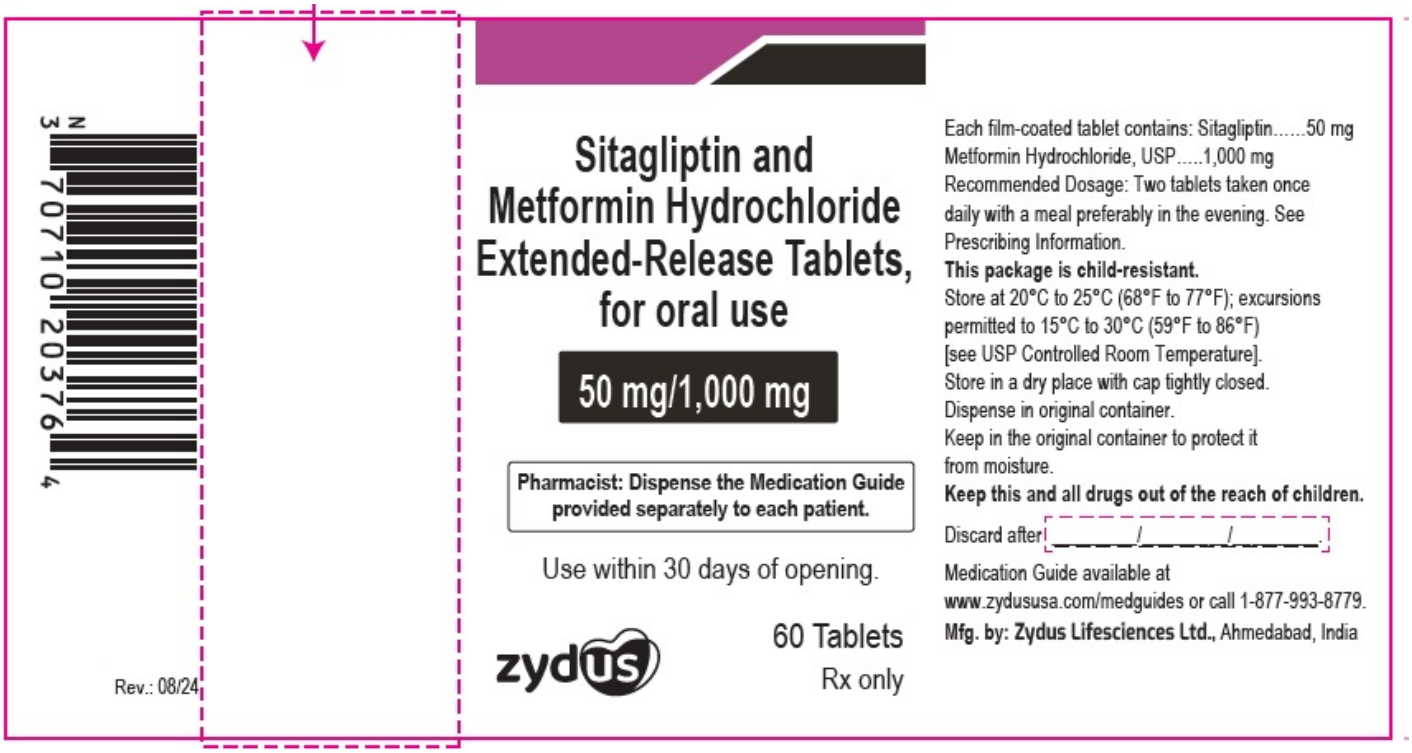
NDC 70771-1887-6

Sitagliptin and metformin hydrochloride extended-release tablets for oral use

50 mg/1000 mg

60 Tablets

Rx only



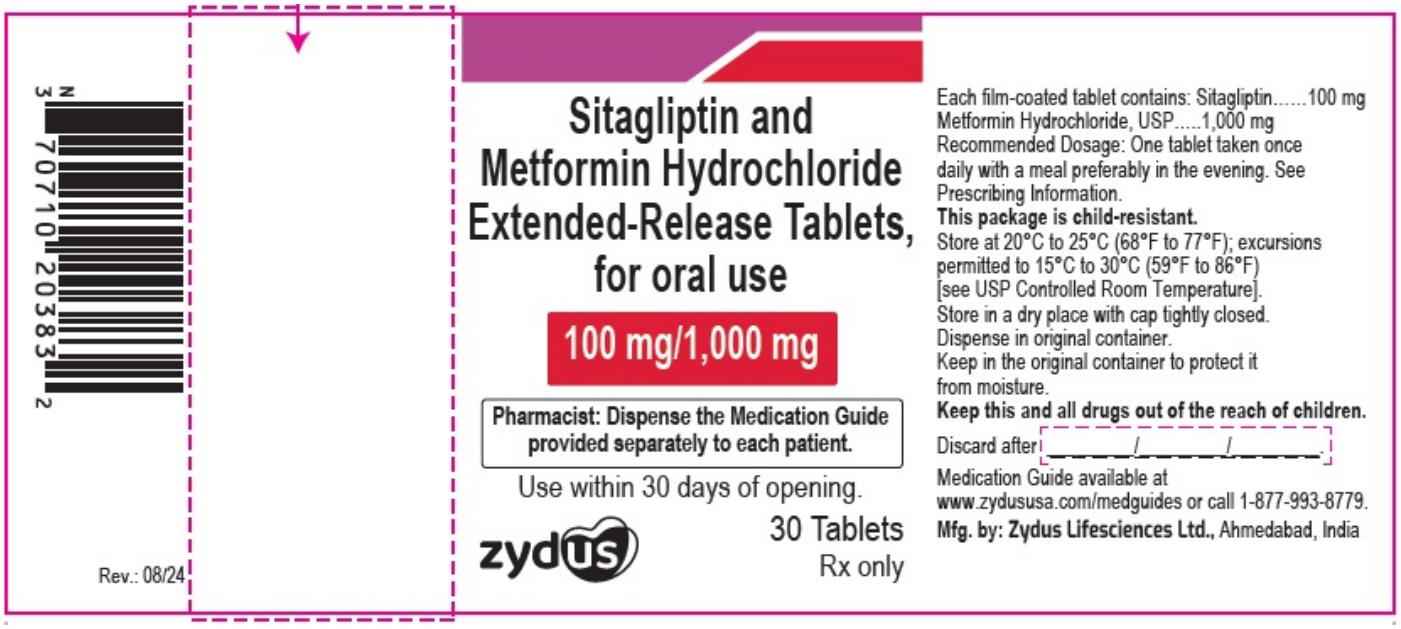
NDC 70771-1888-3

Sitagliptin and metformin hydrochloride extended-release tablets for oral use

100 mg/1000 mg

30 Tablets

Rx only



SITAGLIPTIN AND METFORMIN HYDROCHLORIDE

sitagliptin and metformin hydrochloride tablet, film coated, extended release

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1886
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SITAGLIPTIN (UNII: QFP0P1DV7Z) (SITAGLIPTIN - UNII:QFP0P1DV7Z)	SITAGLIPTIN	50 mg
METFORMIN HYDROCHLORIDE (UNII: 786Z46389E) (METFORMIN - UNII:9100L32L2N)	METFORMIN HYDROCHLORIDE	1000 mg

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
HYPROMELLOSE 2208 (100000 MPA.S) (UNII: VM7F0B23ZI)	
HYPROMELLOSE 2208 (200000 MPA.S) (UNII: LJY3MA129D)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALIC ACID (UNII: 817L1N4CKP)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	YELLOW (Beige Colored)	**Score**	no score
Shape	OVAL	**Size**	22mm
Flavor		**Imprint Code**	1805
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1886-6	60 in 1 BOTTLE; Type 0: Not a Combination Product	10/31/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA authorized generic	NDA216778	10/31/2024	

SITAGLIPTIN AND METFORMIN HYDROCHLORIDE

sitagliptin and metformin hydrochloride tablet, film coated, extended release

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1887
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SITAGLIPTIN (UNII: QFP0P1DV7Z) (SITAGLIPTIN - UNII:QFP0P1DV7Z)	SITAGLIPTIN	50 mg
METFORMIN HYDROCHLORIDE (UNII: 786Z46389E) (METFORMIN - UNII:9100L32L2N)	METFORMIN HYDROCHLORIDE	500 mg

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
HYPROMELLOSE 2208 (100000 MPA.S) (UNII: VM7F0B23ZI)	
HYPROMELLOSE 2208 (200000 MPA.S) (UNII: LJY3MA129D)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALIC ACID (UNII: 817L1N4CKP)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	ORANGE (Light Orange to Beige Colored)	**Score**	no score
Shape	OVAL	**Size**	18mm
Flavor		**Imprint Code**	1804
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1887-6	60 in 1 BOTTLE; Type 0: Not a Combination Product	10/31/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA authorized generic	NDA216778	10/31/2024	

SITAGLIPTIN AND METFORMIN HYDROCHLORIDE

sitagliptin and metformin hydrochloride tablet, film coated, extended release

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1888
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
SITAGLIPTIN (UNII: QFP0P1DV7Z) (SITAGLIPTIN - UNII:QFP0P1DV7Z)	SITAGLIPTIN	100 mg
METFORMIN HYDROCHLORIDE (UNII: 786Z46389E) (METFORMIN - UNII:9100L32L2N)	METFORMIN HYDROCHLORIDE	1000 mg

Inactive Ingredients	
Ingredient Name	Strength
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
HYPROMELLOSE 2208 (100000 MPA.S) (UNII: VM7F0B23ZI)	
HYPROMELLOSE 2208 (200000 MPA.S) (UNII: LJY3MA129D)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALIC ACID (UNII: 817L1N4CKP)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI)	

STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	BROWN (Reddish brown to brown colored)	**Score**	no score
Shape	OVAL	**Size**	22mm
Flavor		**Imprint Code**	1806
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1888-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	10/31/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA authorized generic	NDA216778	10/31/2024	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Global FZE (850107010)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		863362789	ANALYSIS(70771-1886, 70771-1887, 70771-1888) , MANUFACTURE(70771-1886, 70771-1887, 70771-1888)

Revised: 8/2024 Zydus Lifesciences Limited