

ZITUVIMET XR- sitagliptin and metformin hydrochloride tablet, film coated, extended release
Zydus Lifesciences Limited

ZITUVIMET® XR (sitagliptin and metformin hydrochloride) extended-release tablets, for oral use

SPL MEDGUIDE

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

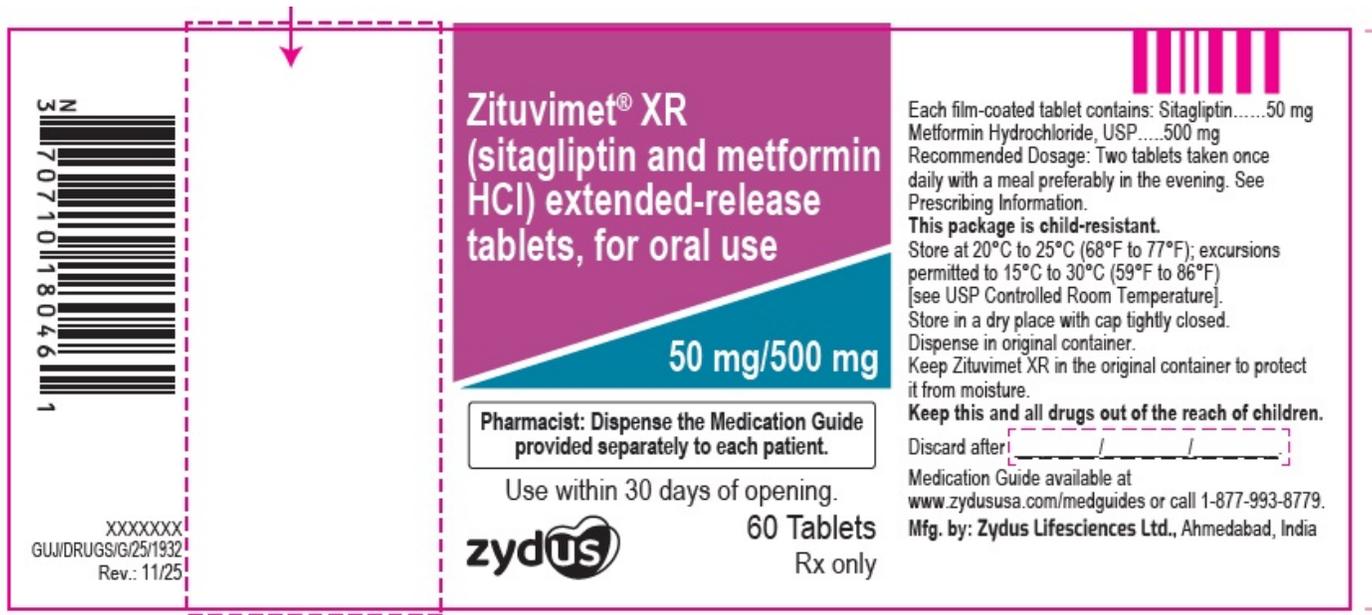
NDC 70771-1879-6

ZITUVIMET® XR (sitagliptin and metformin hydrochloride extended-release) tablets

50 mg/500 mg

60 Tablets

Rx only



NDC 70771-1880-6

ZITUVIMET® XR (sitagliptin and metformin hydrochloride extended-release) tablets

50 mg/1,000 mg

60 Tablets

Rx only

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XXXXXXXX
GUJ/DRUGS/G/25/1932
Rev.: 11/25

Zituvimet® XR
(sitagliptin and metformin HCl) extended-release tablets, for oral use

50 mg/1,000 mg

Pharmacist: Dispense the Medication Guide provided separately to each patient.

Use within 30 days of opening.

zydus

60 Tablets
Rx only

Each film-coated tablet contains: Sitagliptin.....50 mg
Metformin Hydrochloride, USP.....1,000 mg
Recommended Dosage: Two tablets taken once daily with a meal preferably in the evening. See Prescribing Information.
This package is child-resistant.
Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature].
Store in a dry place with cap tightly closed.
Dispense in original container.
Keep Zituvimet XR in the original container to protect it from moisture.
Keep this and all drugs out of the reach of children.
Discard after: / /
Medication Guide available at www.zydususa.com/medguides or call 1-877-993-8779.
Mfg. by: Zydus Lifesciences Ltd., Ahmedabad, India

NDC 70771-1881-3

ZITUVIMET® XR (sitagliptin and metformin hydrochloride extended-release) tablets

100 mg/1,000 mg

30 Tablets

Rx only

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70710118063
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XXXXXXXX
GUJ/DRUGS/G/25/1932
Rev.: 11/25

Zituvimet® XR
(sitagliptin and metformin HCl) extended-release tablets, for oral use

100 mg/1,000 mg

Pharmacist: Dispense the Medication Guide provided separately to each patient.

Use within 30 days of opening.

zydus

30 Tablets
Rx only

Each film-coated tablet contains: Sitagliptin.....100 mg
Metformin Hydrochloride, USP.....1,000 mg
Recommended Dosage: One tablet taken once daily with a meal preferably in the evening. See Prescribing Information.
This package is child-resistant.
Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature].
Store in a dry place with cap tightly closed.
Dispense in original container.
Keep Zituvimet XR in the original container to protect it from moisture.
Keep this and all drugs out of the reach of children.
Discard after: / /
Medication Guide available at www.zydususa.com/medguides or call 1-877-993-8779.
Mfg. by: Zydus Lifesciences Ltd., Ahmedabad, India

ZITUVIMET XR

sitagliptin and metformin hydrochloride tablet, film coated, extended release

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1880
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: 3WJQ0SDW1A)	
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:70771-1880-6	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	NDA216778	10/31/2024	

ZITUVIMET XR

sitagliptin and metformin hydrochloride tablet, film coated, extended release

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1879
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: 3WJQ0SDW1A)	
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:70771-1879-6	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	NDA216778	10/31/2024	

ZITUVIMET XR

sitagliptin and metformin hydrochloride tablet, film coated, extended release

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1881
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: 3WJQ0SDW1A)	
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:70771-1881-3	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	NDA216778	10/31/2024	

Labeler - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		863362789	ANALYSIS(70771-1879, 70771-1880, 70771-1881) , MANUFACTURE(70771-1879, 70771-1880, 70771-1881)

Revised: 1/2026

Zydus Lifesciences Limited