

Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

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Product Details for ANDA 205981

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SAXAGLIPTIN AND METFORMIN HYDROCHLORIDE (METFORMIN HYDROCHLORIDE; SAXAGLIPTIN HYDROCHLORIDE).
500MG;EQ 5MG BASE
Marketing Status: Prescription

Active Ingredient: METFORMIN HYDROCHLORIDE; SAXAGLIPTIN HYDROCHLORIDE
Proprietary Name: SAXAGLIPTIN AND METFORMIN HYDROCHLORIDE
Dosage Form; Route of Administration: TABLET, EXTENDED RELEASE; ORAL
Strength: 500MG;EQ 5MG BASE
Reference Listed Drug: No
Reference Standard: No
TE Code: AB
Application Number: A205981
Product Number: 001
Approval Date: Jul 31, 2023
Applicant Holder Full Name: MYLAN PHARMACEUTICALS INC
Marketing Status: Prescription
Patent and Exclusivity Information ([patent_info.cfm?Product_No=001&Appl_No=205981&Appl_type=A](#))

SAXAGLIPTIN AND METFORMIN HYDROCHLORIDE (METFORMIN HYDROCHLORIDE; SAXAGLIPTIN HYDROCHLORIDE).
1GM;EQ 2.5MG BASE
Marketing Status: Prescription

Active Ingredient: METFORMIN HYDROCHLORIDE; SAXAGLIPTIN HYDROCHLORIDE
Proprietary Name: SAXAGLIPTIN AND METFORMIN HYDROCHLORIDE
Dosage Form; Route of Administration: TABLET, EXTENDED RELEASE; ORAL

Strength: 1GM;EQ 2.5MG BASE
Reference Listed Drug: No
Reference Standard: No
TE Code: AB
Application Number: A205981
Product Number: 002
Approval Date: Jul 31, 2023
Applicant Holder Full Name: MYLAN PHARMACEUTICALS INC
Marketing Status: Prescription
**Patent and Exclusivity Information (patent_info.cfm?
Product_No=002&Appl_No=205981&Appl_type=A)**

**SAXAGLIPTIN AND METFORMIN HYDROCHLORIDE (METFORMIN
HYDROCHLORIDE; SAXAGLIPTIN HYDROCHLORIDE).**
1GM;EQ 5MG BASE
Marketing Status: Prescription

Active Ingredient: METFORMIN HYDROCHLORIDE; SAXAGLIPTIN HYDROCHLORIDE
Proprietary Name: SAXAGLIPTIN AND METFORMIN HYDROCHLORIDE
Dosage Form; Route of Administration: TABLET, EXTENDED RELEASE; ORAL
Strength: 1GM;EQ 5MG BASE
Reference Listed Drug: No
Reference Standard: No
TE Code: AB
Application Number: A205981
Product Number: 003
Approval Date: Jul 31, 2023
Applicant Holder Full Name: MYLAN PHARMACEUTICALS INC
Marketing Status: Prescription
**Patent and Exclusivity Information (patent_info.cfm?
Product_No=003&Appl_No=205981&Appl_type=A)**