

Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

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Product Details for NDA 209862

EVZIO (AUTOINJECTOR) (NALOXONE HYDROCHLORIDE)
2MG/0.4ML (2MG/0.4ML)

Marketing Status: Prescription

Active Ingredient: NALOXONE HYDROCHLORIDE

Proprietary Name: EVZIO (AUTOINJECTOR)

Dosage Form; Route of Administration: SOLUTION; INTRAMUSCULAR, SUBCUTANEOUS

Strength: 2MG/0.4ML (2MG/0.4ML)

Reference Listed Drug: Yes

Reference Standard: Yes

TE Code:

Application Number: N209862

Product Number: 001

Approval Date: Oct 19, 2016

Applicant Holder Full Name: KALEO INC

Marketing Status: Prescription

[Patent and Exclusivity Information \(patent info.cfm?](#)

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