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Product Details for NDA 021038

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PRECEDEX (DEXMEDETOMIDINE HYDROCHLORIDE)
EQ 80MCG BASE/20ML (EQ 4MCG BASE/ML) Marketing Status: Prescription

PRECEDEX (DEXMEDETOMIDINE HYDROCHLORIDE)
EQ 200MCG BASE/2ML (EQ 100MCG BASE/ML) Marketing Status: Prescription

Active Ingredient: DEXMEDETOMIDINE HYDROCHLORIDE
Proprietary Name: PRECEDEX
Dosage Form; Route of Administration: INJECTABLE; INJECTION
Strength: EQ 200MCG BASE/2ML (EQ 100MCG BASE/ML)
Reference Listed Drug: Yes
Reference Standard: Yes
TE Code: AP
Application Number: N021038

Product Number: 001
Approval Date: Dec 17, 1999
Applicant Holder Full Name: HOSPIRA INC
Marketing Status: Prescription
Patent and Exclusivity Information

PRECEDEX (DEXMEDETOMIDINE HYDROCHLORIDE)
EQ 200MCG BASE/50ML (EQ 4MCG BASE/ML) Marketing Status: Prescription

PRECEDEX (DEXMEDETOMIDINE HYDROCHLORIDE)
EQ 400MCG BASE/100ML (EQ 4MCG BASE/ML) Marketing Status: Prescription