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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 <u>Patent and Exclusivity Information</u>		
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

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U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
1-888-INFO-FDA (1-888-463-6332)

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