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Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

Search results from the "OB_Rx" table for query on "021038."

Active Ingredient:	DEXMEDETOMIDINE HYDROCHLORIDE
Dosage Form;Route:	INJECTABLE;INJECTION
Proprietary Name:	PRECEDEX
Applicant:	HOSPIRA
Strength:	EQ 200MCG BASE/2ML (EQ 100MCG BASE/ML)
Application Number:	N021038
Product Number:	001
Approval Date:	Dec 17, 1999
Reference Listed Drug	Yes
RX/OTC/DISCN:	RX
TE Code:	**AP**
Patent and Exclusivity Info for this product:	View

Active Ingredient:	DEXMEDETOMIDINE HYDROCHLORIDE
Dosage Form;Route:	INJECTABLE;INJECTION
Proprietary Name:	PRECEDEX
Applicant:	HOSPIRA
Strength:	EQ 200MCG BASE/50ML (EQ 4MCG BASE/ML)
Application Number:	N021038
Product Number:	002
Approval Date:	Mar 13, 2013
Reference Listed Drug	Yes
RX/OTC/DISCN:	RX
TE Code:	
Patent and Exclusivity Info for this product:	View

Active Ingredient:	DEXMEDETOMIDINE HYDROCHLORIDE
Dosage Form;Route:	INJECTABLE;INJECTION
Proprietary Name:	PRECEDEX
Applicant:	HOSPIRA
Strength:	EQ 400MCG BASE/100ML (EQ 4MCG BASE/ML)
Application Number:	N021038
Product Number:	003
Approval Date:	Mar 13, 2013
Reference Listed Drug	Yes
RX/OTC/DISCN:	RX
TE Code:	
Patent and Exclusivity Info for this product:	View

Active Ingredient:	DEXMEDETOMIDINE HYDROCHLORIDE
Dosage Form;Route:	INJECTABLE;INJECTION
Proprietary Name:	PRECEDEX
Applicant:	HOSPIRA
Strength:	EQ 80MCG BASE/20ML (EQ 4MCG BASE/ML)
Application Number:	N021038
Product Number:	004
Approval Date:	Nov 14, 2014
Reference Listed Drug	Yes
RX/OTC/DISCN:	RX
TE Code:	

Patent and Exclusivity Info for this product: View

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Patent and Exclusivity Search Results from query on Appl No 021038 Product 001 in the OB_Rx list.

Patent Data

Appl No	Prod No	Patent No	Patent Expiration	Drug Substance Claim	Drug Product Claim	Patent Use Code	Delist Requested
N021038	001	6716867	Mar 31, 2019			U - 1472	
N021038	001	6716867*PED	Oct 1, 2019				

Exclusivity Data

Appl No	Prod No	Exclusivity Code	Exclusivity Expiration
N021038	001	M - 61	Jun 17, 2016
N021038	001	PED	Dec 17, 2016

Additional Information:

1. Patents are published upon receipt by the Orange Book Staff and may not reflect the official receipt date as described in 21 CFR 314.53(d)(5).
2. Patents listed prior to August 18, 2003 are flagged with method of use claims only as applicable and submitted by the sponsor. These patents may not be flagged with respect to other claims which may apply.

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