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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:
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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:

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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

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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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