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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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### Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

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
<a href="#">N021038</a>	001	6716867	Mar 31, 2019			<a href="#">U - 1472</a>	
<a href="#">N021038</a>	001	6716867*PED	Oct 1, 2019				

#### Exclusivity Data

Appl No	Prod No	Exclusivity Code	Exclusivity Expiration
<a href="#">N021038</a>	001	<a href="#">M - 61</a>	<a href="#">Jun 17, 2016</a>
<a href="#">N021038</a>	001	<a href="#">PED</a>	<a href="#">Dec 17, 2016</a>

#### 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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