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Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

Search results from the "OB_Rx" table for query on "200533."

Active Ingredient: TAPENTADOL HYDROCHLORIDE
Dosage Form;Route: TABLET, EXTENDED RELEASE;ORAL
Proprietary Name: NUCYNTA ER
Applicant: JANSSEN PHARMS
Strength: EQ 50MG BASE
Application Number: N200533
Product Number: 001
Approval Date: Aug 25, 2011
Reference Listed Drug: No
RX/OTC/DISCN: RX
TE Code:

Patent and Exclusivity Info for this product: [View](#)

Active Ingredient: TAPENTADOL HYDROCHLORIDE
Dosage Form;Route: TABLET, EXTENDED RELEASE;ORAL
Proprietary Name: NUCYNTA ER
Applicant: JANSSEN PHARMS
Strength: EQ 100MG BASE
Application Number: N200533
Product Number: 002
Approval Date: Aug 25, 2011
Reference Listed Drug: No
RX/OTC/DISCN: RX
TE Code:

Patent and Exclusivity Info for this product: [View](#)

Active Ingredient: TAPENTADOL HYDROCHLORIDE
Dosage Form;Route: TABLET, EXTENDED RELEASE;ORAL
Proprietary Name: NUCYNTA ER
Applicant: JANSSEN PHARMS
Strength: EQ 150MG BASE
Application Number: N200533
Product Number: 003
Approval Date: Aug 25, 2011
Reference Listed Drug: No
RX/OTC/DISCN: RX
TE Code:

Patent and Exclusivity Info for this product: [View](#)

Active Ingredient: TAPENTADOL HYDROCHLORIDE
Dosage Form;Route: TABLET, EXTENDED RELEASE;ORAL
Proprietary Name: NUCYNTA ER
Applicant: JANSSEN PHARMS
Strength: EQ 200MG BASE
Application Number: N200533
Product Number: 004
Approval Date: Aug 25, 2011
Reference Listed Drug: No

Purdue Exhibit 1095
Purdue Pharma L.P. v. Depomed, Inc.
Case IPR2014-00377, -00378, -00379

RX/OTC/DISCN: RX
TE Code:
Patent and Exclusivity Info for this product: [View](#)
Active Ingredient: TAPENTADOL HYDROCHLORIDE
Dosage Form;Route: TABLET, EXTENDED RELEASE;ORAL
Proprietary Name: NUCYNTA ER
Applicant: JANSSEN PHARMS
Strength: EQ 250MG BASE
Application Number: N200533
Product Number: 005
Approval Date: Aug 25, 2011
Reference Listed Drug: Yes
RX/OTC/DISCN: RX
TE Code:
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Patent and Exclusivity Search Results from query on Appl No 200533 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
N200533	001	6071970	Jun 6, 2017			U - 1178	
N200533	001	6071970	Jun 6, 2017			U - 1276	
N200533	001	7994364	Jun 27, 2025	Y	Y	U - 1178	
N200533	001	7994364	Jun 27, 2025	Y	Y	U - 1276	
N200533	001	8075872	Nov 20, 2023		Y		
N200533	001	8114383	Oct 10, 2024		Y		Y
N200533	001	8309060	Nov 20, 2023		Y	U - 1178	
N200533	001	8309060	Nov 20, 2023		Y	U - 1276	
N200533	001	8420056	Nov 20, 2023		Y		
N200533	001	8536130	Sep 22, 2028			U - 1276	
N200533	001	RE39593	Aug 5, 2022	Y	Y	U - 1178	
N200533	001	RE39593	Aug 5, 2022	Y	Y	U - 1276	

Exclusivity Data

Appl No	Prod No	Exclusivity Code	Exclusivity Expiration
N200533	001	I - 656	Aug 28, 2015
N200533	001	NCE	Nov 20, 2013
N200533	001	NDF	Aug 25, 2014

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Patent Data

Appl No	Prod No	Patent No	Patent Expiration	Drug Substance Claim	Drug Product Claim	Patent Use Code	Delist Requested
N200533	002	6071970	Jun 6, 2017			U - 1178	
N200533	002	6071970	Jun 6, 2017			U - 1276	
N200533	002	7994364	Jun 27, 2025	Y	Y	U - 1178	
N200533	002	7994364	Jun 27, 2025	Y	Y	U - 1276	
N200533	002	8075872	Nov 20, 2023		Y		
N200533	002	8114383	Oct 10, 2024		Y		Y
N200533	002	8309060	Nov 20, 2023		Y	U - 1178	
N200533	002	8309060	Nov 20, 2023		Y	U - 1276	
N200533	002	8420056	Nov 20, 2023		Y		
N200533	002	8536130	Sep 22, 2028			U - 1276	
N200533	002	RE39593	Aug 5, 2022	Y	Y	U - 1178	
N200533	002	RE39593	Aug 5, 2022	Y	Y	U - 1276	

Exclusivity Data

Appl No	Prod No	Exclusivity Code	Exclusivity Expiration
N200533	002	I - 656	Aug 28, 2015
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N200533	002	NDF	Aug 25, 2014

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Patent Data

Appl No	Prod No	Patent No	Patent Expiration	Drug Substance Claim	Drug Product Claim	Patent Use Code	Delist Requested
N200533	003	6071970	Jun 6, 2017			U - 1178	
N200533	003	6071970	Jun 6, 2017			U - 1276	
N200533	003	7994364	Jun 27, 2025	Y	Y	U - 1178	
N200533	003	7994364	Jun 27, 2025	Y	Y	U - 1276	
N200533	003	8075872	Nov 20, 2023		Y		
N200533	003	8114383	Oct 10, 2024		Y		Y
N200533	003	8309060	Nov 20, 2023		Y	U - 1178	
N200533	003	8309060	Nov 20, 2023		Y	U - 1276	
N200533	003	8420056	Nov 20, 2023		Y		
N200533	003	8536130	Sep 22, 2028			U - 1276	
N200533	003	RE39593	Aug 5, 2022	Y	Y	U - 1178	
N200533	003	RE39593	Aug 5, 2022	Y	Y	U - 1276	

Exclusivity Data

Appl No	Prod No	Exclusivity Code	Exclusivity Expiration
N200533	003	I - 656	Aug 28, 2015
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N200533	003	NDF	Aug 25, 2014

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Appl No	Prod No	Patent No	Patent Expiration	Drug Substance Claim	Drug Product Claim	Patent Use Code	Delist Requested
N200533	004	6071970	Jun 6, 2017			U - 1178	
N200533	004	6071970	Jun 6, 2017			U - 1276	
N200533	004	7994364	Jun 27, 2025	Y	Y	U - 1178	
N200533	004	7994364	Jun 27, 2025	Y	Y	U - 1276	
N200533	004	8075872	Nov 20, 2023		Y		
N200533	004	8114383	Oct 10, 2024		Y		Y
N200533	004	8309060	Nov 20, 2023		Y	U - 1178	
N200533	004	8309060	Nov 20, 2023		Y	U - 1276	
N200533	004	8420056	Nov 20, 2023		Y		
N200533	004	8536130	Sep 22, 2028			U - 1276	
N200533	004	RE39593	Aug 5, 2022	Y	Y	U - 1178	
N200533	004	RE39593	Aug 5, 2022	Y	Y	U - 1276	

Exclusivity Data

Appl No	Prod No	Exclusivity Code	Exclusivity Expiration
N200533	004	I - 656	Aug 28, 2015
N200533	004	NCE	Nov 20, 2013
N200533	004	NDF	Aug 25, 2014

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N200533	005	6071970	Jun 6, 2017			U - 1178	
N200533	005	6071970	Jun 6, 2017			U - 1276	
N200533	005	7994364	Jun 27, 2025	Y	Y	U - 1178	
N200533	005	7994364	Jun 27, 2025	Y	Y	U - 1276	
N200533	005	8075872	Nov 20, 2023		Y		
N200533	005	8114383	Oct 10, 2024		Y		Y
N200533	005	8309060	Nov 20, 2023		Y	U - 1178	
N200533	005	8309060	Nov 20, 2023		Y	U - 1276	
N200533	005	8420056	Nov 20, 2023		Y		
N200533	005	8536130	Sep 22, 2028			U - 1276	
N200533	005	RE39593	Aug 5, 2022	Y	Y	U - 1178	
N200533	005	RE39593	Aug 5, 2022	Y	Y	U - 1276	

Exclusivity Data

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N200533	005	NCE	Nov 20, 2013
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