



U.S. Food and Drug Administration
Protecting and Promoting *Your Health*

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Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations
Search results from the "OB_Rx" table for query on "021196."

Active Ingredient:	SODIUM OXYBATE
Dosage Form;Route:	SOLUTION;ORAL
Proprietary Name:	XYREM
Applicant:	JAZZ PHARMS
Strength:	500MG/ML
Application Number:	N021196
Product Number:	001
Approval Date:	Jul 17, 2002
Reference Listed Drug	Yes
RX/OTC/DISCN:	RX
TE Code:	

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

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FDA/Center for Drug Evaluation and Research
Office of Generic Drugs
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Orange Book Data Updated Through April 2014

Patent and Generic Drug Product Data Last Updated June 11, 2014

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Patent and Exclusivity Search Results from query on Appl No 021196 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
N021196	001	6780889	Jul 4, 2020		Y		
N021196	001	7262219	Jul 4, 2020		Y		
N021196	001	7668730	Jun 16, 2024			U - 1110	
N021196	001	7765106	Jun 16, 2024			U - 1069	
N021196	001	7765107	Jun 16, 2024			U - 1070	
N021196	001	7851506	Dec 22, 2019			U - 1101	
N021196	001	7851506	Dec 22, 2019			U - 1102	
N021196	001	7895059	Dec 17, 2022			U - 1110	
N021196	001	8263650	Dec 22, 2019		Y	U - 1101	
N021196	001	8263650	Dec 22, 2019		Y	U - 1102	
N021196	001	8324275	Dec 22, 2019			U - 1101	
N021196	001	8324275	Dec 22, 2019			U - 1102	
N021196	001	8457988	Dec 17, 2022			U - 1110	
N021196	001	8589182	Dec 17, 2022			U - 1110	
N021196	001	8731963	Dec 17, 2022			U - 1110	

Exclusivity Data

There is no unexpired exclusivity for this product.

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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