Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

Patent and Exclusivity Search Results from query on Appl No 022410 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
N022410	001	8017150	Feb 13, 2023		Y		
N022410	001	8475832	Mar 26, 2030		Y	U - 1411	
N022410	001	8603514	Apr 3, 2024		Y	U - 1464	

Exclusivity Data

Appl No	Prod No	Exclusivity Code	Exclusivity Expiration
N022410	001	NDF	Aug 30, 2013

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.

View a list of all patent use codes
View a list of all exclusivity codes
Return to Electronic Orange Book Home Page[6]

FDA/Center for Drug Evaluation and Research
Office of Generic Drugs
Division of Labeling and Program Support
Update Frequency:
Orange Book Data - **Monthly**
Generic Drug Product Information & Patent Information - **Daily**
Orange Book Data Updated Through September 2014
Patent and Generic Drug Product Data Last Updated November 06, 2014

Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

Search results from the "OB_Rx" table for query on "022410."

Active Ingredient:	BUPRENORPHINE HYDROCHLORIDE; NALOXONE HYDROCHLORIDE
Dosage Form;Route:	FILM;SUBLINGUAL
Proprietary Name:	SUBOXONE
Applicant:	RECKITT BENCKISER
Strength:	EQ 2MG BASE;EQ 0.5MG BASE
Application Number:	N022410
Product Number:	001
Approval Date:	Aug 30, 2010
Reference Listed Drug	No
RX/OTC/DISCN:	RX
TE Code:	
Patent and Exclusivity Info for this product:	View

Active Ingredient:	BUPRENORPHINE HYDROCHLORIDE; NALOXONE HYDROCHLORIDE
Dosage Form;Route:	FILM;SUBLINGUAL
Proprietary Name:	SUBOXONE
Applicant:	RECKITT BENCKISER
Strength:	EQ 8MG BASE;EQ 2MG BASE
Application Number:	N022410
Product Number:	002
Approval Date:	Aug 30, 2010
Reference Listed Drug	No
RX/OTC/DISCN:	RX
TE Code:	
Patent and Exclusivity Info for this product:	View

Active Ingredient:	BUPRENORPHINE HYDROCHLORIDE; NALOXONE HYDROCHLORIDE
Dosage Form;Route:	FILM;SUBLINGUAL
Proprietary Name:	SUBOXONE
Applicant:	RECKITT BENCKISER
Strength:	EQ 4MG BASE;EQ 1MG BASE
Application Number:	N022410
Product Number:	003
Approval Date:	Aug 10, 2012
Reference Listed Drug	No
RX/OTC/DISCN:	RX

TE Code:	
Patent and Exclusivity Info for this product:	View

Active Ingredient:	BUPRENORPHINE HYDROCHLORIDE; NALOXONE HYDROCHLORIDE
Dosage Form;Route:	FILM;SUBLINGUAL
Proprietary Name:	SUBOXONE
Applicant:	RECKITT BENCKISER
Strength:	EQ 12MG BASE;EQ 3MG BASE
Application Number:	N022410
Product Number:	004
Approval Date:	Aug 10, 2012
Reference Listed Drug	Yes
RX/OTC/DISCN:	RX
TE Code:	
Patent and Exclusivity Info for this product:	View

Return to Electronic Orange Book Home Page[6]

FDA/Center for Drug Evaluation and Research
Office of Generic Drugs
Division of Labeling and Program Support
Update Frequency:
Orange Book Data - **Monthly**
Generic Drug Product Information & Patent Information - **Daily**
Orange Book Data Updated Through September 2014
Patent and Generic Drug Product Data Last Updated November 06, 2014

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. http://www.fda.gov/default.htm
4. http://www.fda.gov/Drugs/InformationOnDrugs/default.htm
5. ../default.cfm
6. ../default.cfm

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)