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Drug Details

Drug Name(s)	ZUBSOLV
FDA Application No.	(NDA) 204242
Active Ingredient(s)	BUPRENORPHINE HYDROCHLORIDE; NALOXONE HYDROCHLORIDE
Company	OREXO US INC
Original Approval or Tentative Approval Date	July 3, 2013
Chemical Type	5 New formulation or new manufacturer
Review Classification	S Standard review drug

- [There are no Therapeutic Equivalents](#)
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Products on Application (NDA) #204242

Click on a column header to re-sort the table:

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	RLDTE Code
ZUBSOLV	BUPRENORPHINE HYDROCHLORIDE; NALOXONE HYDROCHLORIDE	EQ 1.4MG BASE; EQ 0.36MG BASE	TABLET;SUBLINGUAL	Prescription No	None
ZUBSOLV	BUPRENORPHINE HYDROCHLORIDE; NALOXONE HYDROCHLORIDE	EQ 5.7MG BASE; EQ 1.4MG BASE	TABLET;SUBLINGUAL	Prescription Yes	None
ZUBSOLV	BUPRENORPHINE HYDROCHLORIDE; NALOXONE HYDROCHLORIDE	EQ 8.6MG BASE; EQ 2.1MG BASE	TABLET;SUBLINGUAL	Prescription No	None
ZUBSOLV	BUPRENORPHINE HYDROCHLORIDE; NALOXONE HYDROCHLORIDE	EQ 11.4MG BASE; EQ 2.9MG BASE	TABLET;SUBLINGUAL	Prescription No	None
ZUBSOLV	BUPRENORPHINE HYDROCHLORIDE; NALOXONE HYDROCHLORIDE	EQ 2.9MG BASE; EQ 0.71MG BASE	TABLET;SUBLINGUAL	Prescription No	None

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