Drug Details

Drug Name(s)	**ZUBSOLV**
FDA Application No.	**(NDA) 204242**
Active Ingredient(s)	**BUPRENORPHINE HYDROCHLORIDE; NALOXONE HYDROCHLORIDE**
Company	**OREXO AB**
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**
- **Approval History, Letters, Reviews, and Related Documents**
- **Medication Guide[12]**
- **Label Information**
- **REMS[11]**

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	RLD	TE 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

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