Drugs@FDA: FDA Approved Drug Products

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New Drug Application (NDA): 203496
Company: UNITED THERAP

Products on NDA 203496

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Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	RLD	TE Code
ORENITRAM	TREPROSTINIL DIOLAMINE	EQ 0.125MG BASE	TABLET, EXTENDED RELEASE;ORAL	Prescription	Yes	None
ORENITRAM	TREPROSTINIL DIOLAMINE	EQ 0.25MG BASE	TABLET, EXTENDED RELEASE;ORAL	Prescription	Yes	None
ORENITRAM	TREPROSTINIL DIOLAMINE	EQ 1MG BASE	TABLET, EXTENDED RELEASE;ORAL	Prescription	Yes	None
ORENITRAM	TREPROSTINIL DIOLAMINE	EQ 2.5MG BASE	TABLET, EXTENDED RELEASE;ORAL	Prescription	Yes	None
ORENITRAM	TREPROSTINIL DIOLAMINE	EQ 5MG BASE	TABLET, EXTENDED RELEASE;ORAL	Prescription	Yes	None

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Approval Date(s) and History, Letters, Labels, Reviews for NDA 203496

Original Approvals or Tentative Approvals

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Action Date	Submission	Action Type	Submission Classification	Review Priority; Orphan Status	Letters, Revie
12/20/2013	ORIG-1	Approval	Type 3 - New Dosage Form	STANDARD ; Orphan	**Label (PDF) (https://www.accessdata.fda.gov/ Letter (PDF) (https://www.accessdata.fda.gov/ Review (https://www.accessdata.fda.gov/drug Summary Review (PDF) (https://www.accessd**

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Supplements

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Action Date	Submission	Submission Classification	Letters, Reviews, Labels, Patient Package Insert
01/24/2017	SUPPL-6	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/203496s0 Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/2034**
01/28/2016	SUPPL-2	Efficacy-Labeling Change With Clinical Data	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/203496s0 Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2016/2034**
10/06/2014	SUPPL-1	Manufacturing (CMC)	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/203496s0 Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2014/2034**

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Labels for NDA 203496