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New Drug Application (NDA): 203496

Company: UNITED THERAP

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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****CSVExcelPrint**

Action Date	Submission	Action Type	Submission Classification	Review Priority; Orphan Status	Letters, Reviews, Labels, Patient Package Insert
12/20/2013	ORIG-1	Approval	Type 3 - New Dosage Form	STANDARD ; Orphan	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/203496s01.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2013/203496s01.pdf) Review (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2013/203496s01.pdf) Summary Review (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2013/203496s01.pdf)

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Supplements**CSVExcelPrint**

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/2017/203496s06.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/203496s06.pdf)
01/28/2016	SUPPL-2	Efficacy- Labeling Change With Clinical Data	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/203496s02.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2016/203496s02.pdf)
10/06/2014	SUPPL-1	Manufacturing (CMC)	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/203496s01.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2014/203496s01.pdf)

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Labels for NDA 203496

