Drugs@FDA: FDA Approved Drug Products

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New Drug Application (NDA): 021272
Company: UNITED THERAP

Products on NDA 021272

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Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	RLD	TE Code
REMODULIN	TREPROSTINIL	1MG/ML	INJECTABLE;IV (INFUSION), SUBCUTANEOUS	Prescription	Yes	None
REMODULIN	TREPROSTINIL	2.5MG/ML	INJECTABLE;IV (INFUSION), SUBCUTANEOUS	Prescription	Yes	None
REMODULIN	TREPROSTINIL	5MG/ML	INJECTABLE;IV (INFUSION), SUBCUTANEOUS	Prescription	Yes	None
REMODULIN	TREPROSTINIL	10MG/ML	INJECTABLE;IV (INFUSION), SUBCUTANEOUS	Prescription	Yes	None

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Approval Date(s) and History, Letters, Labels, Reviews for NDA 021272

Original Approvals or Tentative Approvals

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Action Date	Submission	Action Type	Submission Classification	Review Priority; Orphan Status	Letters, Reviews, Labels
07/05/2001	ORIG-1	Approval	Type 1 - New Molecular Entity	PRIORITY ; Orphan	**Label (PDF) (https://www.accessdata.fda.gov/d Letter (PDF) (https://www.accessdata.fda.gov/d Review (https://www.accessdata.fda.gov/drugs**

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Supplements

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Action Date	Submission	Submission Classification	Letters, Reviews, Labels, Patient Package Insert
01/22/2016	SUPPL-22	Manufacturing (CMC)	
12/22/2014	SUPPL-19	Labeling-Package Insert, Labeling-Container/Carton Labels	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/021272s0 Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2014/0212**
01/03/2014	SUPPL-21	Manufacturing (CMC)	

Action Date	Submission	Submission Classification	Letters, Reviews, Labels, Patient Package Insert
09/26/2013	SUPPL-20	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/021272s0 Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/021272s0 Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2013/0212 Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2013/0212 Review (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2013/021272Ori**
02/08/2011	SUPPL-15	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/021272s0 Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2011/0212**
01/08/2010	SUPPL-11	Labeling	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/021272s0 Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2010/0212**
09/12/2008	SUPPL-8	Labeling	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2008/021272s0 Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2008/0212**
02/04/2008	SUPPL-9	Labeling	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2008/021272s0 Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2008/0212**
03/20/2006	SUPPL-5	Efficacy-Accelerated Approval	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2006/021272S Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2006/0212 Review (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2006/021272Ori**
01/20/2006	SUPPL-3	Labeling	**Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2006/0212**

Action Date	Submission	Submission Classification	Letters, Reviews, Labels, Patient Package Insert
11/24/2004	SUPPL-2	Efficacy-New Route Of Administration	**Review (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2004/021272Ori**

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Labels for NDA 021272