

# Drugs@FDA: FDA Approved Drug Products

 [SHARE \(HTTPS://WWW.FACEBOOK.COM/SHARER/SHARER.PHP?U=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=BASICSEARCH.PROCESS\)](https://www.facebook.com/sharer/sharer.php?u=https://www.accessdata.fda.gov/scripts/cder/da/index.cfm?event=basicsearch.process)

 [TWEET \(HTTPS://TWITTER.COM/INTENT/TWEET/?TEXT=DRUGS@FDA: FDA APPROVED DRUG PRODUCTS&URL=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=BASICSEARCH.PROCESS\)](https://twitter.com/intent/tweet?text=Drugs@FDA: FDA Approved Drug Products&url=https://www.accessdata.fda.gov/scripts/cder/da/index.cfm?event=basicsearch.process)



 [EMAIL \(MAILTO:?SUBJECT=DRUGS@FDA: FDA APPROVED DRUG PRODUCTS&BODY=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=BASICSEARCH.PROCESS\)](mailto:?subject=Drugs@FDA: FDA Approved Drug Products&body=https://www.accessdata.fda.gov/scripts/cder/da/index.cfm?event=basicsearch.process)

[Home \(index.cfm\)](#) | [Previous Page](#)

New Drug Application (NDA): 022387

Company: UNITED THERAP

 [EMAIL \(MAILTO:?SUBJECT=DRUGS@FDA: FDA APPROVED DRUG PRODUCTS&BODY=HTTP://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=OVERVIEW.PROCESS%26VARAPPLNO=022387\)](mailto:?subject=Drugs@FDA: FDA Approved Drug Products&body=http://www.accessdata.fda.gov/scripts/cder/da/index.cfm?event=overview.process%26varapplno=022387)

- [Usage Instructions \(http://www.accessdata.fda.gov/drugsatfda\\_docs/label/2009/022387UsagelInstr.pdf\)](http://www.accessdata.fda.gov/drugsatfda_docs/label/2009/022387UsagelInstr.pdf)

## Products on NDA 022387

### CSVExcelPrint

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	RLD	TE Code
TYVASO	TREPROSTINIL	0.6MG/ML	SOLUTION;INHALATION	Prescription	Yes	None

Showing 1 to 1 of 1 entries

## Approval Date(s) and History, Letters, Labels, Reviews for NDA 022387

Original Approvals or Tentative Approvals

[CSVExcelPrint](#)

Action Date	Submission	Action Type	Submission Classification	Review Priority; Orphan Status	Letters, Reviews, Labels, Patient Package Insert
07/30/2009	ORIG-1	Approval	Type 5 - New Formulation or New Manufacturer	STANDARD ; Orphan	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/07302009.pdf">Label (PDF)</a> ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/07302009.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/07302009.pdf</a> ) <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2009/07302009.pdf">Letter (PDF)</a> ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2009/07302009.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2009/07302009.pdf</a> ) <a href="https://www.accessdata.fda.gov/drugsatfda_docs/drug/2009/07302009.pdf">Review</a> ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/drug/2009/07302009.pdf">https://www.accessdata.fda.gov/drug/2009/07302009.pdf</a> )

Showing 1 to 1 of 1 entries

**Supplements****CSVExcelPrint**

Action Date	Submission	Submission Classification	Letters, Reviews, Labels, Patient Package Insert
06/06/2016	SUPPL-14	Labeling- Package Insert	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/022387s01.pdf">Label (PDF)</a> ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/022387s01.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/022387s01.pdf</a> ) <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2016/022387s01.pdf">Letter (PDF)</a> ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2016/022387s01.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2016/022387s01.pdf</a> )
06/23/2015	SUPPL-12	Manufacturing (CMC)	
08/01/2014	SUPPL-11	Labeling- Package Insert, Labeling- Container/Carton Labels, Labeling- Patient Package Insert	
05/20/2014	SUPPL-9	Efficacy-Labeling Change With Clinical Data	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/022387s01.pdf">Label (PDF)</a> ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/022387s01.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/022387s01.pdf</a> ) <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2014/022387s01.pdf">Letter (PDF)</a> ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2014/022387s01.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2014/022387s01.pdf</a> )
04/30/2013	SUPPL-8	Labeling- Package Insert	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/022387s01.pdf">Label (PDF)</a> ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/022387s01.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/022387s01.pdf</a> ) <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2013/022387s01.pdf">Letter (PDF)</a> ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2013/022387s01.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2013/022387s01.pdf</a> )

Action Date	Submission	Submission Classification	Letters, Reviews, Labels, Patient Package Insert
01/07/2013	SUPPL-7	Manufacturing (CMC)	
02/08/2011	SUPPL-4	Labeling- Package Insert	<b>Label (PDF)</b> ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/022387s0">https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/022387s0</a> ) <b>Letter (PDF)</b> ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2011/022387s0">https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2011/022387s0</a> )

Showing 1 to 7 of 7 entries

**[Labels for NDA 022387](#)**

