Drugs@FDA: FDA Approved Drug Products

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New Drug Application (NDA): 021779
Company: ACTELION PHARMS LTD

Products on NDA 021779

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Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	RLD	TE Code
VENTAVIS	ILOPROST	20MCG/2ML (10MCG/ML)	SOLUTION;INHALATION	Discontinued	No	None
VENTAVIS	ILOPROST	10MCG/ML (10MCG/ML)	SOLUTION;INHALATION	Prescription	Yes	None
VENTAVIS	ILOPROST	20MCG/ML (20MCG/ML)	SOLUTION;INHALATION	Prescription	Yes	None

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Approval Date(s) and History, Letters, Labels, Reviews for NDA 021779

Original Approvals or Tentative Approvals

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Action Date	Submission	Action Type	Submission Classification	Review Priority; Orphan Status	Letters, Reviews, Labels,
12/29/2004	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
01/05/2015	SUPPL-16	Manufacturing (CMC)	
11/10/2014	SUPPL-15	Manufacturing (CMC)	
11/25/2013	SUPPL-14	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2 Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2013/0217**
04/26/2012	SUPPL-13	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2 Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2012/0217**
02/08/2011	SUPPL-12	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2 Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applett**
04/20/2010	SUPPL-10	Labeling-Container/Carton Labels	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2 Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applett**

Action Date	Submission	Submission Classification	Letters, Reviews, Labels, Patient Package Insert
08/07/2009	SUPPL-9	Labeling-Package Insert, Labeling-Container/Carton Labels	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2(Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applett Review (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2**
09/22/2008	SUPPL-8	Labeling	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2(Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applett**
03/04/2008	SUPPL-6	Labeling	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2(Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applett**
12/08/2005	SUPPL-3	Manufacturing (CMC)-Control	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2(Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applett**
08/24/2005	SUPPL-2	Manufacturing (CMC)-Formulation	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2(Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2005/0217**
08/24/2005	SUPPL-1	Efficacy-New Indication	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2(Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2005/0217**

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Labels for NDA 021779