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New Drug Application (NDA): 021290

Company: ACTELION PHARMS LTD

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- [Medication Guide \(http://www.accessdata.fda.gov/drugsatfda_docs/label/2012/021290s022mq.pdf\)](http://www.accessdata.fda.gov/drugsatfda_docs/label/2012/021290s022mq.pdf)
- [REMS \(http://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=61\)](http://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=61)

Products on NDA 021290

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Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	RLD	TE Code
TRACLEER	BOSENTAN	62.5MG	TABLET;ORAL	Prescription	Yes	None
TRACLEER	BOSENTAN	125MG	TABLET;ORAL	Prescription	Yes	None

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Approval Date(s) and History, Letters, Labels, Reviews for NDA 021290

Original Approvals or Tentative Approvals**CSVExcelPrint**

Action Date	Submission	Action Type	Submission Classification	Review Priority; Orphan Status	Letters, Reviews, L
11/20/2001	ORIG-1	Approval	Type 1 - New Molecular Entity	STANDARD ; Orphan	Label (PDF) (https://www.accessdata.fda.gov/) Letter (PDF) (https://www.accessdata.fda.gov/) Review (https://www.accessdata.fda.gov/drug/)

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Supplements**CSVExcelPrint**

Action Date	Submission	Submission Classification	Letters, Reviews, Labels, Patient Package Insert
12/16/2016	SUPPL-30	REMS-Modified	Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2016/02129)
10/20/2016	SUPPL-33	Labeling- Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/02129) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2016/02129)
12/04/2015	SUPPL-29	Labeling- Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/02129) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2015/02129)
12/04/2015	SUPPL-27	REMS-Modified	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/021290s0) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2015/02129)
07/01/2013	SUPPL-25	REMS-Modified	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/02129) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2013/02129)
06/03/2013	SUPPL-24	Manufacturing (CMC)	

Action Date	Submission	Submission Classification	Letters, Reviews, Labels, Patient Package Insert
10/04/2012	SUPPL-22	Efficacy-Labeling Change With Clinical Data	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/021290s01.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2012/021290s01.pdf)
02/08/2011	SUPPL-19	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/021290s01.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2011/021290s01.pdf)
02/19/2010	SUPPL-18	REMS-Modified	Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2010/021290s01.pdf)
08/07/2009	SUPPL-16	REMS-Proposal, Labeling	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/021290s01.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2009/021290s01.pdf)
08/07/2009	SUPPL-12	Efficacy-New Indication	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/021290s01.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2009/021290s01.pdf) Summary Review (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/021290s01.pdf)
03/17/2009	SUPPL-15	Labeling	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/021290s01.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2009/021290s01.pdf)
02/13/2009	SUPPL-14	Labeling	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/021290s01.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2009/021290s01.pdf)
06/01/2007	SUPPL-11	Labeling	Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2007/021290s01.pdf)
02/15/2007	SUPPL-10	Efficacy-Labeling Change With Clinical Data	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2007/021290s01.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2007/021290s01.pdf)
11/29/2005	SUPPL-7	Labeling	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2005/021290s01.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2005/021290s01.pdf)

Action Date	Submission	Submission Classification	Letters, Reviews, Labels, Patient Package Insert
11/29/2005	SUPPL-6	Efficacy-Labeling Change With Clinical Data	<p>Label (PDF) https://www.accessdata.fda.gov/drugsatfda_docs/label/2005/021290s0</p> <p>Letter (PDF) https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2005/021290</p>
11/24/2004	SUPPL-4	Labeling	<p>Letter (PDF) https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2004/21290</p>
10/06/2003	SUPPL-1	Efficacy-Labeling Change With Clinical Data	<p>Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2003/001_tracleer_lbl.pdf)</p> <p>Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2003/001ltr.pdf)</p> <p>Review (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2003/21)</p>

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Labels for NDA 021290