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New Drug Application (NDA): 022081

Company: GILEAD

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- [Medication Guide \(http://www.fda.gov/downloads/Drugs/DrugSafety/ucm088617.pdf\)](http://www.fda.gov/downloads/Drugs/DrugSafety/ucm088617.pdf)
- [REMS \(http://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=28\)](http://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=28)

## Products on NDA 022081

### CSVExcelPrint

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	RLD	TE Code
LETAIRIS	AMBRISENTAN	5MG	TABLET;ORAL	Prescription	Yes	None
LETAIRIS	AMBRISENTAN	10MG	TABLET;ORAL	Prescription	Yes	None

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## Approval Date(s) and History, Letters, Labels, Reviews for NDA 022081

**Original Approvals or Tentative Approvals****CSVExcelPrint**

Action Date	Submission	Action Type	Submission Classification	Review Priority; Orphan Status	Letters, Reviews, Labels
06/15/2007	ORIG-1	Approval	Type 1 - New Molecular Entity	PRIORITY ; Orphan	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2007/008121orig1s1.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2007/008121orig1s1.pdf</a> ) Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/letter/2007/008121orig1s1.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/letter/2007/008121orig1s1.pdf</a> ) Review ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/nda/2007/008121orig1s1.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/nda/2007/008121orig1s1.pdf</a> )

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**Supplements****CSVExcelPrint**

Action Date	Submission	Submission Classification	Letters, Reviews, Labels, Patient Package Insert
12/15/2016	SUPPL-36	REMS - MODIFIED - D-N-A	Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2016/022081s01.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2016/022081s01.pdf</a> )
03/21/2016	SUPPL-35	Manufacturing (CMC)	
10/02/2015	SUPPL-33	Efficacy-New Indication	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/022081s01.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/022081s01.pdf</a> ) Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/022081s01.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/022081s01.pdf</a> )
09/25/2015	SUPPL-34	Manufacturing (CMC)	
10/29/2014	SUPPL-32	REMS-Modified	Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2014/022081s01.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2014/022081s01.pdf</a> )

Action Date	Submission	Submission Classification	Letters, Reviews, Labels, Patient Package Insert
09/26/2014	SUPPL-28	Manufacturing (CMC)	
07/02/2014	SUPPL-26	Manufacturing (CMC)	
05/05/2014	SUPPL-29	Labeling- Package Insert	<b>Label (PDF)</b> ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/022081s0">https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/022081s0</a> ) <b>Letter (PDF)</b> ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2014/022081s0">https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2014/022081s0</a> )
01/31/2014	SUPPL-30	REMS-Modified	<b>Label (PDF)</b> ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/022081s0">https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/022081s0</a> ) <b>Letter (PDF)</b> ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2014/022081s0">https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2014/022081s0</a> )
08/17/2013	SUPPL-19	REMS- Modified, REMS- Assessment	<b>Label (PDF)</b> ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/022081s0">https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/022081s0</a> ) <b>Letter (PDF)</b> ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2013/022081s0">https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2013/022081s0</a> )
01/16/2013	SUPPL-24	Manufacturing (CMC)	
01/10/2013	SUPPL-23	Manufacturing (CMC)	
10/19/2012	SUPPL-22	Labeling- Package Insert	<b>Label (PDF)</b> ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/022081s0">https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/022081s0</a> ) <b>Letter (PDF)</b> ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2012/022081s0">https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2012/022081s0</a> )

<b>Action Date</b>	<b>Submission</b>	<b>Submission Classification</b>	<b>Letters, Reviews, Labels, Patient Package Insert</b>
02/15/2012	SUPPL-14	Efficacy-Labeling Change With Clinical Data, REMS-Assessment	<b>Label (PDF)</b> ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/022081s0">https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/022081s0</a> ) <b>Letter (PDF)</b> ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2012/022081s0">https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2012/022081s0</a> )
07/19/2011	SUPPL-18	Labeling	<b>Label (PDF)</b> ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/022081s0">https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/022081s0</a> ) <b>Letter (PDF)</b> ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2011/022081s0">https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2011/022081s0</a> )
03/03/2011	SUPPL-17	Labeling- Package Insert, REMS-Modified	<b>Label (PDF)</b> ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/022081s0">https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/022081s0</a> ) <b>Letter (PDF)</b> ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2011/022081s0">https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2011/022081s0</a> ) <b>Review (PDF)</b> ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/nda/2011/022081Orig1s01.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/nda/2011/022081Orig1s01.pdf</a> )
10/13/2010	SUPPL-12	Labeling, REMS-Assessment	<b>Label (PDF)</b> ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/022081s0">https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/022081s0</a> ) <b>Letter (PDF)</b> ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2010/022081s0">https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2010/022081s0</a> )
08/24/2010	SUPPL-16	REMS-Modified	<b>Letter (PDF)</b> ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2010/022081s0">https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2010/022081s0</a> )
08/05/2009	SUPPL-10	Labeling	<b>Label (PDF)</b> ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/022081s0">https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/022081s0</a> ) <b>Letter (PDF)</b> ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2009/022081s0">https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2009/022081s0</a> )
07/01/2009	SUPPL-11	REMS-Modified, Labeling	<b>Label (PDF)</b> ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/022081s0">https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/022081s0</a> ) <b>Letter (PDF)</b> ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2009/022081s0">https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2009/022081s0</a> )
05/29/2009	SUPPL-8	REMS-Proposal, Labeling	<b>Label (PDF)</b> ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/022081s0">https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/022081s0</a> ) <b>Letter (PDF)</b> ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2009/022081s0">https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2009/022081s0</a> )

Action Date	Submission	Submission Classification	Letters, Reviews, Labels, Patient Package Insert
10/08/2008	SUPPL-4	Labeling	<b>Label (PDF)</b> ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2008/022081s0">https://www.accessdata.fda.gov/drugsatfda_docs/label/2008/022081s0</a> ) <b>Letter (PDF)</b> ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2008/022081s0">https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2008/022081s0</a> )
02/14/2008	SUPPL-2	Labeling	<b>Label (PDF)</b> ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2008/022081s0">https://www.accessdata.fda.gov/drugsatfda_docs/label/2008/022081s0</a> ) <b>Letter (PDF)</b> ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2008/022081s0">https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2008/022081s0</a> )
11/29/2007	SUPPL-1	Labeling	<b>Letter (PDF)</b> ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2007/022081s0">https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2007/022081s0</a> )

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**Labels for NDA 022081**