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New Drug Application (NDA): 204819

Company: BAYER HLTHCARE

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- [Medication Guide \(http://www.accessdata.fda.gov/drugsatfda_docs/label/2017/204819s006lbl.pdf#page=24\)](http://www.accessdata.fda.gov/drugsatfda_docs/label/2017/204819s006lbl.pdf#page=24)
- [REMS \(http://www.accessdata.fda.gov/scripts/cder/remis/index.cfm?event=IndvRemsDetails.page&REMS=149\)](http://www.accessdata.fda.gov/scripts/cder/remis/index.cfm?event=IndvRemsDetails.page&REMS=149)

Products on NDA 204819



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Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	RLD	TE Code
ADEMPAS	RIOCIGUAT	0.5MG	TABLET;ORAL	Prescription	Yes	None
ADEMPAS	RIOCIGUAT	1MG	TABLET;ORAL	Prescription	Yes	None
ADEMPAS	RIOCIGUAT	1.5MG	TABLET;ORAL	Prescription	Yes	None
ADEMPAS	RIOCIGUAT	2MG	TABLET;ORAL	Prescription	Yes	None

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	RLD	TE Code
ADEMPAS	RIOCIGUAT	2.5MG	TABLET;ORAL	Prescription	Yes	None

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Approval Date(s) and History, Letters, Labels, Reviews for NDA 204819 **Original Approvals or Tentative Approvals****CSVExcelPrint**

Action Date	Submission	Action Type	Submission Classification	Review Priority; Orphan Status	Letters, Review
10/08/2013	ORIG-1	Approval	Type 1 - New Molecular Entity	STANDARD ; Orphan	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/0204819s01.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/letter/2013/0204819s01.pdf) Review (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/review/2013/0204819s01.pdf) Summary Review (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/summary_review/2013/0204819s01.pdf)

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Supplements**CSVExcelPrint**

Action Date	Submission	Submission Classification	Letters, Reviews, Labels, Patient Package Insert
02/23/2017	SUPPL-8	Labeling- Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/204819s01.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/letter/2017/204819s01.pdf)
01/17/2017	SUPPL-6	REMS - MODIFIED - D-N-A	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/204819s01.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/letter/2017/204819s01.pdf)
10/04/2016	SUPPL-7	REMS - MODIFIED - D-N-A	Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/letter/2016/204819s01.pdf)

Action Date	Submission	Submission Classification	Letters, Reviews, Labels, Patient Package Insert
12/04/2015	SUPPL-4	REMS-Modified	Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2015/20481)
02/23/2015	SUPPL-3	Manufacturing (CMC)	
06/11/2014	SUPPL-1	REMS-Modified	Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2014/20481)
05/06/2014	SUPPL-2	Labeling- Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/204819s0) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2014/20481)

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Labels for NDA 204819