Drugs@FDA: FDA Approved Drug Products

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New Drug Application (NDA): 204819
Company: BAYER HLTHCARE

- Medication Guide (http://www.accessdata.fda.gov/drugsatfda_docs/label/2017/204819s006lbl.pdf#page=24)
- REMS (http://www.accessdata.fda.gov/scripts/cder/rems/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

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Action Date	Submission	Action Type	Submission Classification	Review Priority; Orphan Status	Letters, Revie
10/08/2013	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 Summary Review (PDF) (https://www.accessd**

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Supplements

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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/2017/204819s0 Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/20481**
01/17/2017	SUPPL-6	REMS - MODIFIED - D-N-A	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/204819s0 Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/20481**
10/04/2016	SUPPL-7	REMS - MODIFIED - D-N-A	**Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2016/20481**

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/appletter/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/appletter/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/appletter/2014/20481**

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Labels for NDA 204819