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New Drug Application (NDA): 207947
Company: ACTELION PHARMS LTD

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Products on NDA 207947



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Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	RLD	TE Code
UPTRAVI	SELEXIPAG	0.2MG	TABLET;ORAL	Prescription	Yes	None
UPTRAVI	SELEXIPAG	0.4MG	TABLET;ORAL	Prescription	Yes	None
UPTRAVI	SELEXIPAG	0.6MG	TABLET;ORAL	Prescription	Yes	None
UPTRAVI	SELEXIPAG	0.8MG	TABLET;ORAL	Prescription	Yes	None
UPTRAVI	SELEXIPAG	1MG	TABLET;ORAL	Prescription	Yes	None
UPTRAVI	SELEXIPAG	1.2MG	TABLET;ORAL	Prescription	Yes	None
UPTRAVI	SELEXIPAG	1.4MG	TABLET;ORAL	Prescription	Yes	None
UPTRAVI	SELEXIPAG	1.6MG	TABLET;ORAL	Prescription	Yes	None

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Approval Date(s) and History, Letters, Labels, Reviews for NDA 207947



Original Approvals or Tentative Approvals

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Action Date	Submission	Action Type	Submission Classification	Review Priority; Orphan Status	Letters, Review
12/21/2015	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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Labels for NDA 207947

