

# Drugs@FDA: FDA Approved Drug Products

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

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## Products on NDA 207947



### CSVExcelPrint

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**

**CSVExcelPrint**

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	<a href="https://www.accessdata.fda.gov/label/label.cfm?label=207947">Label (PDF) (https://www.accessdata.fda.gov/label/label.cfm?label=207947)</a> <a href="https://www.accessdata.fda.gov/drugatc/nda/207947orig1s1/label/label.cfm">Letter (PDF) (https://www.accessdata.fda.gov/drugatc/nda/207947orig1s1/label/label.cfm)</a> <a href="https://www.accessdata.fda.gov/drugatc/nda/207947orig1s1/label/label.cfm">Review (https://www.accessdata.fda.gov/drugatc/nda/207947orig1s1/label/label.cfm)</a> <a href="https://www.accessdata.fda.gov/drugatc/nda/207947orig1s1/label/label.cfm">Summary Review (PDF) (https://www.accessdata.fda.gov/drugatc/nda/207947orig1s1/label/label.cfm)</a>

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**Labels for NDA 207947**

