

## Mekinist - (0.5 mg and 2 mg ; Tablet)

<b>Generic Name</b>	Trametinib	<b>Innovator</b>	Novartis
<b>Dosage</b>	0.5 mg and 2 mg ; Tablet	<b>Branded US Sales</b>	Less Than \$1000 mn
<b>Probable FTF</b>	Less Than 5	<b>Known Para IV Filers</b>	Less Than 5
<b>Other ANDA developers</b>	More Than 5	<b>Tentative Approvals</b>	None
<b>Final Approvals</b>	None	<b>Generic Launches</b>	None
<b>Indication</b>	MEKINIST is a kinase inhibitor indicated as a single agent for the treatment of BRAF-inhibitor treatment-naïve patients with unresectable or metastatic melanoma with BRAF V600E or V600K mutations as detected by an FDA approved test. MEKINIST is indicated, in combination with dabrafenib, for: • the treatment of patients with unresectable or metastatic melanoma with BRAF V600E or V600K mutations as detected by an FDA-approved test. • the adjuvant treatment of patients with melanoma with BRAF V600E or V600K mutations, as detected by an FDA-approved test, and involvement of lymph node(s), following complete resection. • the treatment of patients with metastatic non-small cell lung cancer (NSCLC) with BRAF V600E mutation as detected by an FDA-approved test. • the treatment of patients with locally advanced or metastatic anaplastic thyroid cancer (ATC) with BRAF V600E mutation and with no satisfactory locoregional treatment options. • the treatment of adult and pediatric patients 6 years of age and older with unresectable or metastatic solid tumors with BRAF V600E mutation who have progressed following prior treatment and have no satisfactory alternative treatment options. This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).		
<b>Complexities</b>	Yes		

### Chronology Of Events

Please Contact [contact@researchdelta.com](mailto:contact@researchdelta.com) to get Detailed Information.

### Executive Summary

Please Contact [contact@researchdelta.com](mailto:contact@researchdelta.com) to get Detailed Information.

### Patent Status

Please Contact [contact@researchdelta.com](mailto:contact@researchdelta.com) to get Detailed Information.

### Launch Timelines and Competition

Address: G4 Sani Apt., Subhanpura, Vadodara, Gujarat, India - 390 023

Tel: +91.9909919584 | E-mail: [contact@researchdelta.com](mailto:contact@researchdelta.com) | Website: [www.researchdelta.com](http://www.researchdelta.com)

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