Mekinist - (0.5 mg and 2 mg ; Tablet)

Generic Name	Trametinib	**Innovator**	Novartis
Dosage	0.5 mg and 2 mg ; Tablet	**Branded US Sales**	Less Than $1000 mn
Probable FTF	Less Than 5	**Known Para IV Filers**	Less Than 5
Other ANDA developers	More Than 5	**Tentative Approvals**	None
Final Approvals	None	**Generic Launches**	None
Indication	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).		
Complexities	Yes		

Chronology Of Events

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Chronology Of Events

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Mekinist - (EQ 0.05MG BASE/ML ; Solution)

Generic Name	Trametinib	**Innovator**	Novartis
Dosage	EQ 0.05MG BASE/ML ; Solution	**Branded US Sales**	Less Than $1000 mn
Probable FTF	None	**Known Para IV Filers**	None
Other ANDA developers	More Than 5	**Tentative Approvals**	None
Final Approvals	None	**Generic Launches**	None
Indication	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		
Complexities	Yes		

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Mekinist - (1 mg ; Tablet)

Generic Name	Trametinib	**Innovator**	Novartis
Dosage	1 mg ; Tablet	**Branded US Sales**	Less Than $1000 mn
Probable FTF	Less Than 5	**Known Para IV Filers**	Less Than 5
Other ANDA developers	More Than 5	**Tentative Approvals**	None
Final Approvals	None	**Generic Launches**	None
Indication	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).		
Complexities	Yes		

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