Generic Name:
Dabrafenib, trametinib
Trade Name:
Tafinlar, Mekinist
Company:
Novartis
Notes:

FDA approved dabrafenib and trametinib, administered together, for treatment of anaplastic thyroid cancer (ATC) that cannot be removed by surgery or is metastatic and that is mutation positive for the *BRAF V600E* gene.

It is the first FDA-approved treatment for patients with this aggressive form of thyroid cancer, and the third cancer with this specific gene mutation that this drug combination has been approved to treat.

Both dabrafenib and trametinib are also approved for use, alone or in combination, to treat *BRAF V600* mutation-positive metastatic melanoma, and for use, in combination, to treat *BRAF V600E* mutation-positive, metastatic non?small cell lung cancer.

Efficacy of dabrafenib and trametinib in treating ATC was shown in an open-label clinical trial of patients with rare cancers with the *BRAF V600E* mutation. Data from trials in *BRAF V600E* mutation-positive, metastatic melanoma or lung cancer and results in other *BRAF V600E* mutation-positive rare cancers provided confidence in the results seen in patients with ATC.

The trial measured the percent of patients with a complete or partial reduction in tumor size (overall response rate). Of 23 evaluable patients, 57% experienced a partial response, and 4% experienced a complete response; in 9 (64%) of the 14 patients with responses, there were no significant tumor growths for 6 months or longer.

Adverse effects in patients with ATC are consistent with those seen in other cancers when the two drugs are used together. Common adverse effects include fever, rash, chills, headache, joint pain, cough, fatigue, nausea, vomiting, diarrhea, myalgia, dry skin, decreased appetite, edema, hemorrhage, hypertension, and difficulty breathing.

Adverse effects of dabrafenib include the development of new cancers, growth of tumors in patients with *BRA*F wild-type tumors, serious bleeding problems, heart problems, severe eye problems, fever that may be severe, serious skin reactions, high blood glucose levels or worsening diabetes, and serious anemia.

Severe adverse effects of trametinib include the development of new cancers; serious bleeding problems; inflammation of intestines and perforation of the intestines; blood clots in the arms, legs or lungs; heart problems; severe eye problems; lung or breathing problems; fever that may be severe; serious skin reactions; and high blood glucose levels or worsening diabetes.

Both drugs can cause harm to a developing fetus; women should be advised of the potential

risk to the fetus and to use effective contraception.

Medication Monitor Categories:

Supplemental Approvals
