Generic Name:
Pembrolizumab
Trade Name:
Keytruda
Company:
Merck
Notes:

FDA approved pembrolizumab in combination with pemetrexed and platinum as first-line treatment of patients with metastatic, nonsquamous non?small cell lung cancer (NSqNSCLC), with no EGFR or ALK genomic tumor aberrations.

Approval was based on the results of KEYNOTE-189, a randomized, multicenter, double-blind, active controlled study enrolling 616 patients receiving first-line treatment for metastatic NSqNSCLC. The trial demonstrated a statistically significant improvement in overall survival for patients randomized to pembrolizumab and chemotherapy in a prespecified interim analysis.

The most common adverse reactions were fatigue/asthenia, nausea, constipation, diarrhea, decreased appetite, rash, vomiting, cough, dyspnea, and pyrexia.

The recommended pembrolizumab dose and schedule for this indication is 200 mg as an I.V. infusion over 30 minutes every 3 weeks.

Medication Monitor Categories:
Supplemental Approvals