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

Pembrolizumab has a new indication for adjuvant treatment of patients with melanoma with involvement of lymph node(s) following complete resection.

Approval was based on a randomized, double-blind, placebo-controlled trial in 1,019 patients with completely resected, stage IIIA (>1 mm lymph node metastasis), IIIB, or IIIC melanoma. The RFS benefit for pembrolizumab compared with placebo was observed regardless of tumor PD-L1 expression.

The most common adverse reactions (reported in at least 10% of pembrolizumab-treated patients) were diarrhea, pruritus, nausea, arthralgia, hypothyroidism, cough, rash, asthenia, influenza-like illness, weight loss, and hyperthyroidism.

The recommended pembrolizumab dose and schedule for adjuvant treatment of melanoma is 200 mg administered as an I.V. infusion over 30 minutes every 3 weeks until disease recurrence or unacceptable toxicity, for a maximum of 1 year.

For more information, see the full prescribing information.

Medication Monitor Categories:
Supplemental Approvals