Generic Name:
Ibrutinib
Trade Name:
Imbruvica
Company:
AbbVie/Janssen Biotech
Notes:

FDA has approved an expanded use of ibrutinib in combination with obinutuzumab for adult patients with previously untreated chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL). Ibrutinib is a once-daily, first-in-class Bruton's tyrosine kinase inhibitor that is administered orally. It was previously approved as a single agent or in combination with bendamustine and rituximab (BR) for adult patients with CLL/SLL.

FDA also updated the ibrutinib label to include additional long-term efficacy follow-up supporting its use as a single agent in CLL/SLL from two Phase III international studies.

The recommended dose for CLL/SLL is 420 mg orally once daily until disease progression or unacceptable toxicity as a single agent or in combination with obinutuzumab or with bendamustine and rituximab.

Warnings and precautions include hemorrhage, infections, cytopenias, cardiac arrhythmias, hypertension, second primary malignancies, tumor lysis syndrome, and embryo-fetal toxicity.

The most common adverse reactions in patients treated with ibrutinib plus obinutuzumab were neutropenia, thrombocytopenia, rash, diarrhea, musculoskeletal pain, bruising, cough, infusion-related reaction, hemorrhage, and arthralgia.

Medication Monitor Categories:
Supplemental Approvals